

# **Superior Economic Performance in a Small State: The Pharmaceutical Industry in Malta**

**By**

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## **Abstract**

Various academic disciplines have attempted to explain the factors underpinning superior economic performance. Generally they neglect the realities of small states.

The literature fails to clearly define a 'small state'. Mainstream theories associate smallness with 'sub-optimality'. Small states studies tend to be conditioned by a 'vulnerability' complex. Yet, a good number of small states have an economic track record which is the envy of much larger states.

This thesis adopts an interdisciplinary approach to investigate the theoretical explanations of superior economic performance, at both the state and firm level. Resource-advantage theory, which claims to be a general theory of competition, offers valuable insights in understanding the superior economic performance of small states.

The field research follows Porter (1998) in studying the performance of particular industries to understand the competitiveness of nations. A qualitative, case study approach, involving both primary and secondary investigation, explores the performance of the pharmaceutical industry in Malta following the country's decision to join the EU.

This work perceives a small state as an organisation with well-defined, but permeable, boundaries. This 'open system' is characterised by both a lack of market power and a small population. Through the secondary field research a small number of 'higher-order' resources, competencies and dynamic capabilities (RCDCs) are identified. The field research's findings affirm the relevance of these arch-RCDCs in creating competitive advantage for the pharmaceutical industry in Malta. It also elucidates the key role played by an external catalyst, foreign direct investment, to circumvent domestic limitations.

The study finds that it is still relevant to study small states and that achieving a strategic fit between the resource base and international market opportunities is essential if small states are to enhance their market power and achieve a superior economic performance.

I hereby certify that all material in the thesis which is not my own work has been identified.  
No material has been previously submitted or approved for the award of a degree by  
Loughborough University or any other institution.

Joseph Vella Bonnici

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## **Dedication**

Anna, Sara and Marc, whose love has helped me through the journey

My parents, who would have been happy to know that this journey has come to an end

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## **Glossary of Abbreviations**

APIs: Active Pharmaceutical Ingredients

CEE: Central East European countries

CPP: Certificate of Pharmaceutical Product

EC: European Commission

EEC: European Economic Community

EFPIA: European Federation of Pharmaceutical Industries and Associations

EGA: European Generic Medicines Association

EPO: European Patent Office

ETC: Employment and Training Corporation (Malta)

EU: European Union

FDA: Food and Drug Agency

FDI: Foreign Direct Investment

GATT: General Agreement on Trade and Tariffs

GDP: Gross Domestic Product

GMP: Good Manufacturing Practices

IDA: International Dispensary Association

INNs: International Non-Proprietary Names

IPR: Inward Processing Relief

MA: Marketing Authorisation

MCAST: Malta College for Arts, Science and Technology

MCESD: Malta Council for Economic and Social Development

ME: Malta Enterprise

MIRAB: Migration, Remittances, Aid and Bureaucracy

MEUSAC: Malta-EU Action and Steering Committee

NCEs: Novel Pharmaceutical-Active Substances

NGOs: Non-Governmental Organisations

NSO: National Statistics Office (Malta)

PL: Partit Laburista (Malta)

PN: Partit Nazzjonalista (Malta)

R-A Theory: Resource-Advantage Theory

RCDC: Resource, Competence and Dynamic Capability

R&D: Research and Development

SEP: Superior Economic Performance

SIDS: Small Island Developing States

SMEs: Small- and Medium-Sized Enterprises

SPC: Supplementary Protection Certificate

TRIPS: Trade-Related Aspects of Intellectual Property Rights

UN: United Nations

UNCTAD: United Nations Conference on Trade and Development

UNDP: United Nations Development Programme

UNIDO: United Nations Industrial Development Organisation

UoM: University of Malta

WIPO: World Intellectual Property Organisation

WHO: World Health Organisation

WTO: World Trade Organisation

## 1. Introduction

*The purpose of this chapter is to set the scene for the subject of the thesis. While some small states have done well economically, many others are still struggling to ensure a good standard of living for their citizens. How will this change in a post-industrial era? An outline as to the reasons motivating this research and its structure is given.*

Every generation believes that it is living an era of significant change. Yet, change has been a constant phenomenon in human history. What varies is the speed at which change occurs. Change destabilises the status quo that creates new winners and losers. As Darwin (1859) said, it is not the strongest, nor the most intelligent, of species that survives, but the most adaptable. The pace and reach of present change is, perhaps, unprecedented. Technological developments in communications, information processing and transport are re-defining our sense of space and time (Herbolzheimer & Amann, 2007). Globalisation has become the hallmark of our time, but the world remains far from being a 'global village', as Levitt (1983) predicted. Humanity continues to be divided by culture, wealth, knowledge and race.

Decolonisation in the 1950s and 1960s led to the emergence of several new nation-states, and many of these states consider themselves as small; they soon realised that they were 'born' in a world which is not designed to cater to their specific needs. They have craved for economic development to strengthen their newly acquired sovereignty and improve their standard of living. They have been campaigning under the banner 'trade not aid' in the hope that international business will help them find their place in the global community. Many of these states initially relied on import substitution to drive economic growth. The 'infant industry' argument became popular among policymakers, who advocated the protection of new enterprises, allowing them time to mature and withstand international competition. Import substitution has generally proven to be wasteful and unsuccessful.

Other small states sought to push for industrialisation by making themselves attractive for foreign direct investment. They attempted to compensate for their perceived disadvantages (e.g. higher transport costs and the lack of technology and significant domestic market) by offering generous tax incentives. Some managed to exploit the advantages of their location, often attracting 'near shore' activities rather than 'offshore' ones. In the 1990s, policymakers

in the Third World came to believe that their only chance at economic development was neo-liberalism, including privatisation and trade liberalisation. Today, many of these states, 'are a mish-mash, combining the productive with the unproductive' (Rodrik, 2011a) and globalisation has been entrenching rather than helping them overcome dualism.

Our understanding of society is defined by context and time. Kor *et al.* (2007, p. 1189) argue that 'time and knowledge belong together'. The foundations of modern economics, as well as business studies, were largely moulded in the industrial age, in times of relative stability. Nowadays, 'firms exist in highly turbulent and chaotic environments that produce disorder, disequilibrium and substantive uncertainty' (Hitt *et al.*, 1998, p. 23). Although competition and market structures have long been a primary concern of economic theory, understanding the dynamics of value creation, requires different assumptions for value creation (Allen, 2004). Neo-classical prescriptions 'are flawed not because they are theoretically unsound, but because we do not live in a neoclassical world' (Wint, 1998, p. 282).

Economists consider size to be a paradox (Mehmet & Tahiroglu, 2003; Prasad, 2004). Small economies are generally regarded as 'sub-optimal' (Downes, 2006). Salvatore's theorem about 'the importance of being unimportant' is an exception (Armstrong & Read, 2003). Salvatore believes that small states are able to exploit their relative insignificance through international free riding and rent seeking. In an era dominated by industrialisation with its emphasis on mass production, mass markets, intensive resource utilisation and economies of scale, small economies were seen as being handicapped. Given existing technologies, a small home market was seen as hindering critical mass and preventing enterprises from operating at the minimum scale, necessary for efficient output. Often lacking reliable suppliers of materials and components, enterprises had to maintain larger stocks. Also, the cost of living is relatively higher due to additional transport costs.

The post-industrial era, and in particular, the increased importance of tertiary activities, opens new opportunities for small states. As the global scenario continues to evolve, small states will have to manage their change process to adapt, if not pre-empt, emerging realities. Globalisation is undercutting the validity of traditional, state-centred forms of social science: 'the exclusive attention to this level of aggregation is becoming less useful in light of the changes occurring in the organisation of economic activities which increasingly tend to slice

through, while still being unevenly contained within, state boundaries' (Henderson *et al.*, 2002, p. 437). 'It is fair to argue that the (nation) state is less capable of providing a suitable reference or explanation to contemporary dynamics' (Baldacchino, 2010, p. 40). Ohmae (1995) proclaims the end of the nation state, insists that it is no longer a meaningful unit and questions its usefulness in understanding and interpreting flows of economic activity. Killick (1999) agrees that the sovereign state is becoming an outmoded entity. Weiss (1998) stresses that globalists tend to over-state and over-generalise state powerlessness.

Globalisation and states are not necessarily antagonistic. Strong states are able 'to adapt, internationalise their capabilities and assist their firms to adjust to the external environment' (Weiss, 1998, p. 206). Globalisation, the latest stage of capitalist development, seems to be losing much of its appeal as has largely failed to deliver many of its promises (Piasecki & Wolnicki, 2004, p. 312). Although globalisation is creating new wealth, some of which is trickling down to people in many corners of the world, for the working classes in more mature economies, globalisation has become a threat to their jobs. Jagdeo (2007) discusses the deep impact, consequences and manifestations of globalisation and warns that globalisation is giving rise to increased income inequality.

'Globalization seems to capture both the menace and the promise of change' (Fonseca, 2002, p. 5). Stiglitz (2003, p. 20) argues that with globalisation, 'even many of those who are better off feel more vulnerable'. The swift emergence of globalisation as a core interpretative category throughout the social sciences is challenging 'not only humanity's understanding of the world but also the tools it uses to develop that understanding' (Kirby, 2006, p. 651). Baldacchino (1998, p. 276) suggests that 'the world is now constituted by both a space of places and a space of flows'. Places are being transformed by flows of capital, labour, knowledge and power, and at the same time, are transforming these flows through their institutional and social structures.

Some small states have sought to overcome the limitations of 'smallness' through economic integration with other states. However, this alone does not necessarily lead to increased efficiency (Mehmet & Tahiroglu, 2003). The 2008 global economic crisis proved to be a reality check for the fundamentalist belief in the supremacy of the 'invisible hand'. The real,

productive economy has been giving way to speculation, which has become a primary determinant of currency values, international prices of commodities and portfolio investment.

Will globalisation lead to a world with fewer borders or an increasing number of small states? (Alesina & Spolaore, 2003). The tasks of national economic management are ever changing (Weiss, 1998, p. 2), and small states are finding it increasingly hard to determine their role in the emerging global constellation. Then, what are the strategic options available? Should small states seek to 'stand-alone' or should they move closer to each other (as is the case of Caribbean countries)? Should they join an economic bloc, as Cyprus and Malta did when they joined the EU? The future of small states largely depends on the emerging global economic scenario. Their openness obliges them to adapt to forces arising from the external environment. Nevertheless, small states continue to look up at bigger states in understanding the threats and opportunities emanating from globalisation (United Nations, 2006).

The key research problem relates to the strategies that small states need to follow so as to enhance their competitiveness and achieve what can be considered as a 'superior economic performance'. To date mainstream theories scarcely give any attention to the specific realities of small states. Small state studies generally fail to give coherent and comprehensive explanations of what needs to be done for them to achieve such a performance. This research proposes to delve into the dynamics underlying small states' competitiveness.

This thesis is motivated by the belief that current academic explanations relating to the competitiveness of small states do not provide adequate guidance to policymakers in these states, which prevents them from managing strategically their economies (especially in their interface with international markets). As a result achieving an 'adequate' economic performance has proven to be a formidable challenge for most small states.

This research brings together three levels of analysis and seeks to argue that 'proximity' (both space and people) as well as 'time' considerations in small states render these levels more interdependent. These three levels are as follows:

- The EU (the supra-national level, which in the context of this research, triggers the change process)



- Malta (the national level, through which most changes arising from the supra-national level are channelled to enterprises within a specific sector)
- The pharmaceutical industry (the sector level, at which change impacts the immediate environment in which enterprises operate).

The externally generated change process which this research examines was triggered by Malta's membership in the EU. For illustrative purposes, the field research will entail a case study of how EU membership impacted on the evolution of the pharmaceutical industry in the country. The pharmaceutical industry is considered as a knowledge-intensive, high value-added economic activity offering good remuneration to employees and is the type of economic activity which all small states wish to develop. The development of the pharmaceutical industry involves many of the challenges that small states have to overcome, at both the sector and enterprise level, to achieve a superior economic performance. At a time when the relative contribution of manufacturing to the Maltese economy was declining, the pharmaceutical sector was growing at a significant pace.

Competition has been the subject of study of various disciplines. Neo classical economists believe that perfect competition, where both suppliers and buyers have no control over price, maximises economic welfare. Under such conditions, all players have the same market power, and none of them reap higher returns (profits). If, for any reason, a player achieves greater market power than the other players, enabling him to manipulate prices and reap abnormal profits, this is deemed to be a 'temporary' phenomenon, as market forces will eventually bring all players back to having the same market power.

By contrast, the very purpose of business studies is to help enterprises perform better than their competitors so as to achieve some desired objective (such as increased market share or higher profits). Achieving such a performance gives an enterprise an advantage over its competitors which, if properly exploited, can help it sustain its market power. Porter (1980) deemed that industries characterised by 'perfect competition' were unattractive. High competitive intensity impacted negatively on the industry's overall profitability and hence its attractiveness. The five forces model proposed by Porter (1980), is based on the structure-conduct-performance paradigm of industrial organizational economics, and eventually provided the thinking for him to study competitiveness at the national level. His approach

was to study successful industries (for example, electronics in Japan, fashion wear in Italy and engineering industries in Germany) to identify forces underlying the competitive advantage of national economies. Porter(1998) came to the conclusion that the achievement of competitive advantage is a localised process. His decision to focus on attractive, 'successful' industries implicitly implied that, not only were they not characterised by perfect condition, but also that enterprises enjoying high market power had managed to extend it to global markets.

The approach taken by this research follows that adopted by Porter (1998) in his seminal work on the competitiveness of nations. The nation is seen as a set of contextual variables which influence the competitive performance of industries and firms. To arrive at the competitiveness of nations, Porter (1998) studies the origins of an industry in that nation, how it grew, when and why the industry's companies developed international competitive advantage. This research goes beyond Porter's work by including changes triggered at the supra-national level and examines their impact at the national and sector level. A limitation of this research is that it does not delve deeply into the enterprise level even if, ultimately, this is the level at which competitive advantage is created (Porter, 1998).

In a tradition set by International Relations, most academic disciplines continue to associate small states to 'lack of power' and hence vulnerability. In the light of the work carried out by Porter (see 1998) a key question for the subject matter of this thesis becomes: what does it take for small states to achieve 'market power' and build a capacity to influence (if not determine) the prices they fetch for their exports? Porter (1998) states that wealth is created not inherited, implying that a superior economic performance is the result of competitive advantage rather than comparative advantage. This does not imply that the wealth of oil-rich Saudi Arabia is not real, but that it is of a lower order than that of for example Japan which competes on innovation.

Adam Smith (1776) argues that free trade is superior to mercantilism as it benefits all participants. According to the law of 'absolute advantage', for this to happen, countries need to specialise and produce those goods in which they have an advantage. The key consideration for small states is: what form should their specialisation take if they are to benefit from international trade? As this research will elaborate later on the search for

specialisation by small states is even more problematic given limited economies of scale and their emphasis on risk minimisation (not being over-dependent on a few economic activities).

The foregoing indicates that there does not exist in mainstream economics and business studies an adequate explanation of the dynamics of small states' competitiveness and this research is intended to help fill this void. The key research questions which this thesis proposes to answer are:

- a. How do small states' economies differ from those of larger states?
- b. Why are these differences important for competitiveness and superior economic performance?
- c. How can insights from existing theories contribute towards developing an alternative approach?
- d. How does EU membership impact on the development of the pharmaceutical industry in Malta?
- e. Does the experience of the pharmaceutical industry in Malta confirm or otherwise the relevance of the major components of the proposed theoretical framework?

This research throws new light on the limited relevance of existing academic explanations and theories on competitiveness and superior economic performance to small states. This should make policymakers and the business community within small states aware about the limited applicability and usefulness of these theories to the strategic management of their economies. The thesis does not stop at explaining why this is so but goes further and proposes an alternative theoretical framework intended to give a better understanding of the dynamics of small state' competitiveness. In particular, this research's focus on the need to develop key competencies has important implications for policymakers and the business community in small states.

This research also opens a new chapter in both International Business and Small State Studies. The former has largely ignored small states as a distinct area of study (even though more recently additional attention has been given to the specific role of small and medium enterprises). The latter have never before applied, or sought to build upon, theory emerging from business studies. In this respect this research opens new horizons which can lead to further research.

Following this introductory chapter, the rest of the thesis is structured as follows:

Chapter two elaborates on academic explanations arising from small state studies and why these are not deemed to offer coherent and comprehensive explanations of what underpins the competitiveness of small states.

Chapter three explores mainstream theoretical explanations of superior economic performance at three levels: state, enterprise as well as state and enterprise. Those relating to the state give no particular attention to the specific conditions of small states. Those relating to the enterprise were considered so as to explore whether explanations offered could be extrapolated to small states and their enterprises.

Drawing on the literature review chapter four proposes an alternative theoretical framework offering an explanation as to the dynamics of building and sustaining competitive advantage in small states.

Chapter five elaborates on the methodology followed by this research and the role played by case studies in qualitative research.

Chapter six presents the results of the case study and these are divided into two parts:

- Those relating to the context of the case study. A schema which draws on Resource-Advantage theory is utilised to help understand the setting of the development of the pharmaceutical industry in Malta after its joining the EU .
- Those emerging from the field research relating to the applicability of the alternative theoretical framework proposed by this research. The proposed framework guided the data gathering process, its analysis as well as evaluation.

Chapter seven presents a discussion, draws some conclusions on the research findings and re-assesses the contribution of this research in the light of the research problem and questions it sought to address.

*This introduction outlines the research layout. The research problem and key research questions were defined in the light of the existing literature gap. The possible contribution of the thesis to academic knowledge as well as to policymakers and the business community is also explored and an outline of the research's structure given.*

## **2. Small States and Superior Economic Performance**

*This chapter focuses on issues relating to small states and theoretical explanations addressing their superior economic performance. The chapter finds that the literature is dominated by a ‘vulnerability’ complexity, equating smallness to weakness. It further argues that economic success achieved by some small states is creating an awareness that this need not be so.*

The decolonisation process and the disintegration of the Soviet Empire (1990s) led to a significant increase in the number of sovereign small states across the world (Read, 2002). Until then, the majority of small independent states were to be found in Europe. Most ‘small states’ are now non-Western nations with economies which are still developing. Within large sovereign states, there has been a tendency towards granting increased economic and political autonomy to regions with distinct identities (Armstrong & Read, 1998). This is ‘further blurring the differences between sovereign states, territories and regions’, especially as globalisation and the build-up of supra-national regional trade blocs accelerate (Read, 2002, p. 171). The world economic order as conceived at Bretton-Woods did not last long. Persistent confrontation between the United State and the Soviet Union escalated tension, and many newly independent countries sought refuge in the UN. This organisation is founded on the principle that every sovereign state, large or small, has a right to self-determination. The fact that every state, irrespective of its size or power, is entitled to one vote at the General Assembly gives small states a sense of importance. Using ‘the United Nations as a forum and a force and claiming “non-alignment” as an important diplomatic innovation, small states have risen to prominence if not power’ (Neumann & Gstohl, 2006, p. 55).

Katzenstein (1985, p. 42) finds that ‘[m]ultilateral commercial diplomacy still focuses primarily on the big states, and small states often find their special needs and interests disregarded’. In 1973 at the UN, the small states, together with other developing countries, voted in favour of the creation of a New International World Order. In reality, no concrete results were obtained and the declaration remains just a statement of good intent. Since the collapse of the Soviet system, a broader distribution of global economic and political power has been emerging, as evidenced by the increased importance of the G8 and G20. Small states are not represented at this level, but this has not discouraged them from being more

active in international forums, emphasising their particular needs arising out of ‘characteristics that pose special development challenges’ (Commonwealth Secretariat and World Bank, 2000, p. ii)

The literature of small states has significantly evolved in the past two decades, drawing primarily on international relations, natural sciences (including geography), economics and public policy. To date, studies on small states by business, strategic and management analysts have been surprisingly limited. This may be due to the inherent belief within these disciplines that a ‘best practice’ has no territorial boundaries.

The modern state system goes back to the Treaty of Westphalia in 1648 and ‘owes much to the enforcement by European states of their concept of an international society of judicially sovereign states’ (Sanders, 2005, p. 57). International relations see the nation state as a 19<sup>th</sup>-century European phenomenon. The state is a political institutional structure having authority over a specific territory, which is acknowledged by other countries and has its own government. The concept of the state too is a messy one (Mann, 1994). Warrington (1994b, p. 4) observes that the term state ‘is itself not unambiguous’ and that, at times, it is used to refer to territories with distinct political/ constitutional status arising from historical or geographical anomalies.

Sovereignty can refer to both internal and external considerations. ‘Internal sovereignty’ acknowledges that the state is the supreme law-making authority within its defined territory and has the coercive power to enforce laws. ‘External sovereignty’ arises from the fact that a state is independent of all other entities and, internationally, speaks and acts for itself. Political sovereignty is not a simple binary variable but a discrete scale ranging from full independence to relative autonomy (Schaffer, 1975). ‘De jure’ economic sovereignty does not necessarily imply ‘de facto’ economic policy autonomy (Read, 2002).

A nation is a collectivity of people who live as a community, share a common heritage and destiny and have mutual identification. Nationhood, with its powerful symbols, has become a potent force that complements statehood. The concept of a small (nation) state is contested in both the theory and practice of international affairs and the simplest way of defining a small state is its not being a great power (Neumann & Gstohl, 2006). Thorhallsson and Wivel

(2006) disagree with such an approach, arguing that such a definition is tautological and evades the real question of what is small. As a state-centric, power-focused discipline, international relations, generally, perceives smallness as being synonymous with weakness. 'Smallness is powerlessness' (Sanders, 2005, p. 38). From a 'legal' point of view, all sovereign states are meant to be equal, but in reality, their power differs. The 'realist' school sees small states as pawns in the games of larger states. Pace (2006, p. 35) remarks that UN resolutions indicate that 'small states may be particularly vulnerable to external threats and acts of interference in their internal affairs'. Smallness is also viewed as a handicap to state action and limiting the capability, influence and survival of states (Browning, 2006). It is a mistake to view micro-states as scaled-down versions of 'ordinary' or normal states (Warrington, 1994a). Baldacchino (2008) agrees that it is not right to think about large jurisdictions and territories as being 'normal'. According to the 2006 CIA World Fact book, out of 237 jurisdictions, only 23 have populations of over 50 million and 158 jurisdictions have populations of less than 10 million, of which 41 have a population of less than 100,000.

Most economic studies of small states adopt the 'rational actor' model, which assumes that the state is a unitary and value-maximising calculator. Small states are often perceived as being more 'unitary' than larger ones. Weiss (1998, p. 15) disputes such a perspective, arguing that far from being unitary or monolithic structures, states are 'organisational complexes whose various 'parts' represent different ages, functions and (at times) orientations'. The Lewis model perceives industrialisation as the key to structural transition 'from low productivity labour-surplus agriculture to more technologically intensive, large scale manufacturing founded upon low-cost, labour-intensive production techniques' (Armstrong & Read, 2003b, p. 102). Smallness is inevitably seen as a negative factor generating diseconomies of scale (Mehmet & Tahiroglu, 2003). Oberst and McElroy (2007) find that small island literature has traced three major threads, sequentially emphasizing various aspects of

- (1) economic structure
- (2) economic performance and
- (3) the role of domestic policy.



Campling and Rosalie (2006) identify three historical shifts in the evolution of the literature on small island states:

1970s: emphasis on structuralism, exploitative forms of neo-colonialism and realisation that an alternative, people-centred development is needed

1980s: shift towards neo-liberal ideology, focusing on the role of export-oriented production and a growing pre-occupation with geopolitical security

1990s: focus on environmental and economic vulnerabilities.

During the 2000s, the primary concern is environmental and economic vulnerabilities coupled with new streams of study trying to explain the 'superior performance' of some small states (resilience and strategic flexibility schools). Rising global concerns on climate change has re-enforced the pre-occupation surrounding the fragile eco-systems of small island states, while geopolitical issues re-surfaced from time to time in the light of the experience of 'failed states' (Scheyvens & Momsen, 2008). Prasad (2004) states that 'country size' has been a paradox in economic theory. He refers to Salvatore's (2007) hypothesis of 'the importance of being unimportant'. Small states, because they are small, have often succeeded 'in dispensing with standard regimens, and in slipping subtly through the nets of conformity' (Baldacchino & Milne, 2000b, p. 238). Offshore financial centres are considered by bigger countries to be illegitimate or as questionable activities with 'capital-distorting effects' (Baldacchino & Milne, 2000, p. 238), while Prasad (2004) claims that export processing zones violate the principles of free trade since they create artificial incentives for investors.

In the effort of small states to circumvent the 'constraints associated with a sub-optimal domestic market size', trade is essential as 'increased specialization improves domestic efficiency and competitiveness' (Read, 2002, p. 175). The degree of openness of an economy influences its flexibility since trade is a 'potent medium both for the transfer of information and for the transmission of incentives to adapt' (Killick, 1995, p. 22). Alesina (2003, p. 230) states that the relationship between country and market size depends on the trade regime and that the 'viable' size of a country decreases with economic integration. 'The bottom line is that small countries can prosper as long as they are open to international trade...Given that small countries need international trade to prosper, they need peace to be able to trade'.

Easterly and Kraay (2000) also find a positive correlation between economic openness and income. Goods embody technological know-how and small states can acquire foreign knowledge through trade (Grossman & Helpman, 1991; Aubert & Chen, 2008). Productivity growth in small states tends to be higher as they are more sensitive to changes in trade-related technology diffusion (World Bank, 2008a). The trade multiplier in small states has a significant impact on economic growth. International trade, however, cannot completely offset the absolute size effects of a small state (Armstrong & Read, 1998). Baldacchino (2006, p. 46) points out that '[i]n the case of small, densely populated territories starved of land – such as the city states of Singapore, Hong Kong, Bermuda and Malta – industrialisation or tertiarisation have been the inevitable growth poles, obliging a quick shift of mind-frame towards export promotion and the penetration of export markets'. International economic theory considers small size to reflect a country's inability to influence its own terms of trade, rendering it a price-taker on world markets (Armstrong & Read, 1998a). Elsewhere, Armstrong and Read (2002, p. 436) state that smallness is equated with the inability of a country to affect its own terms of trade, that is, the world prices of its imports and exports, and conclude that 'this definition can be seen to be the minimum criterion for a large country, rather than a means to classify small states as a distinct group'. Armstrong and Read (2003b) point out that 'structural openness' (a high share of trade in GDP) also has important macroeconomic policy implications in terms of the balance of payments, international monetisation, exchange rate and domestic monetary autonomy. The authors add that any gains from specialisation through trade must be offset against the greater risk of exogenous shocks. Integration with the global trading system creates a critical risk asymmetry for small states (Read, 2002). The World Bank (2008a) notes that small size limits the capacity to diversify risk. Given the experience of Fiji, Malta and Mauritius, Baldacchino (1998, p. 271) cautions that although '[s]ome success has been admittedly achieved in terms of that seductive option: export oriented industrialisation by invitation ... But the price to be paid is heavy and the benefits gained may be largely illusory. The main beneficiary is also likely to be footloose capital which does not generate the sustained, export growth orientation so many microstate governments desire'.

UNCTAD's typology of small states is based on their principal economic activities and includes the following:

- External rental income from worker remittances and the sale of licences from fishing and other resources (MIRAB economies)
- Exports of natural resources and primary products
- Service-oriented, notably tourism, with or without other important economic activities
- Diversified economies possessing large manufacturing sectors

## **2.1 Vulnerability School**

Vulnerability is a multi-dimensional concept (Pace, 2006) with small countries being more vulnerable than large ones, 'economically, politically and militarily' (Katzenstein, 1985, p. 80). The defining feature of smallness is not the lack of economic development opportunities, 'but rather a much higher than average dependency on, and vulnerability to changes in, the wider global political and economic environment' (Heron, 2008, p. 245). Small state vulnerability revolves around their economic viability, environmental degradation, cultural survival, security and demographic instability (Warrington 1994a; 1997a). The social vulnerability of small states arises from illicit drugs, violence, organised corruption, HIV/AIDS and the greater than average risk posed by internal and external factors in undermining social cohesion, introducing systematic pathologies and eroding social capital (Thomas, 2003).

Environmental vulnerability refers to the susceptibility of small states (in particular islands) to natural catastrophes and their ecological and environmental fragility as well as the long-term consequences of global climate change. The impact of natural shocks on aggregate GDP and long-run growth in small states can be devastating (Armstrong & Read, 2003b). The political and strategic vulnerability of small states has long been recognised and it 'arises from their susceptibility to external political pressures and strategic manoeuvring by larger neighbouring states and the major powers' (Armstrong & Read, 2000, p. 286). The economic vulnerability of small states arises from their inherent economic sub-optimality, concentration in domestic economic activity and a high degree of dependence upon external trade, particularly imports (Armstrong & Read, 2003b). Also, the 'adverse macroeconomic shocks

in microstates have the potential for a disproportionately large impact on poverty and human welfare' (Chand, 2006, p. 70).

The implications of smallness have been pursued in all major multilateral circles, including the UN where the focus has been on small island developing states (SIDS) (UNCTAD, 2007). The WTO has a 'Work Programme on Small Economies' but to date, it still has 'no formal or informal definition of small, weak and vulnerable economies' (Faizel, 2006). Small states are portrayed as victims of their geographical circumstances, actions and lack of expertise (Turnball, 2003). Bourne (2003, p. 13) suggests that '[i]t is easy to become pessimistic about the future of small states in a world that is tending so dramatically towards agglomeration and concentration of wealth and power'. It was easy for the 'convention that "smallness equals weak" to take root uncritically' (Baldacchino & Milne, 2000a, p. 4).

### **2.1.1 Vulnerability indices**

Available data 'obscures marked differences in economic performance of small states' (Favoro & Peretz, 2008, p. 266) with methodological problems having hindered the emergence of 'robust evidence concerning the impact of vulnerability on growth' (Armstrong & Read, 2003b, p. 115). GDP per capita and other income-based measures 'do not provide a complete picture of the long-term structural and institutional constraints on their growth' (Armstrong & Read, 2003b, p. 108). A number of indices have been devised to gauge small state vulnerability. The vulnerability indices produced by the University of Malta, Commonwealth Secretariat and United Nations Commission for Development Policy, generally, focus 'on permanent or quasi-permanent features associated with economic vulnerability' (Briguglio *et al* 2006:27).

Briguglio's economic vulnerability index (EcVI) was initially developed to explain the seeming contradiction that a small state can be economically vulnerable and yet, register a relatively high GDP per capita. There are a number of versions of the EcVI produced, first by Briguglio (1992; 1995; 1997) and subsequently, Crowards and Coultier (1998). The conclusion that emerges from these indices is that small (island, developing) states, as a group, tend to be more economically vulnerable than other countries (Briguglio & Galea, 2010). However, empirical results convincingly support the growing view in the literature

that small size is not necessarily a disadvantage (Easterly & Kraay, 2000). Smaller countries are not poorer than average (Browning, 2006) with many registering a relatively strong performance ‘whether in terms of their growth rates or income levels’ (Armstrong & Read, 2006, p. 79). Indeed, of the ten richest countries in the world, in terms of GDP per capita, only four have populations above 1 million (Alesina, 2003). The empirical evidence gathered by Alesina *et al.* (2000) shows that country size does not matter for economic growth or the level of GDP per capita when trade is relatively free. Given that many small states generate a relatively higher GDP per capita, despite their high exposure to exogenous economic shocks, there must be other factors which offset the disadvantages associated with vulnerability (Briguglio *et al.*, 2006b). Briguglio (2003) refers to the seeming contradiction that a country can be highly vulnerable and yet attain high levels of GDP per capita, as the Singapore Paradox.

## 2.2 Resilience

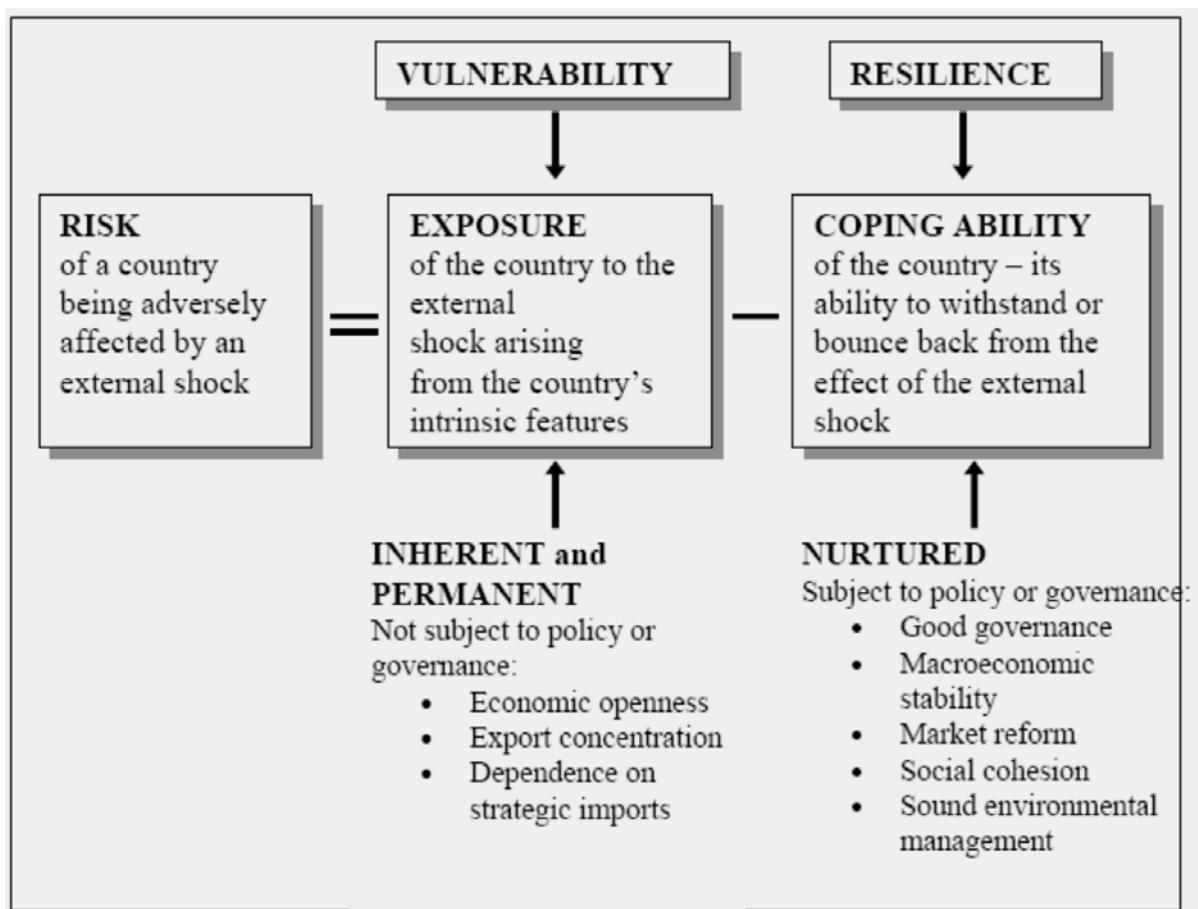
Kuznets was the first economist to observe that small states have advantages which allow them to adapt relatively quickly to change (Easterly & Kraay, 2000). While it is important not to romanticise the situation of small islands (states) or their peoples, ‘it is essential that we recognise their strengths by identifying positive attributes or forces for change, and then to develop strategies which utilise these strengths’ (Scheyvens & Momsen, 2008, p. 502). The search for explanations to the Singapore Paradox gave rise to a branch of the vulnerability school which seeks to identify those factors leading to the ‘resilience’ of successful small states (Pace, 2006). Resilience can be defined in many ways (Briguglio, 2004) and has at least three interpretations relating to the ability to do the following:

- (a) recover quickly from shock: ‘shock-counteraction’
- (b) withstand the effect of shock: ‘shock-absorption’
- (c) avoid shock altogether: ‘shock avoidance’

Generally, the resilience of small states refers to the ability of an economic system to return to its initial steady-state position after a perturbation or exogenous shock (Downes, 2006). GDP per capita is ‘more sensitive to resilience variables than to vulnerability ones’ (Briguglio *et al.*, 2006b, p. 282). Cordina (2008, p. 133) views resilience in terms of the

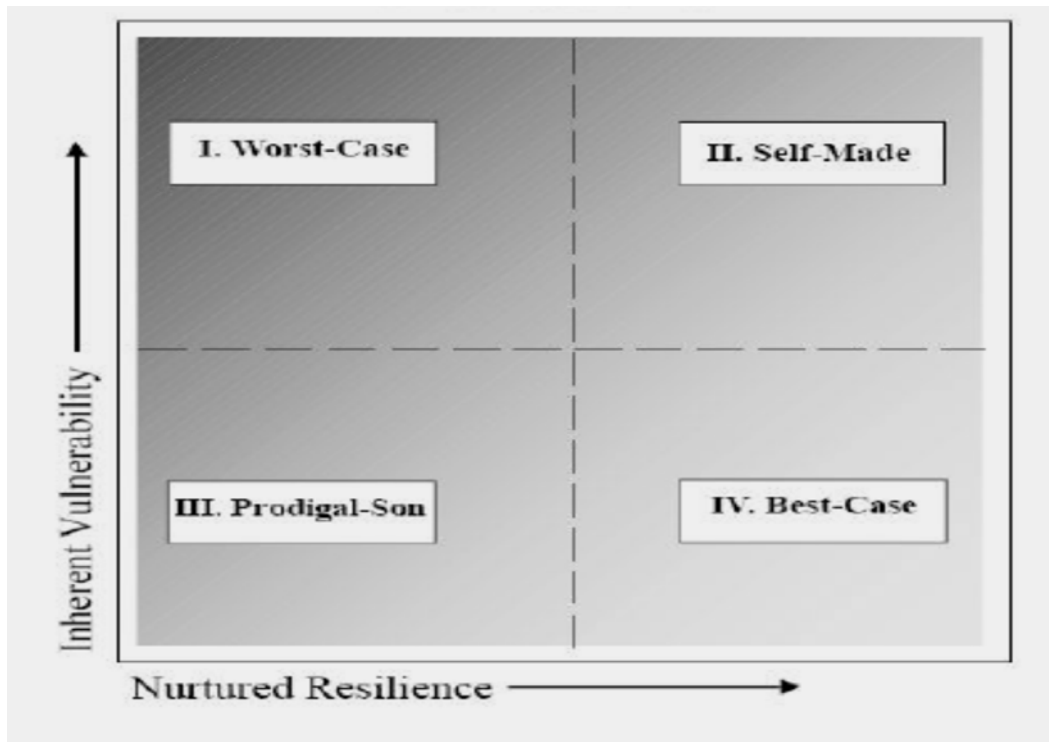
asymmetric effects of shocks to which an economy may be exposed, arguing that ‘[t]ypically, the effects of negative shocks would outweigh those of positive ones’. He adds that after exogenous shocks, it is essential that resources are allocated as efficiently as possible and quickly reallocated to their best possible uses. Briguglio (2004) distinguishes between inherent and nurtured resilience. ‘Inherent’ resilience is the obverse of vulnerability, in the sense that inherently resilient countries should register low vulnerability scores. ‘Nurtured’ resilience is that which is developed and managed and often the result of good policymaking and effective governance (figure 1).

The private sector plays an important and crucial role in building economic resilience. ‘The private sector as opposed to the public sector is generally more exposed and therefore more responsive to market realities and is therefore better equipped to absorb and recover from shocks’ (Vella, 2008, p. 147). Policies aimed at developing the private sector need to be credible and sustained, ‘clear and consistent rules and regulations are critical in this regard’ (Vella, 2008, p. 159).



**Figure 1: Risks Associated with Being Adversely Affected by External Shocks**  
 (Reproduced from Briguglio *et al.*, 2006b)

Briguglio (2004) explains the Singapore Paradox in terms of the juxtaposition of economic vulnerability and resilience. Briguglio *et al.* (2006b, p. 31) presents four possible scenarios that combine inherent vulnerability or resilience with policymaking (figure 2).



**Figure 2: Four Scenarios of Vulnerability and Resilience**  
(Reproduced from Briguglio *et al.*, 2006b)

1. 'self-made' countries: have a high degree of inherent economic vulnerability but adopt the right policies to build economic resilience
2. 'prodigal son' countries: have a relatively low degree of inherent economic vulnerability but have policies that are harmful to economic resilience
3. 'best case' countries: although not inherently vulnerable, these countries still adopt resilience-building policies
4. 'worst case' countries: these compound the adverse effects of inherently high vulnerability by adopting policies that run counter to economic resilience

Briguglio *et al.* (2006b) propose a 'resilience index' intended to measure the effect of shock absorption or shock counteraction policies, which is constructed using the following variables:

- macroeconomic stability
- microeconomic market efficiency
- good governance
- social development

The issue of resilience building in small states is important because it carries the message that these states should not be complacent and adopt measures that boost economic, environmental and social resilience. UNCTAD's (2007) approach to structural weakness and vulnerability rests on the goal of building resilience.

### **2.3 Economic integration**

The World Bank (2008a, p. 4) suggests that rather than focusing on size and geographic considerations, it is more fruitful to study 'the integration of these economies with their neighbours or with the rest of the world'. Productivity improvement in small states has been closely related to integration and those small states that failed to integrate have had much weaker economic performances (Thomas & Pang, 2007). The issue of economic integration is becoming increasingly important, as more small states are considering membership in a regional bloc. 'Neither size nor geography can be changed, but integration can help overcome size and distance disadvantages' (Warrington, 1997a, p. 103). These advantages are not as clear cut given that the growth benefits of economic integration schemes tend to favour relatively developed countries (Armstrong & Read, 1998).

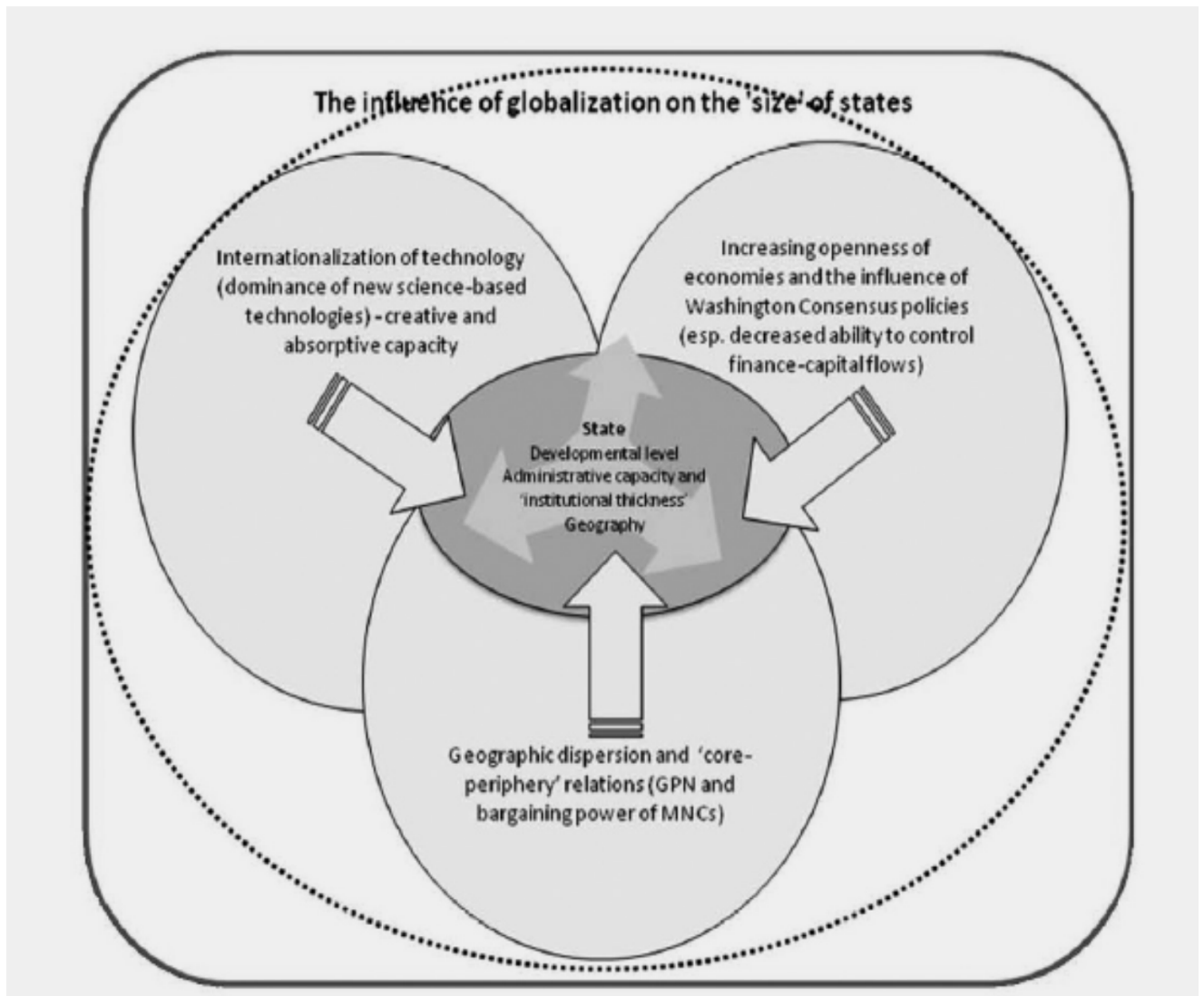
Small state membership in larger blocs can entail the dissolution of the flexible regulatory environment, with which many of them have overcome the structural disadvantages of their economies. 'At the same time, they would have to bear the increased costs of (EU) governance, without any clear prospect of the benefits they could reap there from' (Dózsa, 2008, p. 102). Government and policy advisers should stop thinking of international integration as an end in itself; openness should be part of a development strategy and not a substitute for one (Rodrik, 1999). Economic integration yields benefits only when complementary policies and institutions are domestically in place. Katzenstein (1985, p. 203) points out that '[h]igh integration does not necessarily mean the displacement of "national" economies as the locus of accumulation or weakening of national economic management'. Policymakers must also reinforce their external strategy of liberalisation with an internal



strategy that gives the state substantial responsibility in building physical and human capital and mediating social conflicts (Rodrik, 1999).

Baldacchino and Greenwood (1998, p. 15) observe that ‘the so-called “new economy” of globalisation and information technologies must be engaged critically by small islands’. The emergence of a knowledge society points towards the continued relevance of ‘local’ conditions given that most knowledge creation is tacit, person-embodied and context-dependent (Morgan, 2004). Globalisation is becoming a powerful influence on the future competitiveness of enterprises in the world’s smallest economies (Wignaraja *et al.*, 2004). Globalisation offers small states’ enterprises access to new technologies, skills, markets, financial sources and hence, better outward-oriented growth prospects. But, globalisation also exposes these enterprises to intensive competition from imports, foreign investment and low-cost developing country enterprises. There is a real prospect of winners and losers among small states and enterprises within them. The double-edged nature of globalisation is daunting to both policymakers and enterprises in small states.

Browning (2006) suggests that in the globalisation era, the ‘big-small’ state dichotomy is increasingly less relevant. In the 21st century, ‘smallness’ is not defined by absolute variables, but by processes; globalisation is leading to the emergence of new economic trends, ‘increased openness of economies, internationalization of technology and the geographic dispersion of economic activity’ (Tonurist, 2010, p. 11). These are the real determinants of the ‘size’ of states, and Tonurist outlines how the forces of globalisation ‘determine’ size using the following illustration (figure 3):



**Figure 3: Influence of globalisation on the 'size' of states  
(Reproduced from Tonurist, 2010)**

'Smallness' defined in such a manner has important implications for the economic performance of states. The effects of the chosen processes intensify with the influence of geography (core-periphery relationships), developmental level and technological and industrial specialisation of states (Tonurist, 2010). Seen from this perspective, countries with much larger populations can also be considered 'small'. Baldacchino (1998, p. 276) comments that 'Today, globalisation appears to have replaced development as the onerous strait-jacket, obliging all and sundry to conform'. From the viewpoint of small states, globalisation is not homogeneous, uniform or equal, but messy and often richly asymmetrical (Prasad, 2004). Small states are likely to be extremely sensitive to the impact of globalisation because of the interaction between their high degree of integration in the international economy and their inherent vulnerability (Read, 2002).

## 2.4 Good Governance

Governments' role in driving economic development remains controversial. Neo-classical prescriptions for the appropriate form of government intervention are flawed, not because they are theoretically unsound, but because people do not live in a neoclassical world (Wint, 1998). Governance is defined as the exercise of political, economic and administrative authority in the management of a country's affairs (United Nations Development Programme, 1997). Generally speaking, in small states, a relatively higher degree of government intervention is warranted to rectify market failures. Prasad (2008, p. 947) argues that 'productive transformation' cannot happen automatically through relying exclusively on market forces. Public direction and resources are needed. Basic needs and capabilities are too important to be left solely to market forces'. Policy, more than size, plays a critical role in economic growth (Commonwealth Secretariat, 1997). In today's complex world, there is a need for increased convergence and co-ordination in public policymaking (Inskeep, 1991). Warrington (1994a, p. 109) refers to a state's 'capacity for policy management'. He differentiates between 'good practice' and 'best practice' and expresses a preference for 'good practice', as it indicates that 'decision-makers have a choice of alternative strategies and models of administrative development' and conveys the importance of standards in governance (Warrington, 1997b, p. 5).

Economic growth is significantly conditioned by the quality of a state's bureaucracy (Knack & Keefer, 1995; Campos & Nugent, 1999). All states need good governance, especially small states (Curmi, 2009). Effective public policy has led to the success of various 'micro' European states such as Liechtenstein, Luxembourg and San Marino (Milne, 1999). The state's machinery in small states tends to loom larger than life (House, 1998). Favoro and Peretz (2008) point out that improving public sector efficiency and effectiveness is crucial for small states, where, on average, government consumption as a proportion of GDP is high (20.6%) relative to that of middle-income (14.7%) and low-income countries (11.9 %). Given the relatively greater importance of the public sector in small states, the consequences of policy failure are even more serious (Krueger, 1990). 'Local institutions (or clusters of institutions) and policies (especially in supporting "the technological progress and innovativeness" of enterprises) are of critical importance' (Kozul-Wright & Stanbury, 1998, p. 1) The private sector in many small states is frequently plagued by fragmentation, with too

many representative and business support organisations trying to achieve the same objectives. The private sector in these states needs to be empowered to overcome its dependence on government. Good intentions in public policymaking are necessary but not sufficient. The '[a]bsence of political will, lack of stakeholder participation, policy ambiguity, partisan tensions, poor coordination and communication can all lead to policy failure' (Dodds, 2007, p. 63). Successful outcomes are not necessarily due to good policy design, '[i]mperfect policies may produce successes in propitious circumstances and carefully designed initiatives may come unstuck for unforeseen reason' (Thomas & Pang, 2007, p. 28).

Resilience can be 'nurtured' through good policymaking and effective governance. 'Good governance is an essential underpinning to appropriate policy formulation and hence an indispensable element of economic resilience' (Briguglio *et al.*, 2008, p. 11). It requires not only good practices but also high quality institutions (Prasad, 2008). Proper institutions are key in formulating and implementing policies (Baldacchino & Greenwood, 1998). Institutions have moved to the forefront of the economic development literature (Bertram, 2006; Taymaz, 2009). States are important society-shaping institutions (Weiss, 1998). Institutions are a critical variable in determining how states manage openness and play a key role in how exogenous pressures are translated into new policies. High-quality institutions make a difference in the ability of small countries to manage globalisation (Bräutigam & Woolcock, 2002).

Institutions are self-regenerating 'systems of constraints regulating human interactions' and providing a context for transactions 'in an environment marked by uncertainty' (North, 1990, p. 142). Institutions serve both formal and informal organisations by regulating exchanges and making it easier (relative to individuals) to manage risks. Small states demonstrate high levels of institutional coherence (Scheyvens & Momsen, 2008) and their experience provides considerable material on the diverse role of policies and institutions on development (The World Bank, 2008). Although practically all small states have replaced former colonial institutions with their own institutions, they exhibit relatively stronger institutional quality.

Sutton (2008) identifies four behavioural features which shape the performance of the public service of small states:

- Exaggerated personalism, including domineering ministers and favouritism
- Limited resources, with multiple portfolios and a limited ability to provide a broad range of public services
- Inadequate service delivery, with high cost and the lack of motivation in middle-level management and employees
- High dependence on foreign consultants

Warrington (1999) finds that in emerging polities, the task of institutional innovation is achieved through

- an effective framework capable of meeting growing popular demands
- a high degree of national integration capable of maintaining social order during times of crisis
- an expansion of responsible participation in political processes
- a viable civic culture comprising autonomous and differentiated sectors of society capable of articulating and aggregating interests

## **2.5 Social capital**

The coherence and unitary nature of states tends to be over-emphasised. The state is essentially a ‘conglomeration of varied crystallizations’ (Weiss, 1998, p. 16). Cheung (2008, p. 122) describes the state as ‘a conglomeration of overlapping strategic linkages’. A political economy suggests that polarized societies are prone to competitive rent-seeking by different groups, which have difficulty agreeing on public goods, such as infrastructure and education (Fearon, 2003). Weak states are easily captured by powerful groups, which then exploit their power to extract rents (Fritz, 2003). The effect of shocks on growth is larger: the greater the latent social conflicts in an economy, the weaker its institutions of conflict management (Rodrik, 1998). The literature on small states identifies social cohesion as a primary factor leading to economic success. Small states possess greater social homogeneity and cohesion as well as communal consensus in decision making which contribute to social capital formation and provide an appropriate environment for growth (Armstrong & Read, 2002). Small

European states have been often seen as harmonious manifestations of Bacon's New Atlantis endowed with coherence, agility and intelligence (Katzenstein, 1985).

Sutton (1987) argues that polarisation in party politics is largely absent in small states and this political accord is due to in-group solidarity against constant external threats. Ordinary citizens of small states enjoy a remarkable degree of democratic voice and tend to have direct access to governing elites (Farrugia, 1993). Social development is one of the components of the economic resilience index proposed by Briguglio *et al.* (2006b). Social development in this context refers to the extent to which relationships within a society are properly developed through social dialogue, enabling the undertaking of corrective measures effective in the face of adverse shocks. Social cohesion is generally defined as the 'resourcefulness of a people to respond positively, collectively and responsibly to an identified political, economic, labour-related or social challenge' (Prasad, 2008a, p. 293). Social cohesion and 'social capital' are often used interchangeably. Social capital results from the ability to form 'solidarity', networks of mutual support, in the face of threats or danger (Bertram, 2006) and involves the ability of actors to secure benefits by virtue of membership in such social networks (Portes, 1998). Social capital is also used to include considerations relating to leadership, discipline, personal responsibility, forward planning and adaptability (Connell, 2007).

The level of trust in a society is the cornerstone of economic success (Bartmann, 2000). Strong leadership has an immediate and major impact in small countries because of their limited size. Polarization in party politics is seen to be largely absent in small states and inhabitants identify themselves closely with the state. Political harmony finds its source in the necessity of fostering in-group solidarity against constant external threats (Gagné *et al.*, 2007). Vertical, as well as horizontal, inequalities seem to be less pronounced in small states, and this reduces the risk of internal strife. Micro states are not immune from the conflicts that afflict larger polities, and small-scale societies are not invariably consensual (Warrington, 1997a, p. 105). Small size in itself is no guarantee of lower opportunistic and rent-seeking behaviour (Read, 2006). Gagné *et al.* (2007) note that even if group conflicts in small states tend to be less frequent, once they break out, they may persist and lead to a breakdown of social unity. This is especially true if there is power disparity between the social groups. Warrington (1997a, p. 105) warns that generalisations are risky and that 'the structures of power, political culture, patterns of leadership and discourse of a micro-state will explain

numerous phenomena that might otherwise be glibly attributed to size'. Various studies have sought to pit the assertive, emerging political elite against the traditionally pre-eminent civil servants of small states (Warrington, 1994a, p. 122), but 'by setting up the bureaucracy in opposition to politicians, this view ignores the social roots and values of civil servants'.

Farrugia (1993) notes that 'personal proximity' in small states has its disadvantages and may lead to increased nepotism. Familiarity among the population, coupled with personal, family, and tribal rivalries and/or traditional political and cultural systems, can partiality result in government decisions, making it difficult to generate the necessary consensus and cohesion for sustainable improvements in governance. Social capital is a necessary, although a not sufficient condition for dynamic capabilities (Blyler & Coff, 2003).

## **2.6 Strategic flexibility**

Baldacchino and Bertram (2009, p. 141) observe a 'disposition' among small states to engage with their 'turbulent and dynamic environments' to seize opportunities and create and transfigure resources. They refer to this as 'strategic flexibility' (in this context, 'strategic' is being used in the sense that the action taken is part of a thought-out process and not purely an intuitive one). The flexibility and adaptability of small states has captivated the interest of many analysts. Katzenstein (1985, p. 211) suggests that small European states 'continue to prosper-not because they have found a solution to the problem of change but because they have found a way to live with change'. This has also been found true of small firms in small economies, which seem to prosper by exploiting the benefits of flexibility gained from their need to adapt to forces outside their control (Blazic-Metzner & Hughes, 1982). Although researchers generally find that small states are more flexible and can adjust more quickly to rapid changes (Bräutigam & Woolcock, 2002), not everyone agrees. Favoro and Peretz (2008, p. 275), for example, emphasise that small size 'implies that flexibility to adapt to external shocks is limited'. Why small states are generally more 'strategically flexible' than larger ones, and the dynamics leading to different levels of 'strategic flexibility' among small states themselves, is academically a 'black box', which this research proposes to explore.

*There is no one definition of what is a 'small state'. Over the years the study of small states has moved from structuralism to neo-liberalism to a concern with environmental and economic vulnerability most of these studies associated smallness with being 'sub-optimal' or 'weak'. The Singapore Paradox turned the study of vulnerability into one of resilience. Various other approaches also emphasise the importance of quality public policy, an efficient public service and institutional coherence in achieving a superior performance. Others focus on the role of social cohesion and trust in the formation of 'social capital'. Small states show a high propensity towards flexibility, but no adequate explanation of what drives this is given.*



### **3. Mainstream theories of Superior Economic Performance**

*This chapter explores various theoretical explanations of superior economic performance arising from mainstream academic disciplines. The literature review includes approaches that explain superior economic performance at the state, enterprise as well as the state and enterprise levels. Insights from R-A theory are used to propose a schema meant to help define the research setting to the development of the pharmaceutical industry in Malta following EU accession.*

#### **3.1 State Level**

##### **3.1.1 International Trade Theory**

International trade theory makes a case for countries to participate in trade and rejects interventionist policies, as these distort the international division of labour.

Adam Smith (1776) argues that international trade is a win-win proposition for participating countries and presents the case for specialisation on the assumption that countries have different opportunity cost ratios. His main proposition became known as the theory of absolute advantage. David Ricardo (1817) took this thinking a step further and argued that even if a country is more efficient than another in producing all goods, it still benefits both of them to specialise in them, with each country producing a good in which it is most efficient. This is the essence of Ricardo's theory of comparative advantage. Factors of production (land/raw materials, capital and labour) were considered to be homogeneous (perfectly substitutable) and mobile within, but not between, countries. According to the Heckscher and Ohlin (see Ohlin, 1967) specialisation and comparative advantages arise from a country's relative abundance of factor endowments. Fordism (production on a mass basis) and Taylorism (analysis and simplification of work processes) from the 1930s gave specialisation a new dimension. Specialisation started to be perceived as being structurally determined through cost advantages, derived from tightly controlled work processes.

International trade theory also seeks to provide answers regarding how gains from trade will be shared among the participating countries ('unequal' distribution can lead to superior performance):

- a. Mainstream theory emphasises the role of demand, with the terms of trade being dependent on the relative strength of the demand for the respective products. This is not a fully satisfactory explanation as it fails to clarify how the determinants of demand come about (Caballero *et al.*, 2011).
- b. Structuralism perceives the world as comprising an exploitative centre and an exploited periphery. The Singer-Prebisch thesis (see Singer 1949) contends that while the centre specialises in exporting manufactured industrial products, the periphery exports primary commodities. The terms of trade between them is embedded in the structure of the global trade system, income elasticity of demand for commodities and impact of technological change.
- c. The unequal exchange school views international trade exchanges as being 'unfair' because production conditions (including wages) in the periphery lead to exporting goods and services at cheaper prices. While structuralism focuses on the trend in the terms of trade over time, the proponents of unequal exchange adopt a normative approach towards what these terms should be at a given point in time.
- d. Dependency theorists argue that favourable production conditions at the centre are closely related to unfavourable conditions in the periphery. Inequalities in trade can be attributed to those in development and a colonial past. The whole international economy is seen as a system of domination organised to the advantage of the centre. Real development entails breaking away from the system of dependency through self-centred growth strategies.

Structuralism became popular with policymakers in Third World countries and there emerged the idea that the only way towards industrialisation was through self-reliance and the promotion of South-South trade. Developing countries criticise traditional trade theory as being static and irrelevant to the development process (Salvatore, 2007). Trade theory is silent on the determinants of the economic characteristics of nations, including size (Alesina & Spolaore, 2003). For small states that have a comparative advantage in some commodity or primary product, specialisation has assumed negative connotations as it has generally led to

negative terms of trade and unstable export earnings. Free trade has not led to a win-win situation, as predicted by international trade theory. The experience of many small states is in sharp contrast to the benefits derived from international business by more advanced economies.

### **3.1.2 Economic development studies**

The legacy of the past 50 years of development economics is not as inspiring as one would expect it to be (Piasecki & Wolnicki, 2004).

Keynesian economics, the leading economic paradigm of the post-World War II era reserves an important role for the state which ‘was at the heart of the writings of the early development economists’ (Woo-Cumings, 1999, p. 5). Development evolved into a world view that accords industrialisation higher priority than other societal goals, with the state playing the lead role (Schneider, 1999). Western scholars viewed ‘under-development’ as a permanent ‘slump’ within cyclical growth economics; according to ‘big push’ theory, significant investments are needed to help a country overcome its backwardness.

Soon after Bretton-Woods, the western economic development model was challenged by the Soviet model, with its emphasis on state control over the productive sectors of the economy, the collectivisation of agriculture and the enhancement of industrial power. The Soviets relied on extensive economic planning under the direction of a State Planning Commission.

Johnson (1982) introduced the term ‘capitalist developmental state’ to refer to the experience of modern Japan, which was characterised by strong state intervention and extensive regulation and planning. In this model of capitalism, which is mostly associated with East Asian economies, the state engages in extensive macroeconomic planning and has extensive power and control over the economy. Johnson (1999, p. 32) conceives the term developmental state as ‘[going] beyond the contrast between the American and Soviet economies’. A fundamental goal of the developmental state ‘is the improvement of its economic conditions relative to other states’ (Pempel, 1999, p. 147). The search for superior performance is not only relative to other states, but also, over time, to itself. The

developmental state with its emphasis on economic nationalism and neo-mercantilism is a logical descendent of the German historical school (Pempel, 1999).

Weiss (1998) notes that developmental states have been engaged in three types of economic transformation:

1. Revolutionary: requires breaking the power of the dominant class
2. Structural: involves a shift from agrarian to industrial activities
3. Sector (industrial technological): leads to new sectors of production.

The ruling political elites of 'new' developing countries soon realised that to legitimise their power, they had to underpin political independence with economic development. The ideological warfare over the path towards this development became entangled in the politics of the Cold War. The governments of many new states believed that they should play a leading role in economic development. They often tried to emulate the Yugoslavs, who were combining state ownership of enterprises with market mechanisms. In general, developing states were finding it hard to develop their economies, as they 'could not generate foreign exchange out of their specialisation in the export of primary commodities subject to the declining terms of trade' (Meseguer, 2009, p. 75).

The new states lobbied hard within the UN to change the global trade rules, which they deemed as being detrimental to their economic development. In 1964, the UN called a Conference on Trade and Development to study the economic challenges faced by these new states. Subsequently, UNCTAD was established as a permanent organisation and became another trade forum. This somehow duplicated the work conducted by GATT, but was essentially seen by the new states as a 'club of the rich' countries. As the frustration of the new states grew, development thinking took two contrasting paths: one that followed by neo-liberals, who deemed the interests of nations and social classes as being harmonious, and the other followed by neo-Marxists, structuralists and radicals, for whom development is an extension of class conflict and imperialism and who called for radical social engineering or revolutionary change (Black, 1999).

Both schools of thought shared the conviction that industrialisation was the only way forward (Piasecki & Wolnicki, 2004). Attempts to industrialise led to myopic behaviour by developing economies as they sought to establish the manufacturing industry at a prohibitive cost, especially in their flirtations with import substitution (Wint, 1998). By the mid-1970s a new stream of development thinking began to flourish. Tinbergen (1976) presented to the Club of Rome the publication which he co-ordinated entitled 'RIO: Reshaping the International Order' and which included the work of twenty experts from both developing and developed countries. The Report criticised the more advanced societies for the non-sustainability of their growth trajectories. The term 'sustainable development' was coined by the Brundtland Commission (United Nations, 1987) to project a type of development that meets the needs of the present generation without compromising those of future ones<sup>1</sup>.

In the meantime, a number of Latin American economists, frustrated by the corruption and incompetence of their politicians, and by the selfishness of the bureaucrats who usurped a large part of foreign aid, began to question the role of the state in promoting economic development. Peter Mandelson (2011), former EU trade commissioner, states that African countries over the last 50 years have become 'professional beggars'. By the 1990s, various development theorists such as Parfitt (2002) heralded 'the end of development'. Further, development studies started to be replaced by discourse about the strategies of emancipation, such as 'new social movements' theory, originating in groups such as the Zapatistas of Mexico.

The collapse of the Soviet bloc created a new politico-economic scenario. In 1995, GATT was replaced by the WTO and the Uruguay Round came into effect. Policymakers the world over increasingly adopted a neo-liberal mind-set, moving away from state ownership and direct intervention in the economy. Both academics and practitioners came to view the state as inefficient and corrupt. Government's role was no longer perceived as being that of a doer but rather as a facilitator and regulator. New states also felt obliged to embrace market economics and liberalise their economies. Meseguer (2009, p. xi) remarks that this change in economic paradigm 'marked one of the most important socioeconomic changes in recent

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<sup>1</sup> By its very nature, 'development' should be sustainable as that which is not sustainable is simply growth. The need to refer to sustainable development indicates the degree of confusion that started to permeate the academic development thinking.

decades'. Subsequently, the 'development project' was projected as a blueprint outlining a linear transition towards a modern, market-oriented, private-sector led economy which offers a standard of living comparable to that of advanced economies. This simplistic approach confused the issues and failed to account for the sociocultural complexities of the new states and the multi-dimensional nature of development (Baldacchino, 1998). What is left of the development discourse now assumes secondary importance. Storey and Murray (2001, p. 291) state that 'a clear disjuncture pervaded the study and practice of development which became inspired by a range of perspectives, including post-modernism, post-colonialism, feminism and ecology. Development practice regressed to post-war techno-centric and modernization philosophies'.

By the dawn of the new millennium, the new states started to realise that globalisation was no panacea. The WTO accepted that the next round of multilateral negotiations (The Doha Round) would be a 'round for development'. Although a partial agreement has been reached in Bali in late 2013, the finalisation of the Doha Round still seems far away. The biggest hurdle is the reluctance of the more advanced countries to stop subsidising the export of their agricultural produce. Weiss (1998) challenges the view that globalisation has rendered the state powerless and argues that countries such as Singapore have managed to deepen economic interdependence by forging sophisticated and flexible ties with domestic and international groups. Meseguer (2009) questions whether the 2007 financial meltdown, and subsequent economic crisis in much of the developed world, will lead to the decline of the neo-liberal paradigm. The 'Washington Consensus' is proving to be a mirage just like the 'development project'. Cooper Ramo (2004, p. 4) remarks that 'The Washington Consensus was a hallmark of end-of-history arrogance; it left a trail of destroyed economies and bad feelings around the globe'.

An alternative proposition is emerging, which Cooper Ramo (2004) terms the 'Beijing Consensus': China is marking a path for other nations around the world which are trying to 'figure out not simply how to develop their countries, but also how to fit into the international order in a way that allows them to be truly independent, to protect their way of life and political choices in a world with a single, massively powerful centre of gravity' (Cooper Ramo, 2004, p. 3). The 'Beijing Consensus' acknowledges that it is no blueprint, emphasises the importance of geo-politics and the need for a pro-active approach to development. It

highlights the fact that development entails not only higher GDP per capita but also sustainability of the economic system and an equitable distribution of wealth.

Conventional economic development thinking failed owing to the blind imposition of 'western' modernisation schemes on societies, 'whose traditions, values, habits, social strata, and concepts of economic activity were fundamentally different' (Piasecki & Wolnicki, 2004, p. 312). It is unfortunate that mainstream development thinking seems to be at a dead end. Development is a complex, multi-faceted and multi-speed phenomenon and western academics have generally failed to fully understand its nature. If a new lease of life is to be injected into development thinking, a holistic approach needs to be adopted. In the age of globalisation, 'the past is an exceptionally poor guide to the future', obliging small states to think differently about their economic development trajectory (Williamson & Hu, 1994, p. 52).

Development theory offers various explanations as to why many states, including a great number of small ones, have failed to reach the level of prosperity of more advanced economies. Western economists tend to interpret the lack of development as a special case of cyclical economics, a sort of permanent slump. Other explanations are often framed from an ideological perspective. As a process, economic development became equated to industrialisation, with the government being given a primary role in driving it forward. However, since the early 1990s, neo-liberal thinking (as incorporated in the Washington Consensus) led to the rolling back of the state. The government was expected to take a back seat and its role was confined to that of regulator and facilitator.

Economic development theory seems to have come to a dead end. The development paradigm is fast being replaced by a competitive one. Its major constraint has been that while emphasising the key factors hindering countries from developing, it has been unable to offer pragmatic guidelines as to how countries (including small states) can develop their economies. Politicians find it convenient to speak in terms of competitiveness rather than development as it shifts the focus (and reasons underlying policy failure) to exogenous factors. Storey and Murray (2001) state that although the conditions created by pursuing competitiveness may be unfortunate, they are not as bad as those of being uncompetitive. Small states are presented with little option: they either manage to compete or fall behind.

The issue remains the same as that addressed by economic development: how can ‘competitive’ thinking help a small state achieve ‘superior performance’?

### **3.1.3 Competitiveness**

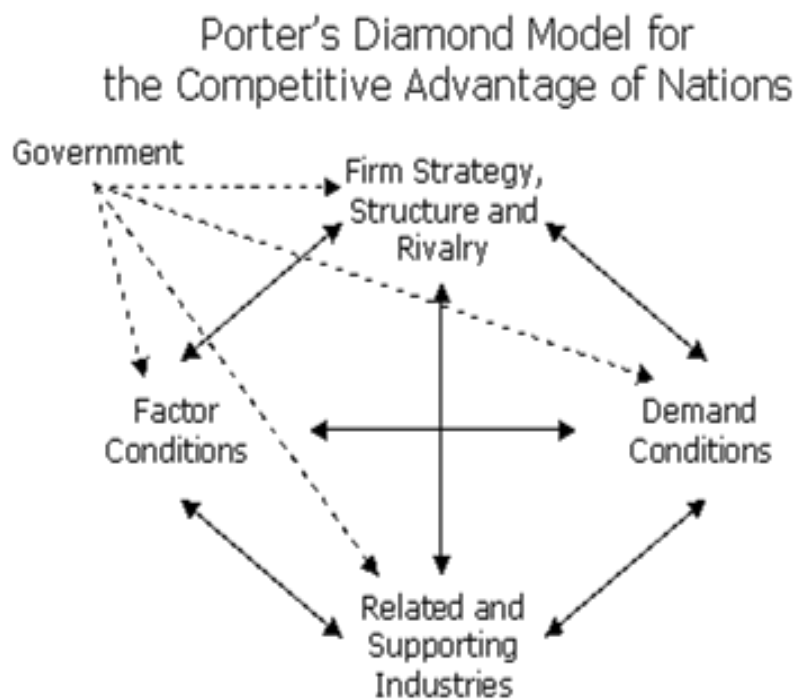
Scholars and analysts of competitiveness try to root their work in the thinking of Adam Smith (1776); in reality, competitiveness represents a paradigm shift given that international trade (and business) is no longer presented as a win-win proposition. Competitiveness implies that some win, while others lose. The study on national competitiveness is rooted in business studies and not economics. The concept of comparative advantage is being replaced by competitive advantage owing to ‘[a] growing awareness that the assumptions underlying factor comparative advantage theories of trade are unrealistic in many industries’ (Porter, 1998, p. 12). What does not change is the importance of specialisation. Porter (1998) asserts that productivity and competitive advantage in an economy require specialisation. He distinguishes between ‘lower-order’ sources of competitive advantage (e.g. low labour costs or cheap raw materials), which are easy to imitate, and ‘higher-order’ advantages (e.g. proprietary process technology and product differentiation), which are more defensible and sustainable.

In ‘The Competitive Advantage of Nations’, Porter (1998) studies the ten most successful economies in the world to determine whether there are a set of key factors underpinning the ‘superior performance’ of these economies. The ‘diamond of national competitiveness’ model is the result of his research. Porter’s diamond represents ‘a theory of investment and innovation’ (Porter, 1998, p. 173), with innovation growing ‘out of pressure and challenge’ (Porter, 2008c, p. 585). Porter’s (1998, p. 8) quest was to find out why nations ‘can or cannot compete in sophisticated industries and activities involving high productivity’. He remarks that competitiveness is not about having a trade surplus, a cheap currency or low unit labour costs and that the particular mix of industries that are exporting is more important than a nation’s average export share. Despite globalisation, nations have become more, not less, important as ‘competitive advantage is created and sustained through a highly localised process’ (Porter, 2008b, p. 155). The national environment is of critical importance in shaping competitive advantage (Kovacic, 2007). Porter (1998) notes that differences in national values, culture, economic structures, institutions and histories all contribute to



competitive success. ‘These determinants create the national environment in which companies are born and learn to compete’ (Cho and Moon, 2000, p. 62). The basic unit of analysis in understanding competition is the industry’s structure, even though ‘[u]ltimately only companies themselves can achieve and sustain competitive challenge’ (Porter, 1998, p. 191).

All industries can use high technology and be knowledge intensive (Porter, 1998d). ‘The diamond of national competitiveness’ (figure 4) has four interrelated components which are mutually reinforcing: (1) factor conditions (2) demand conditions (3) related and supporting industries and (4) firm strategy, structure and rivalry. In addition, there are two exogenous factors: chance and government.



**Figure 4: Porter’s Diamond Model for the Competitive Advantage of Nations**  
 (Reproduced from Value-Based Management)

Governmental policy influences, but does not determine, national advantage (Porter, 1998). Appropriate public policy shifts as nations progress to successive stages of competitive development which includes four distinct stages: factor driven, investment driven, innovation driven and wealth driven. Government’s proper role is that of a catalyst and challenger; it needs to involve an industry in determining the specialised factors to be created. Given that ‘[i]t often takes a decade for an industry to create competitive advantage...but in politics a

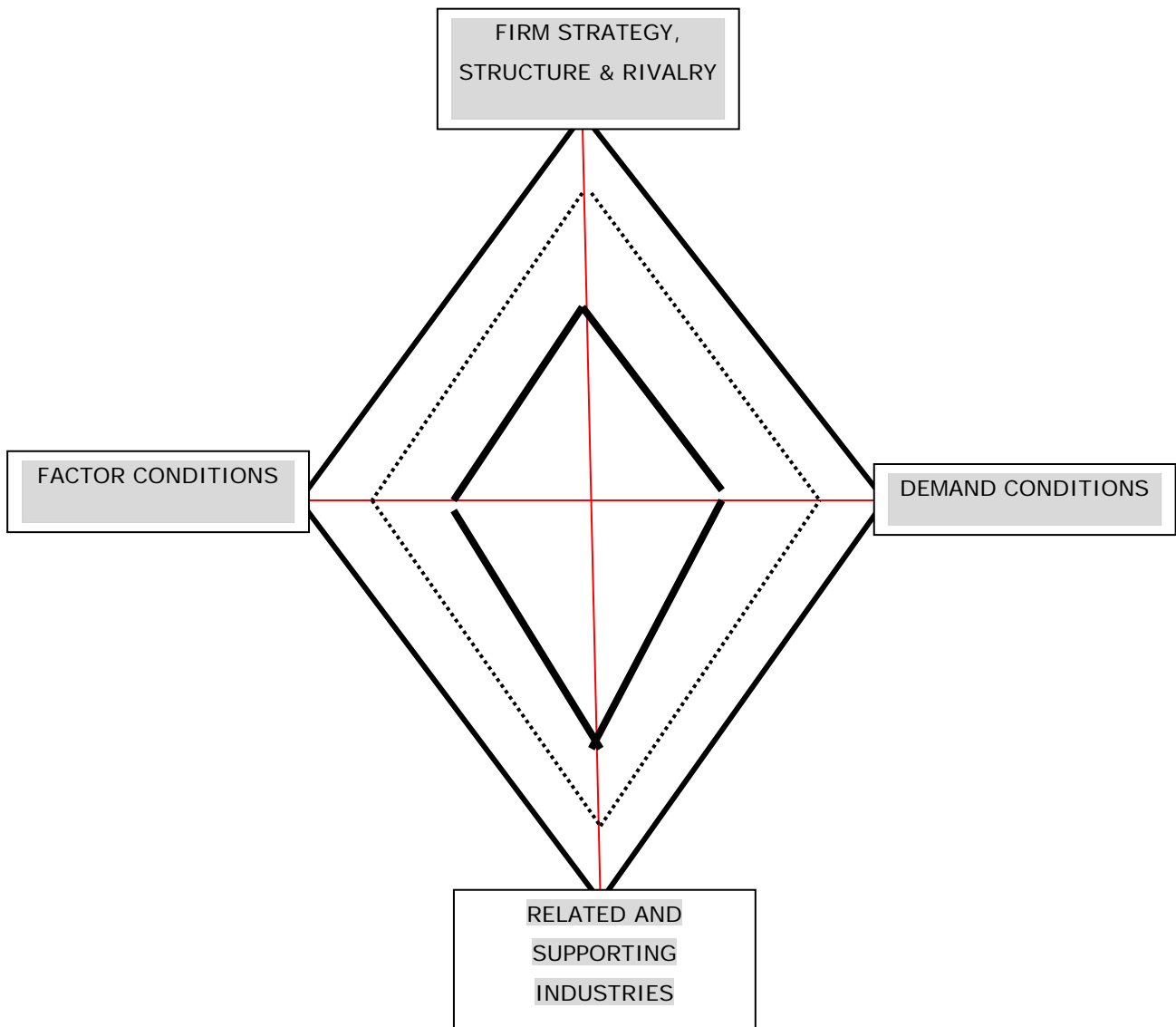
decade is an eternity' (Porter, 1998, p. 185), there emerges an inherent conflict between competitive time for companies and political time for governments.

Porter (2008d) emphasises the importance of clusters in boosting productivity. A firm can no longer be seen as a stand-alone unit but as part of a value chain. Porter (2008d, p. 221) defines a cluster as 'a geographically proximate group of interconnected companies and associated institutions in a particular field linked by commonalities and complementarities'. Clusters capture important linkages, technology spill over, skills, information, marketing and customer needs. Enterprises in a cluster cooperate among themselves while competing (competition). Identifying paths of interrelationships outside a firm is a creative task as most organisational structures in firms work in the opposite direction. Linkages and synergies are of critical importance since they create critical mass and promote specialisation and reputation.

Innovation drives differentiation and higher value added. Innovation requires the right milieu and institutional capacity to be able to flourish (Porter, 1998). Porter argues that while clusters have long been part of the economic landscape, their depth and breadth have significantly increased with the intensification of competition. Conventional agglomeration economics emphasises input cost and specialisation benefits arising from proximity and linkages, whereas Porter's places emphasis on innovation and learning. Equally important is the capacity and flexibility that clusters provide for enterprises to act rapidly.

Competition and rivalry between value chains or clusters at a domestic level is of critical importance in Porter's approach. Domestic competition helps enterprises shape up and prepares them to face competition in the global market. It is Porter's merit that 'nations' are back on the centre stage of 'superior' performance. However, Rugman (1991) criticises Porter's diamond model on the basis that it does not properly account for the role of FDI and multinational enterprises. Rugman (1992) further argues that a more relevant concept prevails in small open economies, namely the double diamond model. Moon *et al.* (1995, 111) build on Rugman's (1992) work to propose their own model, which emphasises two issues: a country's sustainable value-added results from both domestically and foreign-owned firms and that sustainability requires a value-added configuration spread across many countries.

Moon *et al.*'s (1995) double diamond model for small economies is re-produced hereunder (figure 5):



**Figure 5: Generalised Double Diamond**  
(Reproduced from Moon *et al.*, 1995)

The outside diamond represents the global system, while the inside diamond represents the domestic system. The dotted diamond in between is a country's 'international diamond' and represents the interface of the other two diamonds. A comparison of the size and shape of the domestic and international diamonds reveals major strategic differences (Moon *et al.*, 1995).

Governments occupy a central role in Moon *et al.*'s model since it significantly impacts the four factors of the diamond model. The authors deem that 'the government in small

economies as Korea and Singapore is more important than anything else in affecting the other variables' (*Moon et al.*, 1995, p. 130). Small states' dependence on imported technology and overseas demand makes it imperative that they link selectively to the 'diamonds' of other countries. In addition, FDI plays a key role in the economic growth and integration of small economies. Porter (1998, p. 160) states that '[i]nternational trade and foreign investment can both improve a nation's productivity as well as threaten it' as they expose a nation's industries to the test of international standards of productivity. In the case of small states, trade and FDI are not an option.

Although competitiveness is well-defined at a micro level and sufficiently meaningful at the sector level, it is nebulous at the national level. Cho and Moon (2000, p. 25) argue that '[t]he concept of national competitiveness is elusive as countries do not compete against each other in the same way as corporations such as Coke and Pepsi do'. The number of rankings of national competitiveness prepared by governments, consultants and research organisations is growing and becoming increasingly influential in policy formulation (Wignaraja, 2003, p. 15). The World Economic Forum (2010, p. 4) defines competitiveness as 'the set of institutions, policies, and factors that determine the level of productivity of a country', while the IMD (2011) looks at competitiveness more in terms of the ability of nations to create and maintain an environment in which enterprises can compete. Both these institutions produce annual competitiveness reports, whose results vary owing to the different methodologies used, including the weighting given to individual variables. The main problem of existing competitiveness reports is their lack of a strong theoretical background (Moon & Cho, 2000, p. 195). The World Economic Forum (2011) launched the concept of 'sustainable competitiveness', which it defines as 'development that satisfies the needs of the present without compromising the ability of future generations to meet their own needs'. The Forum specifies that sustainability entails the ability to meet society's economic, social and environmental needs. The Report remarks that 'there is not yet a well-established body of literature on the link between productivity (which is at the heart of competitiveness) and sustainability'. The index takes a 20-year perspective and emphasises that in the long run, an economy should be socially cohesive, live within its financial means and ensure the correct and efficient use of its resources (The World Economic Forum, 2011).

Wignaraja (2003) distinguishes between three primary approaches to competitiveness:

1. The macroeconomic perspective which deals with internal–external balance and focuses on real exchange rate management as the principal tool for competitiveness
2. The business strategy that focuses on rivalries between firms and countries and assigns public policy a limited role
3. The technology and innovation approach that brings together the enterprise and national levels and active public policies for competitiveness.

The technology and innovation approach considers technology to be an important determinant of competitive advantage. This is evidenced by the work of various analysts on the absorption capacity of enterprises in developing countries. The technology and innovation perspective associates the concept of competitiveness with the accumulation of technological capabilities at enterprise level and collective learning within the National Innovation System.

Wignaraja (2003) proposes his own competitiveness index for developing economies on the basis of their manufactured exports. This index is built around three sub-components

- Current manufactured exports per capita
- Long-term growth in manufactured exports
- Share of technology-intensive exports

National competitiveness approaches emphasise that competitive advantage is created and not inherited. Porter was instrumental in bringing about this paradigm shift (Cho & Moon, 2000). By linking national competitiveness to the structure of specific markets, Porter shifted the focus of competitiveness from factors which were internal to the firm to external ones.

Not all analysts agree about the merit of studying competitiveness at the national level. Paul Krugman (1994) holds that it is a meaningless concept and what really matters is productivity. He warns that the obsession with national competitiveness is both wrong and dangerous. Howes and Singh (1999, p. 21) disagree with Krugman and argue that at the national level ‘the notion of competitiveness is analytically meaningful and useful to policymakers’. Whatever its rationale and quality, the analysis of national competitiveness clearly responds to a growing policy need (Lall, 2001). The continued popularity of national competitiveness among academics and practitioners is evidenced by the numerous reports on

the subject that are published on a regular basis. The primary merit of national competitiveness is in highlighting the fact that, on international markets, the prospects of a country depend as much on its own performance as on that of its competitors.

Cho and Moon (2000) find that Porter's diamond model is not relevant to small economies because their domestic variables are limited. In particular, it can be argued that this model is of limited value to small states because of the following reasons:

1. Domestic demand is negligible and customers can hardly be expected to be global trend-setters. For small states, demand arises out of global/regional markets.
2. They need to import most of their raw materials and components. Small states typically lack the critical mass necessary to create specialised factors to successfully compete on external markets.
3. The scope for upstream and downstream industries in small economies is limited.
4. While firm rivalry is equally intense and personalised, firm strategy is mostly 'emergent', lacking sophistication and a business planning culture.

Another critical assumption made by Porter in his diamond model is that countries have the market power to manoeuvre and manipulate the global market structure to their advantage. In his model, Porter relates market power to a country having substantial/sustained exports to a wide array of nations and/or significant outbound foreign investment.

Competitiveness theories too give no special consideration to small states. Rather they tend to focus on the degree of sophistication reached by an economy. They generally fail to provide guidelines as what it takes, for example, for 'factor-driven' economies to move up the economic development ladder. Where a prescription is offered (such as with Porter's diamond model) the basic tenet (manipulating market power) is hardly relevant to small states.

### **3.1.4 Explanations from Political Economics**

The relationship between state and society is not merely a relationship between the central state and the whole of society; 'both are subdivided on the vertical and horizontal levels with different levels and organisations having different capacities' (Heberer, 2003, p. 1).

State capacity relates to the ability of the state to get things done in pursuance of defined objectives and goals (Cheung, 2008). It is difficult to identify states with a high degree of capacity in all policy areas (Sorensen, 1993), such that 'an "overall" state capacity does not exist and is impossible to measure' (Weiss, 1998, p. 7).

Heberer (2003) explains that state capacity entails the following:

1. Legitimacy: the acceptance of the political system by its citizens
2. Regulation: its capacity for regulation and social control
3. Resources: they enable enforcement, especially finance and personnel
4. Bargaining: the ability to incorporate new social groups into bargaining processes and find a balance between various interests
5. Learning capacity: the ability to learn from mistakes and failures.

#### **3.1.4.1 Democratic Corporatism**

Democratic corporatism is a form of 'social capital' that hypothesises why certain states perform better than others. It entails '[t]he voluntary, cooperative regulation of conflict over economic and social issues through highly structured and interpenetrating political relationships between business, trade unions, and the state, augmented by the political parties' (Katzenstein, 1985, p. 32).

Katzenstein adds that both liberal and social democratic corporatism are distinguished by three traits:

1. An ideology of social partnership expressed at the national level
2. A relatively centralised and concentrated system of interest groups and
3. Voluntary and informal coordination of conflicting objectives through continuous political bargaining between interest groups, state bureaucracies and political parties

Weiss (1998, p. 25) criticises the corporatist approach for being ‘too narrow’ or ‘too fleeting to allow sustained analysis of transformative capacity’. She adds that this approach tends to overplay tri-partite arrangements at the expense of government–industry relationships.

#### **3.1.4.2 Strong State thesis**

Similarly, the strong state approach seeks to explain differences in state capacity which lead to diverse economic performances by countries. States can have strong or weak capacity depending on the historically formed balance of power between state and society (this, however, is not a reflection of the degree of democracy). A strong state is not necessarily a highly interventionist one. State capacity is measured in terms of its coercive capacity. A strong state is seen as having high capacity to complete four tasks: penetrate society, regulate social relationships, extract resources and allocate them in determined ways (Migdal, 1988). According to Weiss (1998), a strong state requires that the national political executive and the bureaucracy possess three core capabilities:

- Formulate policy goals and strategies for implementation independent of societal pressures
- Alter the behaviour of important domestic groups to get them to further its policies
- Restructure the domestic environment in the pursuit of goals

Strong states are equated with the power they have over society. Such a view of state power makes it virtually impossible to apply to modern states. As mentioned, neither is a state’s strength equally applicable across all issues, nor is its capacity necessarily built on the state’s hard authority to impose its will top-down on society. Rather, it depends on ‘its power to mobilise social and economic support for the achievement of state goals’ (Fritz, 2003, p. 5). Instead of a ‘strong state’, it makes more sense to refer to a ‘functional’ or ‘capable’ state, that is, ‘a state that enables society to respond continuously and dynamically to a changing international environment’ (Fritz, 2003, p. 5).

Rodrik (1999, p. 94) observes that in times of great change, flexibility and adaptability require ‘insulated, autonomous executives who can act speedily and decisively’ and democracy ‘even when not hostile to reform, complicates it’. Democracies are notoriously bad at producing credible bargains that require political commitments over the medium term



(Rodrik, 2011b). Katzenstein (1985) disagrees with this reasoning and deems that although authoritarianism in the short term can achieve results, it is not conducive to longer-term development.

### **3.1.4.3 Finance**

A third approach from political economics emphasises national finance as a primary instrument that enables the implementation of policies. Goal formulation requires the capacity to be implemented, and there exists a causal relationship between a country's financial resources and the capacity of the state to deliver. This approach assumes that there exists an autonomous capacity on the part of the state which insulates it, while at the same time, generating the ability for it to act on relevant groups. Weiss (1998) asks whether this approach really explains or merely restates the problem of differential state capacities.

### **3.1.4.4 Embedded Autonomy**

Originally conceived by Evans (1989), 'embedded autonomy' proposes that an effective state is not only 'sufficiently' autonomous but also sufficiently entrenched in particular networks, which enable it to implement policies. For Evans, the key question is not how much state intervention is necessary for development, but the nature of intervention. States are embedded in a dense network of social ties that enable political elites to negotiate goals, policies and implementation strategies with business actors. These are not personal clientele-type ties, but connections between constituencies and the state as an organisation. A state needs to possess the capacity to combine two apparently contradictory aspects: 'Weberian bureaucratic insulation' and 'intense immersion in the surrounding social structure' (Evans, 1989, p. 561).

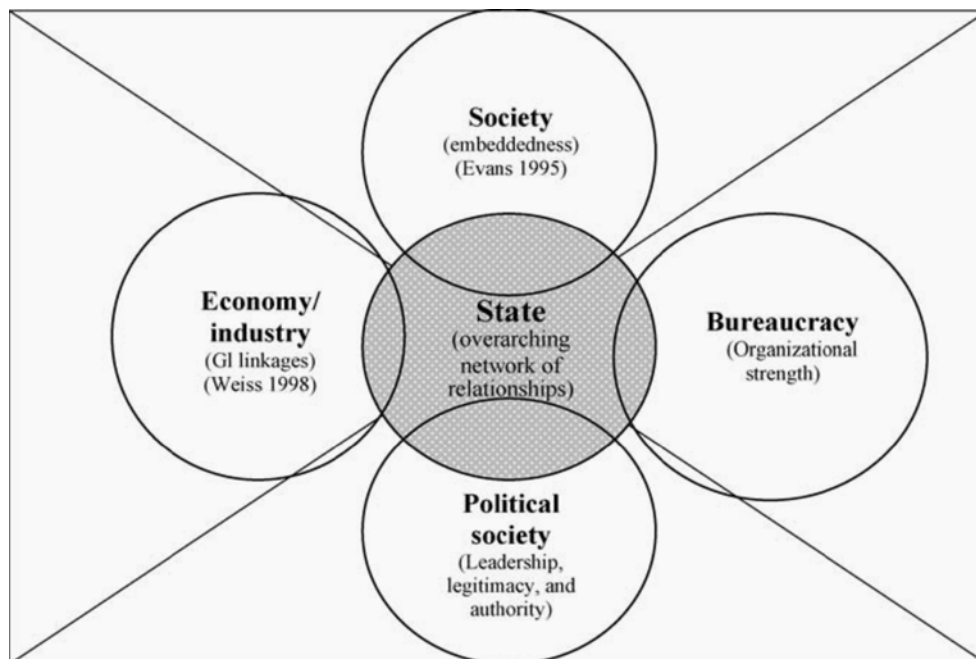
### **3.1.4.5 Governed Interdependence**

While agreeing with Evans about 'embedded autonomy', Weiss (1998) emphasises the existence of a formally institutionalised environment of cooperation between a strong government and a well-organised business sector that ensures the delivery of the state's economic goals. 'Governed interdependence' is achieved through political exchange between the state and societal actors (Weiss, 1998). National variations in political institutions determine the capacity of states to offset the effects of external pressures. Weiss (2000) defines 'transformative capacity' as the ability of a state to adapt to external shocks and

pressures by generating new means of governing the process of industrial change. Weiss adds that transformative capacity is most successful in an environment of ‘governed interdependence’, which requires both a strong state and private sector. Both the state and private sector maintain their autonomy, but it is up to the state to set broad developmental goals and monitor business performance. The state receives the information and cooperation it needs from societal organisations to transform the economy. In return, the state legitimates those organisations, ameliorates social risks surrounding investment and provides a focal point to resolve struggles among firms and sectors.

Cheung (2008) synthesises much of the above thinking and proposes a framework that brings together the primary existing notions of modern state capacity building. His framework, which is re-produced hereunder, brings together four key players:

- political society : strong leadership, legitimacy and authority
- bureaucracy: organisational strength and insulation
- economy/industry link: as per governed interdependence linkages
- society: drawing on ‘social embeddedness’



**Figure 6: Modern State Capacity Building**

**(Reproduced from Cheung, 2005)**

Cheung (2008, p. 122) notes that '[w]hat makes a state effective are its linkages to all these spheres and its ability to inculcate and mobilise social and economic support for the achievement of its goals'. The presumptions behind this framework are as follows:

- (a) a complex and multi-interest society is making governance more challenging
- (b) governance problems cannot be dealt with by the state, society or market, each on its own
- (c) the 'state' has the role, as well as the competence, to 'steer' and 'regulate'

These approaches emphasise the importance of social partners working together to help achieve established economic goals. This is true irrespective of large or small states. The importance of state capacity is closely related to the 'social capital' perspective emerging from small state studies, which will be dealt with further on in this research.

Political economists generally emphasise the role of the state in driving economic transformation and associate competitive advantages with state capacity. State intervention should enable 'society to respond continuously and dynamically to a changing international environment' (Fritz, 2003, p. 5).

'The proposition that state capacities for domestic transformative strategies provide a competitive advantage' lies at the heart of such approaches (Weiss, 1998, p. 5). Although a United Nations (2006) report highlights the serious challenges faced by small states in building state capacity, approaches from political economics largely fail to make reference to the peculiar realities of small states. Although explanations offered by theories from political economics generally offer valid understandings impacting on the ability of states to achieve a superior economic performance, these are not presented in a holistic manner and are not sensitive to the specific conditions of small states.

### **3.2 Enterprise Level**

The limitations of these approaches to adequately account for the 'superior economic performance' of small states induced the researcher to explore explanations relating to

superior economic performance from approaches focusing on the firm. There are essentially two reasons for this. The first was to explore the possibility of learning from such explanations and gather insights which could be extrapolated to the state level. The second relates to the fact that in a small state ‘proximity’ is not just about physical closeness but is also ‘relational’ implying that the impact of the state’s policies, decisions and actions on enterprises (and vice-versa) tend to be greater and faster.

Neo-classical economic philosophy refutes the concept of superior performance at the enterprise level, which it interprets as a ‘temporary’ distortion of market conditions. Williamson (1981) laments the tradition in economics to view with disrespect all market structures that depart from perfect competition. Economists acknowledge that firms are able to reap ‘rents’ out of market imperfections (monopolistic) or innovative initiatives. Innovation is incorporated as variable in the supply or production function, equating it ‘with independent technological and less frequently organisational changes’ (Fonseca, 2002, p. 12). Over a longer period, however, competing firms catch up with innovative ones, creating a new supply–demand equilibrium which eliminates higher returns. Schumpeter (1934) attributes superior performance to scientific and technological innovation as well as the role of the entrepreneur. Unlike neo-classical economists, Schumpeter places innovation inside the economic system. For him, the impact of innovation is on-going and this renders the future unpredictable. Superior business performance can also result from the capability of certain firms to exploit ‘external’ advantages arising from their operating environment. Since the 1980s, the importance of these advantages have been given new life through the extensive work on value chains, networks and clusters conducted by various academics (especially Michael Porter). Externalities are considered to be of vital importance for competitiveness, at both the enterprise and state level.

A firm is a unique entity in time and space as well as a product of its history (Hunt & Morgan, 1995). Ultimately, it is firms which create value and compete (Porter, 1998). Superior performance at the firm (enterprise) level is gauged through higher profits, higher sales, a dominant market share and any other objective which an enterprise sets for itself. Achieving competitive advantage does not imply that a company must out-perform its competitors in all areas all the time (Asikhia, 2006). Deciding which areas to exploit is the central issue in setting competitive priorities for an organisation. The objective of strategic

management is to build sustainable competitive advantage (Amis *et al.*, 1997). There is no generally accepted theory, and much less systematic evidence, on the origins and dynamics of competitive advantage (Cockburn *et al.*, 2000). The processes by which competitive advantages are generated and sustained are complex and continue to attract the interest of scholars in various fields, including organisational economics, strategic management and marketing (Fahy *et al.*, 2004).

### **3.2.1 Environmental View**

According to Cockburn *et al.* (2000), Michael E. Porter transformed the study of ‘imperfect competition’ into a theory of ‘competitive advantage’ and in the process, shifted the focus of strategy research outward, towards the analysis of the firm’s microeconomic environment. During the 1980s, the competitive forces framework of Porter (1980) became the dominant paradigm. It focused on a firm’s actions to create defensible positions against competitive forces. A superior performing firm enhances its ‘market power’, commands better prices and creates ‘entry’ barriers into the industry. Market power can, and does, shift over time. The approach taken by Porter (1980) has its roots in industrial economics, which is primarily concerned with consumer welfare and intra-industry competition. Industry structure is seen as a key determinant of profitability as expressed in the structure-conduct-performance (S-C-P) maxim: industry structure determines conduct, which in turn determines profitability (O’Keeffe *et al.*, 2009). Many of a company’s competitive advantages lie outside the firm (Porter, 1998). An industry’s market structure is both a consequence and determinant of competitive rivalry (Witteloostuijn & Boone, 2006).

The number of firms (density) as well as their size and distribution (concentration) determine the competitive conditions of an industry. Theories of market structure have generally focused on three key questions:

- (1) What determines market structure features?
- (2) How does market structure influence competitive behaviour (and vice versa)?
- (3) How does market structure evolve over time?

The strategic conflict approach became prominent in the late 1980s and focuses on product market imperfections, entry deterrence and strategic interaction. Shapiro (1989) utilises game

theory to analyse the nature of competitive interaction between firms. Shapiro's work paved the way for the game-theoretic school, which views superior performance as resulting from better strategizing. Some managers are able to 'play the game' more effectively than others. The strategic conflict approach holds that 'rents' will flow from privileged market positions resulting 'from strategizing' and 'limitations on competition which firms achieve through raising rivals' costs and exclusionary behaviour' (Teece, 1984, p. 528).

Competitive models are criticised for presenting competition as a zero-sum game; firm profitability seems to depend on developing a position of power over suppliers, customers and competitors. This causes problems, especially with policymakers, who come to view superior firm performance and profitability as taking place at the expense of consumer welfare (O'Keefe *et al.*, 1996). Hamel (1991) observes that Porter's notion of competitive advantage, while providing the means to compute product-based advantages at a given point in time (in terms of cost and differentiation), provides little insight into the process of knowledge acquisition and skill building.

### **3.2.2 Efficiency view**

The resource-based view (RBV) of the firm has its origins in economics, with Penrose (1959) being one of the pioneers (Metais & Meschi, 2004). The notion that firms are fundamentally heterogeneous in terms of their resources and internal capabilities has long been at the heart of the field of strategic management (Peteraf, 1993). The RBV approach gained popularity with both academics and practitioners after the publication of 'The Core Competence of the Corporation' by Prahalad and Hamel (1990). Since then, the RBV framework has been extensively used in marketing, management, economics and business studies. RBV proponents (Table 1) hold that strategic investments should be directed towards developing internal 'activities' and 'resources' because this is more productive and sustainable than developing market advantages to out-perform competitors.

Contributor	Key Findings
McGahan (1999)	36 per cent of the variance in profitability could be attributed to the firms' characteristics and actions
Rumelt (1991)	Corporate—parent explains 1–2 per cent Industry membership explains 9–16 per cent Business unit effect explains 41–46 per cent in business unit performance
McGahan & Porter (1997)	Corporate—Parent explains 4.33 per cent Industry 18.68 per cent Business segment 31.71 per cent
Schmalensee (1985)	Corporate—parent effect is negligible Industry membership explains 20 per cent of firm's total performance Business unit effect is significant
Wernerfelt & Montgomery (1988)	Industry membership explains 12.3–20 per cent depending on controls
Roquebert et al (1996)	Industry explains 10 per cent variance in business unit performance

**Table 1: Studies on Firms' Performance**  
(reproduced from McGahan, 1999)

Firms are portfolios, or bundles, of distinctive and difficult-to-trade 'resources' (Teece, 2007) which persist over time (Eisenhardt & Martin, 2000). Firms achieve superior performance by developing and leveraging resources that are valuable, rare, inimitable and non-substitutable (Barney, 1991).

Competitive advantage stems from individual attributes as well as linkages among resources. Not all resources are of equal importance or possess the potential to be a source of sustainable competitive advantage (Fahy *et al.*, 2004). Resources are developed over time, and hence, 'history matters' (Freiling, 2004, p. 30). Nooteboom (2005, p. 67) proposes that 'firms compete not by striving to do the same thing most efficiently but by trying to offer differentiated products on the basis of firm-specific competencies'. RBV theories of competition require units of selection that are relatively durable and which can be transmitted to successors (Freiling, 2004). The most potent proprietary resources are intangible and tacit and include company and/or brand image and reputation (McGarth *et al.*, 1995). The RBV approach is an inside-out perspective of the firm that seeks to identify the characteristics of firms achieving superior performance and which enables management 'to reconceptualise

what their businesses are, do, and can be' (Rouse & Daellenbach, 2002, p. 492). RBV presents an enactment-based view of strategy formation and implementation, in which firms are seen to proactively manage and shape their environments and not to simply respond to exogenous uncontrollable forces. Bingham and Eisenhardt (2008) classify RBV strategic logics into three categories: leverage, position and opportunity. Each logic potentially leads to competitive advantage; different logics may be useful at different stages of market evolution and each addresses distinct objectives.

The nature of competition influences resource accumulation and hence, the competitive advantage of individual firms (O'Keefe *et al.*, 1996). To be strategic, moves must entail resource commitments which are irreversible (Teece *et al.*, 2000). Resources can be dissipated, atrophied or simply squandered by several internal factors, including failing to adapt and reinvest as well as the presence of causal ambiguity (Fahy *et al.*, 2004). Causal ambiguity is the most effective barrier to imitation as competitors find it difficult to understand the competencies on which the advantage is based. Wilson (2008) criticises the RBV approach for failing to give an adequate account of how firms identify and use unique 'resources' and for not being sufficiently dynamic to adequately explain competitive advantage in situations of rapid and unpredictable change. RBV is vague and tautological (Priem & Butler, 2001).

### **3.2.2.1 Competencies**

An off-shoot of the RBV school, the competencies approach emphasises the role of a firm's competencies, rather than its resources, in determining competitive advantage. Hamel and Prahalad (1994, p. 199) define competencies as a 'bundle of skills and technologies that enables a company to provide a particular benefit to customers'. Freiling (2004, p. 34) describes competencies as 'inter-personal patterns of action which rest upon the division of work and which support a goal-oriented social interaction of persons in a non-random manner'.

In contrast to RBV, this approach views the firm as an 'open' organisation with strategically monitored boundaries, creating a state of 'permeability'. Assets, and sometimes even resources, can be transferred between economic actors (Freiling, 2004) with possible competitive advantages through the assets or resources of a network of firms and the blending



of a firm's capabilities with those of 'partner' firms (Dyer and Singh, 1998; Lorenzoni & Lipparini, 1999).

One of the strategic capabilities of the firm is its ability to integrate knowledge (Grant, 1996) and transform dispersed, tacit and explicit competencies into a wide body of organisational knowledge (Nonaka, 1994). The ability to integrate knowledge, residing both within and outside the firm's boundaries, emerges as a distinctive organisational capability (Lorenzoni & Lipparini, 1999). Competences are embedded in interfirm resources and routines and can provide an effective way to organise knowledge transfer (or access) in dynamically competitive domains or in contexts wherein complex knowledge is scattered or specialised. Nooteboom (2005, p. 67) sees competencies as a special kind of resource and asserts that 'tacitness of knowledge, organisational structure and culture form an important part of the reason that competence does not spill-over easily'. A firm's competitiveness is a function of its pace, efficiency and extent of knowledge accumulation (Hamel, 1991). Competences have a long-term character, implying that they are planned and built into strategic perspectives (Hulsmann & Wycisk, 2008).

### **3.2.2.2 Dynamic Capabilities**

The dynamic capability (DC) approach is another branch of the RBV school. It seeks to incorporate dynamic and temporal elements (Teece *et al.*, 1997). Dynamic capabilities are an eclectic paradigm drawing from multiple disciplines that are emerging as the paradigm of modern business firms (Teece & Pisano, 2004). The dynamic capabilities approach maintains that in turbulent environments, firms need to develop and nurture a unique set of constantly evolving 'resources'. Eisenhardt and Martin (2000, p. 1116) describe dynamic capabilities as 'the organisational and strategic routines by which firms achieve new resource configurations as markets emerge, collide, spilt, evolve, and die'. The value of dynamic capabilities for competitive advantage lies in their ability to alter the resource base. The term 'dynamic' refers to the firm's capacity to renew competences to achieve congruence with the changing business environment, while 'capabilities' emphasise the key role of strategic management in appropriately adapting, integrating and reconfiguring internal and external organisational skills, resources and functional competences to match the requirements of a changing environment (Teece *et al.*, 1997).

The capacity to reconfigure and transform is itself a learned organisational skill. The more frequently practiced, the easier it is accomplished. 'Change is costly and so firms must develop processes to minimise low pay-off change' (Teece *et al.*, 1997, p. 522). Dynamic capabilities thinking seeks to combine strategic decision making with a set of specific and identifiable processes (e.g. product development). Dynamic capabilities are embedded in organisational processes and are considered more important than assets since they are seen as a major driver that gives operational sense to a firm's tangible and intangible assets. Teece and Pisano (2004) argue that the very essence of capabilities or competences is that they cannot be readily assembled through markets. Firms develop capabilities through learning and building knowledge (Slater & Narver, 1995). The literature on capabilities has placed a lot of emphasis on market orientation, organisational learning and strategic flexibility.

Teece (2007, p. 1347) states that the dynamic capabilities framework goes beyond traditional approaches and seeks to understand competitive advantage in that 'it not only emphasises the traits and processes needed to achieve good positioning in a favourable ecosystem, but it also endeavours to explicate new strategic considerations and the decision-making disciplines needed to ensure that opportunities, once sensed, can be seized; and how the business can be reconfigured when the market and/or the technology inevitably is transformed once again'. Effective dynamic capabilities depend on the inherent flexibility of the resources available to a firm and its flexibility in applying these resources (Sanchez, 1995). To transform dynamic capabilities into organisational innovativeness, a firm has to provide flexible structures, operations and strategic posture. Eventually, dynamic capabilities translate into strategic flexibility.

Teece (2007) observes that maintaining dynamic capabilities requires entrepreneurial management. He adds that entrepreneurship is about sensing and understanding opportunities (and not about analysing and optimising), getting things started and finding new and better ways of putting things together. Firms, at various points in time, make long term, quasi-irreversible commitments to certain domains of competence (Teece & Pisano, 2004). What a firm can do and where it can go are constrained by its positions and paths (Teece *et al.*, 1997). The strategic alternatives (paths) available to the firm are determined by its existing socio-technical processes (routines) and are shaped by its resource and capability position. In

the short run, the capabilities approach sets definite limits on strategic options, as capabilities have to be developed since they cannot easily be bought. From the capabilities perspective, strategy ‘involves choosing among and committing to long-term paths or trajectories of competence development’ (Teece *et al.*, 1997, p. 529).

In a rapidly changing environment, firms need to balance exploration and exploitation. Operational effectiveness demands continuity, whereas dynamic capabilities emphasise ‘adaptation’ and ‘innovation’. Related diversification builds on or extends existing capabilities and is the only form of diversification that a resources or capabilities framework is likely to view as meritorious (Teece *et al.*, 1997). ‘Given that the functionality of dynamic capabilities can be duplicated across firms, their value lies in the resource configurations that they create, not in the capabilities themselves’ (Eisenhardt & Martin, 2000, p. 1118). Here, the emphasis is on developing and exploiting distinctive configurations, not specific products or sectors. The dynamic capability approach supports growth and diversification that builds on or extends existing capabilities. The capacity of a firm to transform itself is a learned skill; practice renders managing change as less demanding and less costly (Hulsmann & Wycisk, 2008).

Long-term competitive advantage is not easily achieved in dynamic markets and ‘managers seek to compete by creating a series of temporary advantages’ (Eisenhardt & Martin, 2000, p. 1117). These authors add that the strategic logic of dynamic capabilities has to be a combination of the leverage logic (enhancing existing resource configurations in the pursuit of long-term competitive advantage) with the opportunity logic (formulating new resource configurations in the pursuit of temporary advantages). Dynamic capabilities may create sustainable competitive advantage in fast-changing markets through a series of temporary competitive advantages. D’Aveni’s (1994) ‘New 7S Framework’ deals with the fleeting nature of competitive advantage. Porter (1998) concludes that ultimately the only way to sustain a competitive advantage is to upgrade it. Core capabilities, which produce significant value, could later hinder the firm if they develop into core rigidities (Leonard-Barton, 1992). Dynamic capabilities are linked to the concept of bounded rationality which deems that managers do not have complete information regarding future events, alternatives or consequences and are only able to consciously process a limited amount of information

(Gavetti, 2005). Wilson (2008, p. 88) proposes that ‘strategic decision-making does not rest on “all-knowing” rationality but on satisfying and approximation’.

Although the concept of dynamic capability has become an important strategic analysis tool, its definition and usage is still relatively nebulous. Coh (2005, p. 11) notes that ‘[g]eneral consensus on nature and properties of dynamic capabilities has not yet emerged’.

Rouse and Daellenbach (2002), following an RBV approach, propose the following framework:

- (a) resources (tangible and intangible) which are bundled, linked, incorporated, converted and organised
- (b) socio-technical processes (e.g. knowledge, routines, structures of relationships and cultures) some of which are rare, inimitable (or costly to duplicate) and non-substitutable that form
- (c) capabilities and core competencies which become sources of competitive advantage when leveraged into products and services
- (d) value and competitive advantage indicated by their performance consequences

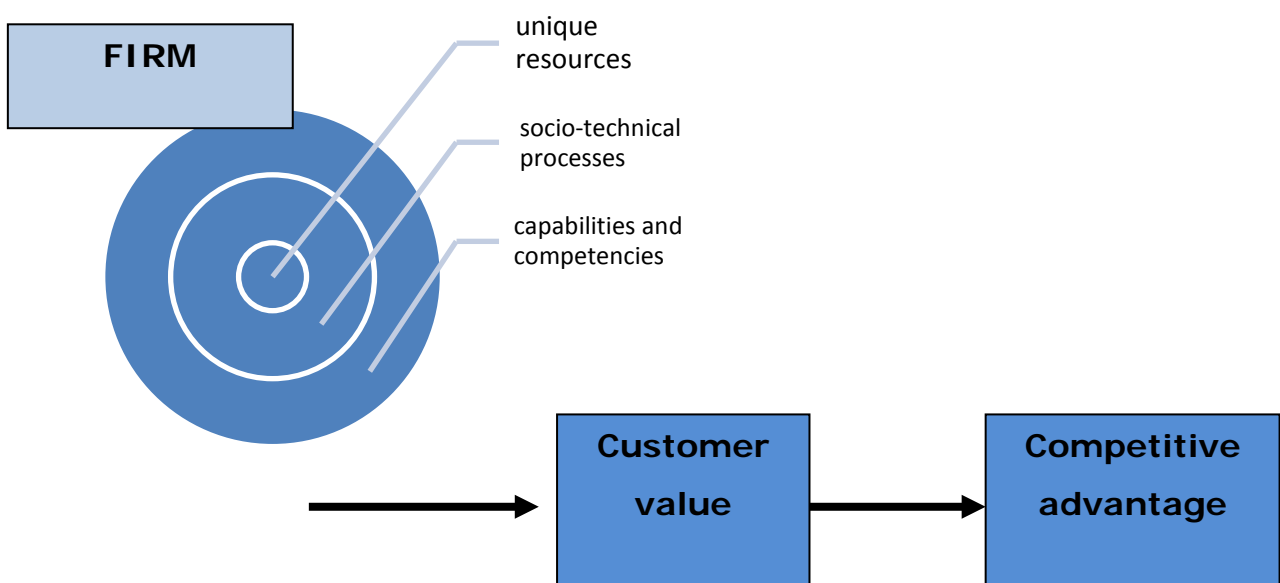


Figure 7: RBV Framework Leading to Competitive Advantage

(Adapted from Rouse & Daellenbach, 2002)

### 3.2.3 Convergence of the Two Schools

The efficiency and environmental paradigms are often presented in juxtaposition to one another. Teece *et al* (1997) note that these paradigms should be seen as being complementary, rather than in competition, with one another.

The external forces for change and complexity are re-enforced by equally important transformations occurring within many organisations (Barlett & Ghoshal, 1998). Barney (1991, p. 100) finds it odd that most research has focused either on external or internal factors, given that ‘since the 1960s ‘the SWOT framework’ (figure 8) has been used to consider both external and internal phenomena in determining competitive advantage’.

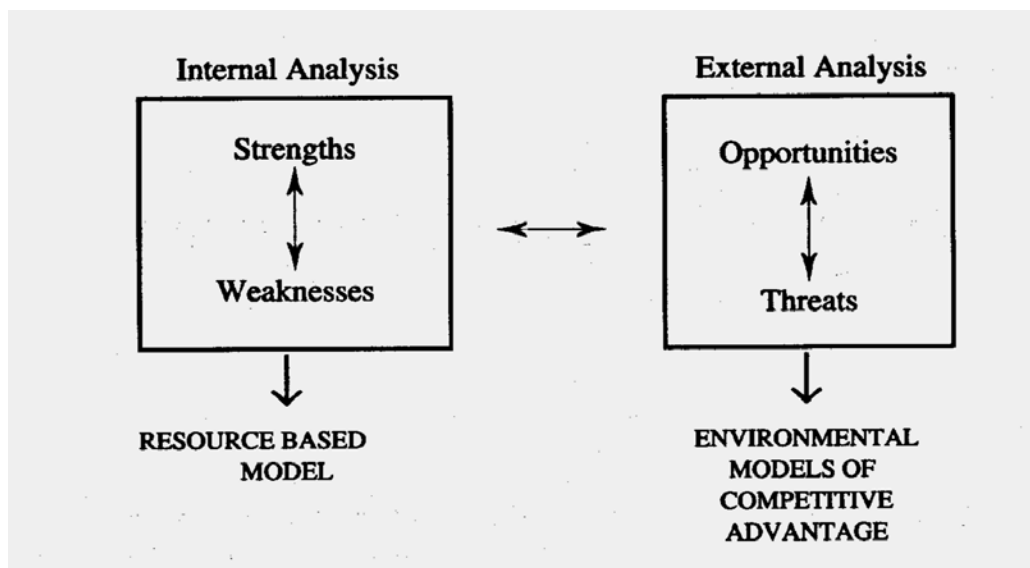


Figure 8: SWOT Analysis, RBV and Market Power Models  
(Reproduced from Barney, 1991)

Hill and Westbrook (1997, p. 47) note that good strategy involves the ‘fit between the external situation a firm faces (threats and opportunities) and its own internal qualities or characteristics (strengths and weaknesses)’. Amit and Schoemaker (1993) and Cockburn *et al.* (2000) agree that the two approaches are essentially complementary, but Teece *et al.* (1997, p. 526) emphasise that ‘in several important respects the perspectives are also competitive’. Table 2, I re-produces a comparative analysis of both approaches.

	1980's view	1990's view
External unit of analysis	industry	market segment
market definition	industry wide definition of market	market definition is only relevant at the segment level
consumer-firm relationship	win-lose battle among firms, and between firms and consumers	win-win and creation of superior value
key strategy challenge	industry-firm fit	organisational learning to develop key resources and competencies
management's main task	portfolio analysis and resource allocation	resource creation and development
main profit influencers	industry concentration and market power	delivering superior value to the customer
the ideal outcome	monopoly position	superior financial performance
achieved by	barriers to entry	distinctive competencies causally ambiguous resources

**Table 2: Perspectives on Competitive Strategy**  
**(Reproduced from O'Keefe *et al.*, 1996)**

Porter (1998, p. 67) suggests that 'sustaining and improving competitive position ultimately requires that a firm develops its internal capability in areas competitive to advantage'.

From the above, it can be concluded that the two schools essentially complement each other: the relative importance of either being context-specific. Ajitabh and Momaya (2004) suggest that a key reason for low usage of both theories by practitioners is the weak understanding of the proposed frameworks and models.

### 3.3 State and Enterprise Level

#### 3.3.1 R-A Theory

R-A theory proposes to be ‘a general theory of competition’ (Hunt & Morgan, 2005, p. 154). Although the theory emerged from marketing, it draws on various disciplines, ‘not only with regard to its pedigree—its ancestors comprising eleven different research traditions—but also with regard to its implications for an understanding of firms, industries and markets’ (Hunt, 2000, p. 385).

Among the theories and research traditions on which R-A theory draws, and with which it has affinities, are evolutionary economics, ‘Austrian’ economics, historical tradition, industry–organisation economics, resource-based tradition, competence-based tradition, institutional economics, transaction cost economics and economic sociology (Hunt & Morgan, 2005, p. 385)

Table 3 synthesises the development of R-A theory and the central issues treated.

Discipline	Exemplar sources	Central issues
1. Marketing	Foss (2000), Hodgson (2000), Hunt (1997a, 1999, 2000b, c, 2001, 2002a, b, 2011), Hunt and Arnett (2001, 2003, 2004), Hunt and Derozier (2004), Hunt et al. (2002), Hunt and Morgan (1995, 1996, 1997), Morgan and Hunt (2002)	Theory development, relationship marketing, public policy, marketing strategy, segmentation strategy, market orientation, competitive advantage, sustainable marketing
2. Management	Hunt (1995, 2000a), Hunt and Lambe (2000)	Productivity, economic growth, competences, strategic management, marketing’s contribution to business strategy
3. Economics	Hunt (1997b, c, d, 2000d, 2002c)	Evolutionary economics, endogenous growth models, wealth of nations, neoclassical economics, general theory of competition
4. Ethics	Arnett and Hunt (2002)	Competitive irrationality, moral philosophy
5. General business	Hunt (1998), Hunt and Duhan (2002)	Productivity, economic growth, resource allocation, resource creation, competition in the third millennium, efficiency advantage, effectiveness advantage

**Table 3: Development of R-A Theory**

**(Reproduced from Hunt & Derozier, 2004)**

Although R-A theory is founded in different disciplines, 'it is not precisely the same thing as any of the works in its pedigree'(Hunt, 1999, p. 47).

R-A theory combines heterogeneous demand theory with the RBV of the firm (Hunt, 2012). It sees resource creation, not allocation, as driving productivity and economic growth (Hunt & Morgan, 2005). RBV and R-A theory are similar in their viewing of a firm combining heterogeneous, imperfectly mobile resources; there are significant differences between the two.

RBV is a theory of the firm, which views

- a) innovation as being exogenous to the firm,
- b) competition among firms as being equilibrating and
- c) demand as being outside the scope of the theory.

RBV makes no reference to the relevance of public policy. By contrast, R-A theory is a theory of competition, which includes a theory of the firm, and which views

- a) innovation as endogenous,
- b) competition to be evolutionary and dis-equilibrating and
- c) demand as an integral part of the theory.

R-A theory deems that public policy significantly impacts competitiveness. It holds that comparative advantages in resources lead to market position advantages, which result in competitive advantage in specific market segments.



Table 4 outlines the foundational premises of R-A theory, which are then explored in detail.

<b>P<sub>1</sub></b>	Demand is heterogeneous across industries, heterogeneous within industries, and dynamic
<b>P<sub>2</sub></b>	Consumer information is imperfect and costly
<b>P<sub>3</sub></b>	Human motivation is constrained self-interest seeking
<b>P<sub>4</sub></b>	The firm's objective is superior financial performance
<b>P<sub>5</sub></b>	The firm's information is imperfect and costly
<b>P<sub>6</sub></b>	The firm's resources are financial, physical, legal, human, organizational, informational, and relational
<b>P<sub>7</sub></b>	Resource characteristics are heterogeneous and imperfectly mobile
<b>P<sub>8</sub></b>	The role of management is to recognize, understand, create, select, implement, and modify strategies
<b>P<sub>9</sub></b>	Competitive dynamics are disequilibrium-provoking, with innovation endogenous
<b>Source:</b> Adapted from Hunt and Morgan (1997)	

**Table 4: Foundational Premises of R-A Theory**

(Reproduced from Hunt & Madhavaram, 2012)

### **3.3.1.1 Demand is heterogeneous and dynamic**

Inter- and intra-industry demand is posited to be both substantially heterogeneous and dynamic. 'Consumers' tastes and preferences differ greatly within a generic product category and are always changing' (Hunt & Morgan, 2005, p. 165). To the extent that demand curves exist at all, they exist at a level of (dis)aggregation that is too fine to be an 'industry' (Hunt & Morgan, 2005, p. 165). R-A theory views industries as 'collections of market segments', with the latter being defined as 'intra-industry groups of consumers whose tastes and preferences with regard to an industry's output are relatively homogeneous' (Hunt, 2012). Products are seen as bundles of attributes, with different market offerings (or 'bundles' of attributes) for different market segments within the same industry (Hunt, 2012).

### **3.3.1.2 Consumer information is imperfect and costly**

While neo-classical theory assumes that consumers have perfect and costless information about the availability, benefits and prices of all products in the marketplace, R-A theory holds that they have imperfect information and often face considerable search costs. These search costs are reduced by societal institutions such as trademarks, patents and licenses, which signal 'the attributes of market offerings' (Hunt & Morgan, 2005, p. 165).

### **3.3.1.3 Human motivation is constrained self-interest seeking**

Etzioni (1988) argues that people have two intricate sources of value: pleasure (P-utility) and morality. People, as consumers as well as managers of firms, are motivated by constrained self-interest rather than profit maximisation. R-A theory follows this line of thought and argues that as a result, firms are not able to maximise profit or wealth. 'Agency' problems 'associated with ethical egoism thwart maximization and because of ethical code mismatches between (and among) owners, managers, and subordinate employees which may result in non-maximising behaviours' (Hunt & Morgan, 2005, p. 172).

### **3.3.1.4 Firm's objective is superior financial performance**

R-A theory acknowledges that the pursuit of 'profits and efficient modes of performance drives much of organizational choice' (Zald 1987, p. 6). The firm's overall objective is to seek superior financial performance and not maximisation (Hunt & Morgan, 2005, p. 17). Such performance is indicated by measures such as profits, earnings per share, return on investment and capital appreciation. R-A theory equates 'superior' with both 'more than' and 'better than' (Hunt & Morgan, 2005). This implies that firms seek a level of financial performance exceeding that of some referent. 'The referent against which the firm's performance is compared can be the firm's own performance in a previous time period, the performance of rival firms, an industry average or a stock-market average' (Hunt & Morgan, 2005, p. 170).

From an R-A theory perspective, it is difficult to use 'normal' industry profits as a referent for comparison purposes since in reality, long-run equilibrium is a rare phenomenon. Given this limitation, superior financial performance cannot be said to lead to 'abnormal profits' or rents. By positing superior financial performance as the primary goal of firms, R-A theory implants dynamism into its framework, with the actions of competing firms being disequilibrating rather than equilibrating. 'Activities that produce turmoil in markets are societally beneficial because they are the engine of economic growth' (Hunt & Morgan, 2005, 170). This 'accords well with the extant dynamism of competition in market-based economies' (Hunt & Morgan, 2005, p. 170).

### **3.3.1.5 Firm's information is imperfect and costly**

R-A theory holds that firms are not able to maximise profit or wealth because of imperfect information and often costly measures to obtain information about customers and

competitors. R-A theory not only refutes that firms have full information and knowledge but also adds 'that occupying marketplace positions provides a major source of organizational learning' (Hunt & Morgan, 1997, p. 79).

#### 3.3.1.6 Resources of the firm

According to R-A theory a firm's resources can be physical, financial, legal, human, organisational, informational and relational (Hunt & Madhavaram, 2012). International trade theory explains the benefits of trade by postulating that countries have heterogeneous and immobile resources. Similarly, R-A theory argues that the resources available to firms within the same industry are heterogeneous and relatively immobile. 'Therefore, analogous to nations, some firms will have a comparative advantage and others a comparative disadvantage' (Hunt, 1997, p. 431). At an enterprise level, a comparative advantage in resources exists when its 'resource assortment (e.g. its competencies) enables it to produce a market offering that, relative to extant offerings by competitors, (1) is perceived by some market segments to have superior value and/or (2) can be produced at lower costs' (Hunt & Morgan, 1995, p. 7).

The neo-classical school considers land, labour and capital as resources, but for R-A theory, resources are the firm's tangible and intangible entities that enable it to produce efficiently and/or effectively a market offering that has value for some market segment(s). The value of a resource is, therefore, measured in terms of its potential to yield competitive differentiation and/or customer value delivery that enhances the firm's performance outcomes (Hunt, 2000). Certain types of resources are more valuable than others. Individual resources may have direct, indirect, mediating or moderating effects (or a combination of all four effects) on firm performance (Hunt & Morgan, 2005, p. 187). R-A theory also posits that there are 'non-resources', which do not enable and/or inhibit the firm, as well as 'contra-resources' that actually inhibit the firm from producing efficient and/or effective market offerings that have value for certain marketing segment(s) (Hunt & Madhavaram, 2012). Different bundles of resources may be equally efficient or effective in producing value for certain market segments (Hunt & Morgan, 1995).

The processes by which various resource types influence the ability of the firm to create unique comparative advantages are complex, and R-A theory emphasises the importance of understanding the role of organisational competencies. R-A theory views competences as

higher-order, socially complex, highly interconnected, combinations of tangible and intangible resources that fit coherently together and enable a firm to efficiently/effectively produce valued market offerings. R-A theory merges with the ‘dynamic capabilities’ approach by delineating the process by which a competence that enables firms to respond creatively to changing market conditions can be successful in achieving superior financial performance. Hunt and Madhavaram (2012) conclude that R-A theory’s concept of ‘higher-order resources’ provides the foundation to understand both marketing and overall business competences and capabilities.

### **3.3.1.7 Resources are heterogeneous and imperfectly mobile**

The development and leveraging of heterogeneous and imperfectly mobile resources enable firms to achieve competitive advantages through greater effectiveness and efficiency. Resource heterogeneity suggests that every firm has an assortment of resources that is in some way unique. Given the interconnectedness and complexity of competences, ‘they are likely to be significantly heterogeneous and asymmetrically distributed across firms in the same industry’. Imperfectly mobile implies that resources, to varying degrees, are not easily or readily bought in the marketplace. Resources may be available, and not necessarily owned, by the firm. Resource heterogeneity can persist through time despite attempts by firms to acquire the same resources of successful competitors (Hunt & Morgan, 2005, p. 173). Given resource heterogeneity and immobility, strategic choices must be made to influence performance. ‘Different firms in an industry will adopt different strategies based on different resource assortments. This suggests that they will target different market segments and have different competitors’ (Hunt & Morgan, 2005, p. 176).

‘Rivals will fail (or take a long time to succeed) when an advantaged firm’s resources are either protected by such societal institutions as patents or the advantage-producing resources are causally ambiguous, socially or technologically complex, tacit, or have time compression diseconomies’ (Hunt & Madhavaram, 2012, p. 586). Heterogeneity and immobility indicate that resources, unlike what RBV proposes, are ‘replicable, not scarce’ (Hunt & Morgan, 1997, p. 79). Moreover, given that R-A theory ‘recognizes that technologies or competencies can be replicated by other firms, it acknowledges that they are non-rival’ (Hunt, 1997, p. 434). The life span (sustainability) of a particular comparative advantage in resources is determined by both internal and external factors and can be neutralised by the actions of consumers, government or competitors (Hunt and Morgan, 1995).

### **3.3.1.8 Role of management and strategy making**

R-A theory is a general theory of competition that provides an integrative, positive and theoretical foundation for business and marketing strategies (Hunt & Derozier, 2004). It demonstrates to managers how these strategies ‘fit into’ the broader issues of competition (Hunt & Madhavaram, 2012). Specifically, the role of management (both owner and non-owner) is ‘to recognise and understand current strategies, create new strategies, select preferred strategies, implement the strategies selected, and modify strategies through time, focused on creating competitive dynamics that are disequilibrium-provoking’ (Hunt & Morgan, 2005, p. 174).

Hunt and Madhavaram (2012) note that the firm’s overall business strategy involves the following four higher-order resources that facilitate managerial action:

1. absorptive capacity
2. market-focused strategic flexibility
3. learning platform capability
4. organisational learning capability

### **3.3.1.9 Competitive dynamics and innovation**

R-A theory is an evolutionary theory of competition, in which each firm in an industry is a unique entity in time and space as a result of its history (Hunt & Morgan, 1997, p. 78). Theorists agree that the firm’s strategic imperative should be sustained, superior financial performance, sought through competitive advantage in the marketplace (Hunt, 1999, p. 155). In contrast to Porter’s industrial economics approach, R-A theory does not perceive an industry’s structure and a firm’s conduct (strategy) to be the sole determinants of superior performance. Firms do not just passively respond but seek to influence or shape their changing environment and improve themselves through renewal competences and proactive innovations. ‘Resource advantage theory cannot restrict itself to only one resource for competitive advantage because it is first and foremost a positive, general theory of competition’ (Hunt & Morgan, 1996, p. 108).

The constant struggle among firms for comparative advantages in resources leads to increased knowledge (Hunt & Morgan, 1997). Competitors attempt to neutralise and/or leapfrog the advantaged firm through acquisition, imitation, substitution or major innovation. ‘This enables them to surpass the previously advantaged competitor in terms of either relative

costs (i.e. an efficiency advantage), or relative value (i.e. an effectiveness advantage), or both' (Hunt, 2012). Firms learn through competition. 'As Hayek (1948) stressed, competition is a knowledge discovery process' (Hunt, 2002, p. 12). The process of competition itself becomes 'a major source of organisational learning as firms learn from the feedback loop from relative financial performance' (Hunt & Morgan, 1997, p. 79).

R-A theory is non-consummatory in that it involves a continuous process of change with no end-stage. 'Although R-A competition is a process that is moving, it is not moving toward some ideal point (such as a Pareto-optimal, general equilibrium)' (Hunt, 1999, p. 147). R-A theory is inherently dynamic. Innovation plays a critical role in R-A theory. 'The renewal competence of firms, motivated by the quest for superior financial performance, contributes to the proactive innovations that result in societal productivity' (Hunt, 1999, p. 154). The quest for superior performance results in innovation which in turn stimulates productivity and constitutes 'the technological progress that results in economic growth' (Hunt, 1999, p. 156). Innovation can be either proactive or reactive. Proactive innovation is motivated by the search for superior financial performance and is not prompted by specific competitive pressures. 'When proactive innovative activities successfully produce innovations that contribute to efficiency and/or effectiveness, firms will be rewarded by...superior financial performance' (Hunt, 1997, p. 435).

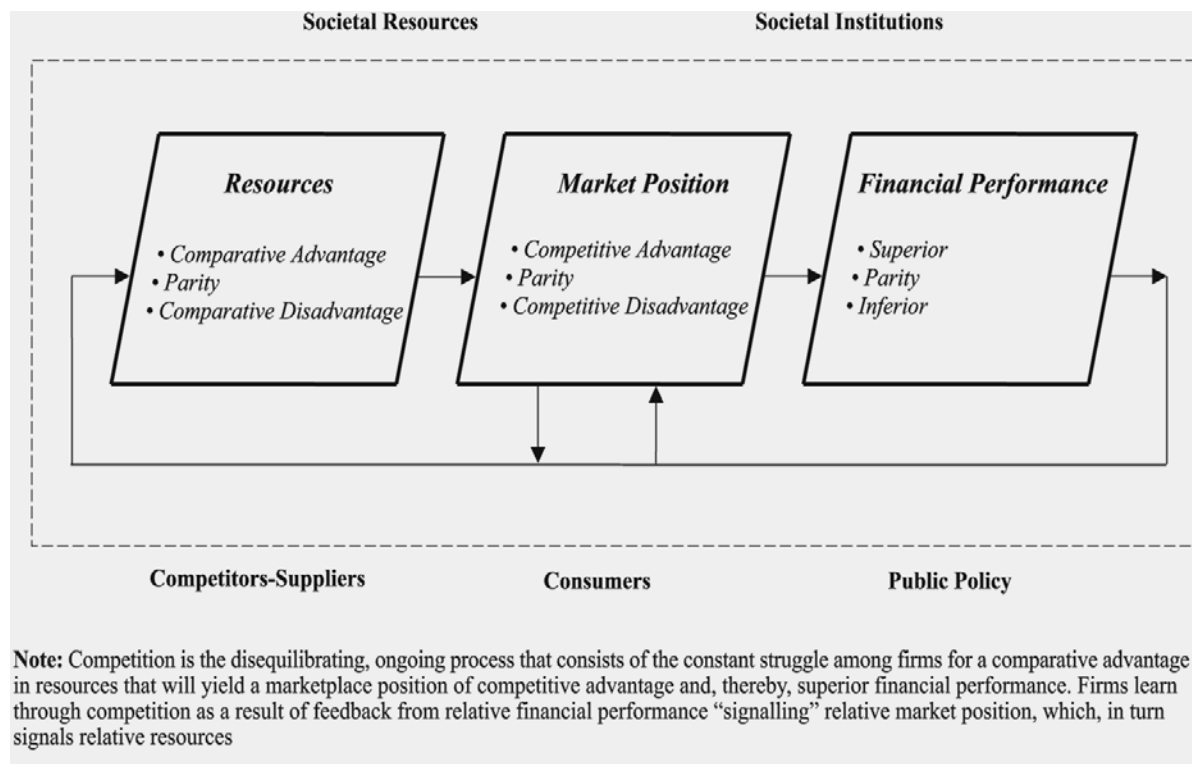
The concept of 'dynamic capabilities' is central to proactive innovation by enabling firms to do the following:

- (1) anticipate potential market segments (unmet, changing and/or new needs, wants and desires)
- (2) envision market offerings that might be attractive to such segments
- (3) foresee the need to acquire, develop or create the required resources, including competences to produce the envisioned market offerings (Hunt & Arnett, 2003, p. 9)

Reactive innovation includes imitating the resource, finding (creating) an equivalent resource or identifying (creating) a superior resource and is directly prompted by the learning process of firms' competing for the patronage of market segments (Hunt & Arnett, 2003, p. 9). Both proactive and reactive innovation can be 'radical' or 'incremental', and both contribute to the

dynamism of R-A competition (Hunt, 2012). Evolutionary theories of competition require entities that can serve as the units of selection in an evolutionary process. These entities must be relatively durable (they can exist, at least potentially, through long periods of time) and heritable (they can be transmitted to successors). Within R-A theory, both firms and resources are proposed as the heritable, durable entities of selection, with competition for comparative advantages in resources constituting the evolutionary selection process (Hunt, 2012).

The list of nine foundational premises of R-A theory has remained unchallenged and there seems to be agreement that they accurately convey the descriptively realistic general case of competition (Hunt, 2012). Figure 9 illustrates how firms achieve superior financial performance.

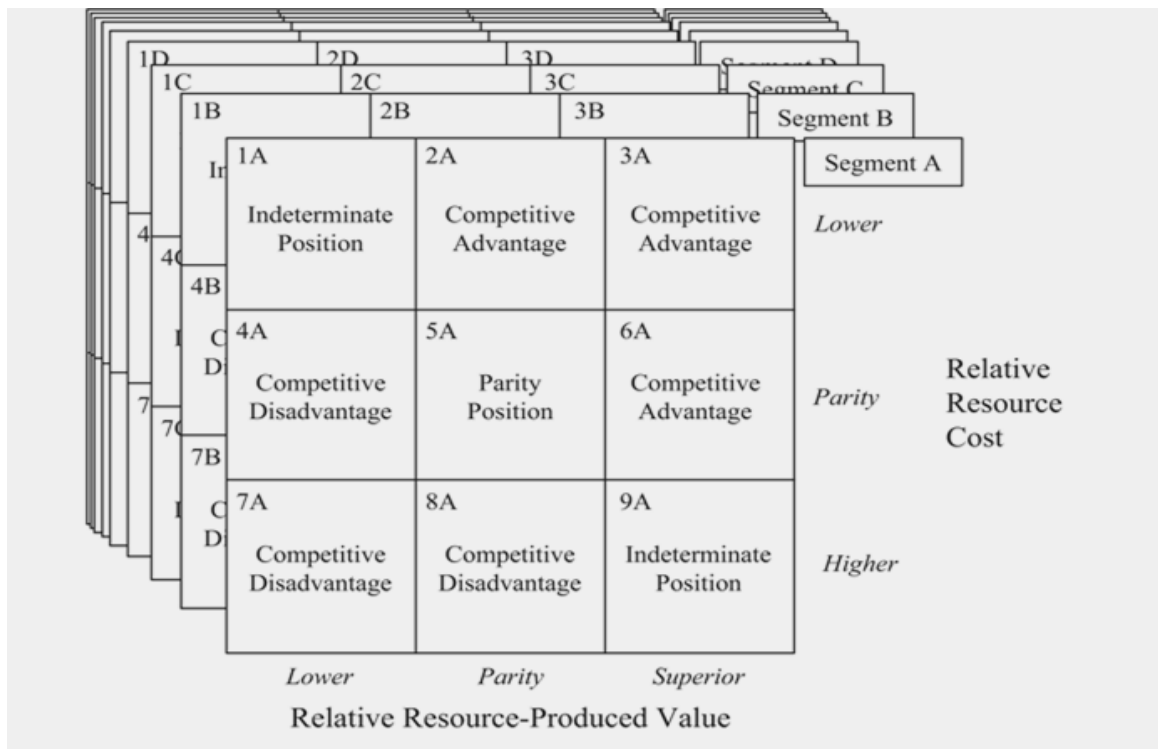


**Figure 9: Comparative Advantage Theory of Competition**  
(Reproduced from Hunt, 2012)

The above figure also demonstrates that the competitive process is significantly influenced by five environmental factors:

- societal resources on which firms draw
- societal institutions that form the ‘rules of the game’ (North,1990)
- actions of competitors
- behaviours of consumers and suppliers
- public policy decisions (Hunt & Morgan, 2005, p. 157)

Figure 10 demonstrates that firms with a comparative advantage in resources can occupy marketplace positions of competitive advantage (i.e. cells 2, 3 and 6). Cell 3 represents the best marketplace position for a firm with a resource portfolio that enables it to produce an offering for some market segment(s), which is perceived to be of superior value and is produced at lower costs. The various market segments indicate the heterogeneity of an industry and is intended to help managers’ analyse their firms’ and competitors’ positions, understand the history of the firm and/or industry and develop new market offerings.



Read: The marketplace position of competitive advantage identified as Cell 3A, for example, in segment A results from the firm, relative to its competitors, having a resource assortment that enables it to produce an offering that (a) is perceived to be of superior value by consumers in that segment and (b) is produced at lower costs than rivals.

**Note:** Each competitive position matrix constitutes a different market segment (denoted as segment A, segment B...)



**Figure 10: Competitive Position Matrix  
(Reproduced from Hunt, 2012)**

As emphasised by the ‘good governance’ school, R-A theory perceives economic action to be embedded in social structures, institutions and culture (Hunt & Arnett, 2003). R-A theory holds that the process of competition is significantly influenced by societal institutions. Given its strong emphasis on innovation, R-A competition requires institutions that protect the property rights of innovators such as patents, copyright laws and laws protecting trade secrets (Hunt, 1997). Poirot (1993, p. 892) states that ‘[i]n order for an existing institutional structure to direct economic activity along a path that is conducive to economic growth, individuals must be able to reap the gains from innovation’ (Hunt, 1997).

R-A theory asserts that successful systems have evolved flexible institutional structures that can survive shocks and changes. Depending on the type of institutions that prevail and their enforcement characteristics, the creation, diffusion and division of knowledge will occur with either high or low transaction costs. The extension of R-A theory to the individual level provides a different way of conceptualising where competitive advantage lies within the firm (Griffith, 2010). Intangible resources of the firm are, to a certain degree, embodied within the employees of the firm and are only firm resources to the degree to which the firm aggregates the resources embodied within employees (Griffith & Lusch, 2007). For example, R-A theory contends that business skills and experience are a key firm resource, but these ‘are resident in firm employees, not the firm itself’ (Griffith, 2010, p. 20). By including institutions, R-A theory broadens its focus to include national comparative systems. R-A theory proposes to provide ‘a theoretical framework for understanding the ‘superior performance’ of firms as well as national economies’ (Griffith, 2010, p 28).

R-A theory seeks to provide an explanation for ‘market-based economies keep getting more efficient and more abundant’ (Hunt & Morgan, 1995, p. 8). The superior productivity of market-based economies is attributed to the fact that ‘superior rewards in such economies will flow to those firms...that engage in specific kinds of innovative activities’ (Hunt & Morgan, 1997, p. 79). These innovative activities are those that lead to the discovery, creation or assembling of resource assortments that enable the innovating firms to efficiently and/or effectively produce valued market offerings (Hunt & Morgan, 1997, p. 79). R-A theory provides a theoretical foundation for formal models of endogenous economic growth (Hunt,

1997b): economies grow due to ‘vigorous, on-going, dis-equilibrating struggles among firms’ (Hunt, 1999, p. 154). This results in innovation that promotes increases in firm productivity throughout the economy, technological progress and economic growth. In contrast to neoclassical economics, R-A theory makes technological growth a result of the specific, profit-driven actions of firms (Hunt, 1999, p. 155).

For R-A theory, superior economic performance is determined in particular by the search for comparative advantage by firms and their propensity to engage in both proactive and reactive innovation. This explains how a country may be poor in natural resources but can still do well economically. R-A theory agrees that history is important even at the state level. A key factor distinguishing wealthy from non-wealthy societies is trust-promoting institutions. The process by which such institutions contribute to (or from) firm-level, superior financial performance can be explained by the fact that societies having moral codes based on deontological ethics (the moral content of an action is not wholly dependent on its consequences) reduce transaction and transformational costs, rendering their competitive processes more efficient and effective. Societies become wealthy over time ‘because the underlying institutional framework persistently reinforced incentives for organizations to engage in productive activity’ (North, 1990, p. 9). The most important deficit of non-wealthy, market-based economies is the lack of certain types of societal institutions that foster productivity and economic growth (North, 1990). For North (1990, p. 9), ‘in many Third World countries today as well as those that have characterised much of the world’s economic history, the opportunities for political and economic entrepreneurs are still a mixed bag, but they overwhelmingly favour activities that promote redistributive rather than productive activity, that create monopolies rather than competitive conditions, and that restrict opportunities rather than expand them’.

‘R-A theory allows for the possibility that social relations and social structures can (and often do) affect competition. The thesis that social structures (i.e. networks of social relations) can be pro-competitive is foreign to neoclassical economic theories’ (Hunt & Arnett, 2003, p. 2 ). Although the works of early scholars (e.g. Max Weber and Emile Durkheim) in economic sociology recognised that economies are embedded in broader social structures, the concept of ‘embeddedness’ is often credited to Polanyi *et al.* (1971), who argued that ‘[t]he human

economy...is embedded and enmeshed in institutions, economic and noneconomic' (quoted by Hunt & Arnett, 2003, p. 2).

R-A theory proposes to be a general theory of competition which is evolutionary and disequilibrating. Superior performance is determined by the search for comparative advantage by enterprises (and states) and their propensity to innovate. This theory builds on the RBV approach and considers competencies as higher-order, socially complex resources. R-A theory perceives economic action to be embedded in societal structures, institutions and culture.

This research finds that R-A theory offers the most comprehensive and relevant theoretical framework to its area of study, given that it

1. is a 'general theory of competition' (Hunt & Morgan, 2005) linking the dynamics of competitiveness at the individual, micro and macro levels
2. offers an explanation as to what constitutes 'superior performance'
3. re-defines resources to include tangible and intangible entities available to the firm that yield competitive differentiation and/or customer value delivery
4. holds that it is a key task of management to build a competence in strategic management
5. embeds the economy within a broader societal framework. R-A theory allows for the possibility that social relations and social structures can (and often do) affect competition (both negatively and positively).

From the perspective of this research, the main limitation of R-A theory lies in the fact that the process of competition is essentially seen as a 'local' process. It tells us little about an economy's or enterprise's interface with international business in developing 'resources' (especially technology) and in pursuing innovation. In small states, the competitive process is inevitably impacted by 'exogenous' forces, with technology being often sourced from overseas (especially through FDI). Also, R-A theory, while acknowledging the impact of societal resources and societal institutions on the competitive process and allowing for the availability of non-rival technologies and competencies to competitors, ignores the possibility of enterprises working together. In the literature, there is growing awareness about the importance of inter-linkages between firms, as well as between economic sectors, in shaping competitiveness at the national level. An advanced economy is perceived as encouraging and

supporting alliances and networking that enable its organisations and enterprises to reap externalities and facilitate the diffusion of knowledge. Little research has been conducted on the scope and nature of such inter-linkages in small economies. In a small economy, the scope of clustering and networking is conditioned by the limited number of players as well as geophysical considerations.

*In concluding the review on mainstream theories explaining 'superior economic performance' it can be stated that while they offer various explanations, they generally fail to provide a convincing account of what drives superior economic performance in the case of a small state. At the state level, international trade theory makes the case for specialisation and free trade, and development studies generally highlight the state's responsibility in creating the 'right' operating environment, while competitiveness approaches emphasise that competitive advantage is created and not inherited as resource endowment.*

*At the enterprise level, the neo-classical school dismisses the very concept of superior performance seeing it as a mere 'passing' situation, which sooner or later will lead to supply-demand equilibrium. Superior performance results in 'rents', which can arise out of market imperfections, technological innovation and entrepreneurship. Both the environmental and efficiency schools seek to explain superior performance. While the environmental school emphasises the ability of an enterprise to use strategy and market power to manipulate the structure of an industry to its advantage. Porter(1998) extended this line of thought to nations in his work on national competitiveness, the efficiency school perceives competitive advantage as primarily arising from the ability of the firm to exploit unique resources, competencies and dynamic capabilities.*

*Although these two schools have often been presented as being in opposition to one another, good strategy involves a 'fit between the external situation a firm faces (threats and opportunities) and its own internal qualities or characteristics (strengths and weaknesses)' (Hill and Westbrook, 1997, p. 47). In a dynamic environment, competitive advantage can only be sustainable, if it is consistently re-created. The individual enterprise was the unit of study of both approaches. What is more important for the purpose of this research is that while the environmental approach with its emphasis of market power is not relevant to small states and their enterprises, the efficiency view offers a plausible alternative that can be the*

*basis for further study. R-A theory is an off-shot of the efficiency school and its logic and insights were instrumental for the course of this research.*

#### **4. Research Methodology**

*This chapter outlines the research design of this thesis highlighting the methodology that has been followed with particular attention being given to defining the research setting as well as elaborating on the data collection and data analysis processes.*

Given the nature of the research problem of this thesis which seeks to understand a complex economic phenomenon embedded in broader social change, it was deemed appropriate to follow a qualitative approach, which tends to generate words, rather than numbers, as data for analysis. Gephardt (2004, p. 455) states that '[q]ualitative research starts from and returns to words, talk, and texts as meaningful representations of concepts'. A valid contribution to theory and practice requires a methodological fit as 'an overarching criterion for ensuring quality field research' (Edmondson & McManus, 2007, p. 1155). A methodological fit relates to the fit of research design and subsequent execution with the state of prior relevant theory (Said, 2013). A qualitative approach permits exploring dynamics across different levels of analysis (Bansal & Corley, 2011).

This qualitative approach is complemented by quantitative analysis, given that the researcher collected and analysed the statistics available on the performance of the pharmaceutical industry in Malta around the period of EU accession. The objective of gathering and assessing this data was to obtain a numerically-based assessment as to the success of the pharmaceutical industry in Malta during the period being investigated. This assessment is based on conventional economic criteria including the industry's output, gross value added, employment and exports.

This research is based on social constructionism, which acknowledges that the social researcher is a product of a particular context (time and space) and is part of the phenomenon being investigated. Evaluation research is intended to present a meaningful reconstruction of the real world and this is shaped by the researcher's own values and experience as an insider. 'Social constructionist epistemologies dismiss the notion that researchers are passive observers or knowers, but rather that social researchers make sense out of meanings, drawing from reflexive approaches to generate understandings as a basis for theory creation' (Said, 2013, p. 8). Researchers' orientations are influenced by 'their socio-historical locations, including the values and interests that these locations confer upon them' (Hammersley & Atkinson, 2009, p. 551 cited by Said, 2013). According to social constructionism, knowledge is built through selection and structuring on the basis of an interchange between actors in a social system. Research should be sensitive to not only the researcher's bias but also interpretation, understanding and constructions of all those contributing, directly or indirectly, to the gathering of information and data.

Social constructionism as a paradigm has three primary concepts:

- (a) researchers make subjective meanings of their experiences
- (b) meanings are diverse and multiple
- (c) meanings are formed by interaction with others and shaped by historical, social and cultural contexts

The researcher's mind-set tends to take a systems view of reality and it is this orientation which led to perceiving a small state as an organisation, with well-defined but permeable boundaries. Such an organisation has been termed as an 'open system' and a schema (figure 12) developed so as to help define the research setting of this thesis. Such a schema follows the logic of systems approach and is considered appropriate owing to the constructs of inter-relatedness of the features of the 'open-system', acknowledging the central importance of the external environment and its dynamic and evolving nature. Systems thinking characterises also the proposed theoretical framework relating to the role of arch-RCDCs in determining competitive advantage. A basic postulate of the framework (Figure 14) is that its components have to be always present as their inter-relationships are essential for the final outcome. A systems approach embraces complexities in a holistic but pragmatic way. Godet (2006, p. 14)

points out that a systems analysis ‘is a way of thinking’ and ‘an act of epistemological faith since it supposes that the observer is capable of self-observation and observation simultaneously’. In an increasingly dynamic and complex world, a systems approach leads to not only learning but also effective decision making (Stermann, 2000). Systems analysis involves moving beyond gathering facts, attempting to make sense of the ‘myriad human, political, social, cultural and contextual elements involved’ (Wallman, 2005, p. 119). According to the US National Defence University (2011), the systems paradigm is to be viewed as a tool which leaders can use to improve an organisation’s capability to

- (1) analyse tactical and strategic environments,
- (2) develop and enact strategies in response to environmental demands and
- (3) sustain an adaptive and productive organisational culture.

According to Stacey (2003, p. 30), the systems approach tries to ‘understand phenomena as a whole formed by the interaction of the parts’. A system as a whole comprises two or more parts (Bierema, 2003). It consists of sub-systems that are inter-related and interdependent. Each sub-system within the system, and the system itself, has a boundary separating it from other sub-systems and systems. Systems’ thinking is based upon ‘a spatial metaphor of inside and outside’ and follows a linear notion of time (Stacey, 2003, p. 313). This research adopts a temporal development perspective, where the process triggered by external change is seen as a sequence of events, with meanings and perceptions changing over time. Multiple parts tend to create multiple relationships. Enhancing one aspect of the system largely depends on the interaction of a specific sub-system with other parts of the total system (Rhydderch *et al.*, 2004). Systems analysts tend to believe that the ‘whole’ is greater than the sum of the sub-systems. A system relies on its relationships and holistic principles to achieve optimal performance (Rhydderch *et al.*, 2004).

A case study research is sympathetic to the principles of systems analysis (Stake, 1995). Given that the rationale for choosing a case study is its ability in explaining the presumed causal links in complex, real life interventions, it was deemed to be the most appropriate approach to study the impact of the changes generated by EU membership on the Maltese pharmaceutical industry. This choice is further due to the fact that changes generated by EU membership are unlikely to have well-defined outcomes. Case studies “are the preferred

strategy when ‘how’ and ‘why’ questions are being posed, when the investigator has little control over events and when the focus is on a contemporary phenomenon within some real-life context” (Yin, 2003, p 1). A case study is a detailed, holistic empirical investigation into a complex entity that emphasises the uniqueness and context of the case and typically draws on various data sources (Ridder *et al*, 2009). “It copes with the technically distinctive situation in which there will be many more variables of interest than data points” (Yin, 2003, p.13). A case study is ‘an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident’ (Yin, 2003, p. 13). Case studies offer an in-depth evaluation, making it ideal for new or poorly researched fields. Case studies represent a comprehensive research strategy which “comprises an all-encompassing method-covering the logic of design, data collection techniques and specific approaches to data analysis” (Yin, 2003 p. 14). Case study research relies on well-established criteria including a clear definition of the case, appropriate allocation of resources and varied and multiple data sources. Deconstructing and reconstructing the case leads the researcher to ‘new meaning’. The ‘case’ has both uniqueness and commonality that is relevant and interesting and advances knowledge within the field being studied (Stake, 1995). This research’s case study follows an ‘instrumental’ approach, given that its focus is on learning about the validity of the proposed theoretical framework on the role of arch-RCDCs in determining the strategic flexibility and competitive advantage of an ‘open system’ rather than learning from the case itself (Stake, 1995).

Collecting multiple sources of data enhances the trustworthiness of a case study research and can provide richer contextual information for the cases (Yin, 2009). This research’s case study relies on secondary data (collected from various sources including statistics from government sources, newspapers and the internet) as well as primary data compiled through personal interviews conducted by the researcher. Katzenstein (1985, p. 12) notes that ‘using newspapers is not without risks’. Given the timeframe of the selected case study, newspapers are seen as a valid source in capturing the ‘immediacy’ of the moment, even if this may be shrouded in a non-technical approach. One of the main challenges in a case study is to balance description, analysis and interpretation (Yin, 2009). Case study has long been stereotyped as a weak sibling among social science methods and denigrated as having insufficient objectivity, precision and rigour (Yin, 2003). However, a case study is not meant to represent a ‘sample’. Its purpose is to “expand and generalise theories not to enumerate



frequencies” (Yin, 2003, p.10). Given that the literature review did not yield an appropriate knowledge base on the subject in hand, it was inevitable that this research proposes an alternative theoretical framework related to the competitive advantage of small states (figure 14).

The primary field research of this thesis entails two types of interviews, those with policymakers and other stakeholders, which follow an open-ended approach and subsequent interviews with the top management of pharmaceutical enterprises operating in Malta conducted on a semi-structured basis. The intention of holding preliminary open-ended interviews (Table 5) is to enable the researcher to learn more about the subject matter, keep the interview as flexible as possible so as to learn as much as possible on the interviewees perceptions on the subject matter. The advantage of having a semi-structured interview (see Annex 1 for an illustrative list of questions) is to help the interviewee understand better the subject matter, enable some probing by the researcher without upsetting the rapport with the interviewee. Interviews have the advantage of being versatile and highly specific, especially when the number of interviews being held is relatively small. The disadvantages associated with interviews include reliance on interviewees’ memory and bias and are generally directed to reflect the researcher’s own interests and reactions to the information from the interviewee. This is especially the case with open-ended interviews. Constructionism views the interview as an engagement in constructing meaning. Experience is never ‘raw’ but embedded in a social web of interpretation. It is not just what is said which is important but how it is said.

**Table 5. Interviews with Relevant Public Institutions in Malta**

<b>Organisation</b>	<b>Interviewee</b>	<b>Position</b>	<b>Date</b>
Malta Enterprise	Galea, M.	Advisor to Chairman	26.06.2012/10.03.2013
Chemistry Dept. UoM	Farrugia, C.	Senior Lecturer	10.11. 2012
Chemistry Dept. UoM	Sinagra, M.	Professor	19.11.2012
Malta Medicines Authority	Vella Bonanno, P.	CEO	03.07.2012/20.07.2012
National IP Office, Commerce Dept.	Warr, G.	Director General	03.07.2012
Institute of Applied Science, MCAST	Rizzo, A.	Head	25.07.2013
Malta College Science & Technology	Castillo, N.	Director, Policy & FP7	23.07.2013

The semi-structured interviews are meant to help test the validity of the theoretical framework. Given the small number of enterprises involved (Table 6), interviews were held with each one of them.

**Table 6. Interviews with Pharmaceutical Companies Operating in Malta**

<u>Company</u>	<u>Interviewee</u>	<u>Position</u>	<u>Date</u>
Actavis Ltd.	Cachia, P.	General Manager	17.07.2013
Acatvis Group	Vella, S.	VP Manf. West Europe	26.07.2013
Amino Chemicals Ltd.	Antonio, S.	Managing Director	11.06.2013
Siegfried Generics Malta Ltd.	Giromini, V.	Managing Director	13.07.2013
Combino Pharm Ltd.	Allegrucci, P.	Managing Director	09.08.2013
Medichem Malta Ltd.	Mangion, D.	Managing Director	18.06.2013
APL Swift Services Ltd (Aurobindo)	Schembri, F.	Managing Director	20.06.2013
Starpharma Ltd.	Galea Kenely, M	CEO	05.07.2013
Institute of Cellular Pharmacology Ltd.	Saliba, C	Managing Director	22.08.2013
Solea Pharma Ltd.	Martin, P.	CEO	06.08.2013
Pharmadox Healthcare Ltd.	Seychell, P.	Managing Director	23.07.2013
Pharmacare Premium Ltd.	Khour, B.	Managing Director	29.06.2013/11.09.2013
Alpha Farma Ltd.	Debono, M.	Managing Director	17.06.2013
Actavis Ltd.	Zammit, J.	Group HR Manager	09.01.2013
Pharmamed (Actavis)	Grioli, J.	Managing Director	21.01.2013

In total twenty six face-to face interviews were held. All of the interviewees were very open and willing to discuss the various issues raised during the discussion (the researcher was known to many of them) but they were less willing to give specific information relating to the financial performance of their company. The illustrative list of interview questions helped to guide discussions, which at times did not keep with the researcher's line of inquiry as the

respondents felt it opportune to comment on issues which they felt important for the conversation. As can be expected, the contribution made by interviewees differed significantly. This was due to such factors as whether the company was already operating in Malta prior to EU membership, the number of years they were personally involved in the pharmaceutical industry in Malta and the level of autonomy of the local operation from the parent company.

Data collection and analysis is organised in two phases: A first phase involving gathering and analysing information and data resulting from the secondary data and a second phase which relates to obtaining and assessing information through field research. In the first phase the researcher seeks to ensure that Malta qualified as an 'open system'. EU membership has blurred the real state of the Maltese economy and there is a popular tendency to assume that since Malta now forms part of an advanced economic group, it automatically shares the same strengths and advantages. Indeed, despite EU membership, Malta's share of world exports as well as trade with the EU has been showing a downward trend since 2000. Malta's terms of trade have also been worsening indicating that the prices that Malta obtains for its exports are declining relative to the prices it pays for its imports.

The researcher had to obtain the official data relating to the pharmaceutical industry in Malta so as to get a better understanding of the performance of the pharmaceutical industry in Malta around the time of the country's accession into the EU. Unfortunately, there are no sector studies on the pharmaceutical industry in Malta and the official statistics are not published at this level of detail. The statistics were made available to the researcher by the National Office of Statistics. These were then charted and assessed along conventional criteria which included: output, gross value added, employment, gross value added per employee, exports, exports per employee and exports related to output. The statistics help show the rapid growth that the Maltese pharmaceutical industry achieved between 2000 and 2011. Data was also obtained from the both National Intellectual Property Office of Malta as well as the National Office of Statistics with regards to the number of patents being filed by the pharmaceutical industry and the amount of investment it was making into R & D respectively. This was

deemed important as it could help indicate the extent to which the pharmaceutical industry is dependent on R & D for its success.

To get additional information on the local pharmaceutical industry, the researcher managed to find some theses on the industry at the University of Malta. These were mostly presented by law students and focused on the legislative changes involving the pharmaceutical industry that Malta had to implement as part of its obligation to transpose the EU's 'acquis communautaire'. This led to an extensive analysis of the European pharmaceutical industry as its policies, institutions and structures impacted on local legislation (such as the Medicines Act of 2003) and the creation of new institutions (such as the Medicines Authority). Secondary data was generally collected from open sources especially the internet (including newspaper reports). This was deemed necessary as some key individuals who were operating in the Maltese pharmaceutical industry at the time of its accession to the EU were no longer available for interview (mostly expatriates who had returned home). This material helped in formulating the illustrative list of interview questions and to fill some of the deficiencies in information obtained from the primary research.

The second phase focuses on interviews with both policymakers involved directly or indirectly with the local pharmaceutical industry as well as with top management of local enterprises. The interviews with the policymakers are opened ended and are intended to help the researcher obtain as much relevant information on the industry. When needed (in two instances) a follow-up meeting was organised so as to obtain additional information or clarifications to points discussed in the first interview. The information gathered together with the proposed theoretical framework helped to prepare a set of illustrative questions which are used to guide discussion in the interviews with the enterprises. The idea of having such a list of questions is to have a semi-structured interview with the management of local pharmaceutical enterprises so as to ensure that sufficient attention is given to the research's line of inquiry, there is still the possibility of the interviewee making comments which (s)he deem important and which could be missing from the proposed model. The illustrative list of interview questions proved invaluable not only in gathering information but also in coding and assessing the data collected.

The first three questions are intended to get the interviewee to express his (her) opinion on the impact of Malta's EU membership on the local pharmaceutical industry, its operating environment as well as on his enterprise. These questions help to establish clearly the general line of enquiry but are vague enough so as to allow the interviewee to give his own ideas on the matter. The fourth question relates to the perceived primary challenges currently facing the pharmaceutical industry in Malta. Once this is answered, the interviewee is asked how these challenges have changed since 2004 (the year Malta joined the EU). This question links with the previous three questions and indirectly seeks to re-affirm the impact of EU membership, especially at an industry level. The fifth question seeks to establish what the interviewee deems to underpin the competitiveness of local pharmaceutical enterprises and to what extent they are still dependent on charging low prices as they are mainly competing on costs. The sixth question attempts to determine the operating philosophy of the enterprise and whether it had a clear plan as to how to increase value added. (Value added is generally associated with increasing output and/or lowering unit costs, but it can also result from the enterprise capitalising on its market power and push up its prices). Question seven is closely linked to the previous one and directly asks as to the perceived ability of the enterprise to influence the prices it gets for its products. Question eight goes back to the impact of EU membership on local enterprises and seeks to gauge whether the interviewee believes that they have enough power to play a role in influencing EU directives and policies. (This given that impact rises out of a dyadic relationship and can work both ways). Question nine seeks to test the propensity of local pharmaceutical enterprises to collaborate and network (alliance capability). This is an open-ended question as it does not specify with whom they collaborate or network. Question ten attempts to determine how the interviewee perceives the strengths of his enterprise: is it its assets (such as technology, machinery, marketing, finance and human resources) or is it in its competencies (such as market sensing, alliance capability, managerial know-how and flexibility). Question eleven too is an open-ended one and seeks to conclude the interview by asking about the perceived future of the pharmaceutical industry in Malta.

The researcher did not record the interviews as it was felt that this could condition interviewees and work against having an atmosphere conducive to open discussion. Hand-written notes were taken during the interview and these were then re-written and expounded shortly after the interview to ensure that salient points emerging from the discussion were still

fresh in the researcher's mind. Following the termination of the field research it was decided to add another component (other RCDCs) to capture those factors which interviewees felt were critical for the development of the pharmaceutical industry in Malta.

As mentioned, the involvement of a researcher as the primary instrument of data collection presents limitations owing to subjectivity and bias. The limitations of a research based on a single case study are obvious, and attempts to generalise the results to a diverse population are inevitably over-simplistic (Lorenzoni & Lipparini, 1999).

*This chapter outlined the methodology followed by this research. Given the complexity of the subject matter a qualitative, case-study approach was adopted. The research is an exercise in social constructionism and follows systems thinking. The proposed theoretical framework relating to the relevance of the identified arch-RCDCs for competitive advantage helped in the preparation of an illustrative list of questions for interviews with the top management of pharmaceutical companies in Malta, to gather information as well as for data analysis.*



## 5. Research Findings

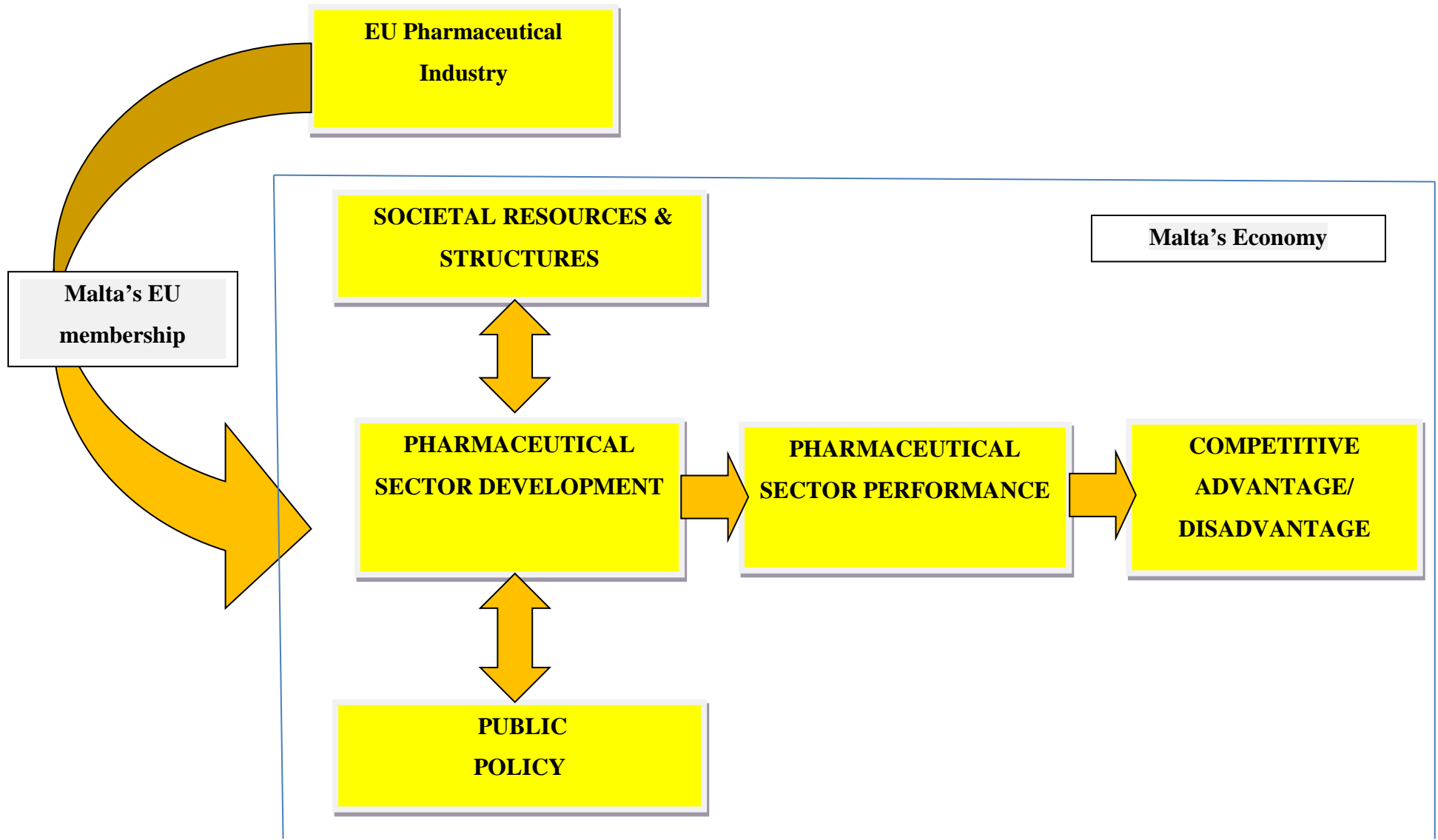
*This chapter presents the results of the secondary and primary research of this thesis. In the first part of the chapter the research setting is delved by applying the proposed schema (figure 12) to the development of the pharmaceutical industry in Malta following EU membership. The credentials of Malta as an open system are established as well as an outline of the EU pharmaceutical industry with a focus on legislation which had to be transposed by Malta and impacted on the country's public policy as well as institutional set-up dealing with the pharmaceutical industry. An analysis of the sector's economic performance follows. In the second part of the chapter, the findings arising from the field research are presented. The theoretical framework (figure 14) relating to the arch-RCDCs and the competitive advantage of an open system helped guide the field research and the analysis of findings at both the sector and enterprise level.*

This research has proposed an alternative approach which views a small state as an organisation, with well-defined but permeable boundaries. Such an organisation has been termed as an 'open system' and a schema (figure 12) developed so as to help define the research setting of this thesis.

When this schema is applied to the pharmaceutical industry in Malta we get figure 18 which proposes to capture the impact of Malta's membership in the EU on the pharmaceutical institutions (including enterprises) in the country, leading to their development, improved sector performance and competitive advantage.



Figure 18 : Impact of EU membership on Malta's Pharmaceutical Industry



## 5.1 Malta as an Open System

The two criteria set by this research for an open system are that the country and its enterprises generally lack ‘market power’ and population does not exceed 1.5 million. Malta has a population of 420,000 and despite the country’s relatively high GDP per capita (€17,000 in 2014), most Maltese enterprises still compete on costs. They are ‘price takers’ with practically no market power. Malta is an archipelago of three inhabited micro islands with a total area of 316 square kilometres. The islands are 93 kilometres south of Sicily and almost 300 kilometres north of Libya (figure 19). Malta’s terrain is low and rocky with coastal cliffs.

The history of the country goes back some six thousand years and the islands are a true melting pot of civilisations. Malta’s strategic location and natural harbours attracted military powers in the Mediterranean which wanted to control this important trade route.

Malta achieved political independence from Great Britain in 1964 and became a Republic ten years later. Today, Malta is a member of the EU, the UN and the Commonwealth. Malta ranks 36<sup>th</sup> out of 187 countries on the UN Human Development Index (2011).



Figure 19: Malta’s Geographical Location

### Fact Sheet: Malta

<b>Population '000 (2012)</b>	425
<b>Territory Size</b>	316 km <sup>2</sup>
<b>Population Density</b>	1250 per km <sup>2</sup>
<b>GDP (2013)</b>	€7.02 b
<b>Per Capita GDP '000 (2013)</b>	€17,000
<b>GDP (PPS): %, EU 27 (2012)</b>	83%
<b>Life Expectancy</b>	79.6 years

Malta's aridity and poor soil do not permit the development of extensive agriculture (even though there were times in the past when the country thrived on olive oil and cotton exports). Malta is highly dependent on the importation of food and other essentials. Over the centuries, the country prospered as a trade hub, especially in times of war, when it capitalised on the increased military spend of its foreign rulers.

Malta boasts a long tradition as a centre for healthcare. During the time of the Knights of St. John (1530–1798), the country had one of the most advanced hospitals in Europe. The Knights set up a medical school which eventually evolved into a multi-faculty university. The British built upon this tradition and exploited Malta's strategic location to house their military medical centre in the Mediterranean. The British ruled Malta between 1800 and 1964. Prior to WWII, Malta had already achieved a degree of industrialisation which involved a complex division of labour supporting the British military services on the islands (Brincat, 2009). In the 1950s, the British government was desperately cutting its military expenditure. The run-down of the British military presence on the islands led to significant economic hardships for the local population. Malta had to quickly diversify its economic activities to create jobs and maintain its standard of living (Brincat, 2005). A large number of Maltese were obliged to migrate to the United Kingdom, United States, Australia and Canada, and immediately after WWII, their remittances kept many local families from falling into extreme poverty.

Brincat (2005) refers to the 'Maltese Model' of industrialisation: export-oriented activities driven by FDI. 'The only practical course is to direct every effort, of investment, administrative measures and legal machinery, and of the skills of the people, towards the achievements of a self-supporting and viable economy' (Development Plan for the Maltese Islands, 1959-64 quoted by Brincat, 2005). Industrialisation was made possible through 'a process that was assisted by certain legacies of the colonial period. These included a 'reserve army of labour' created by the British military rundown, which 'disposed of skills accumulated over one and a half centuries of servicing naval and other military hardware' (Brincat, 2009, p. 36). During the 1960s, Malta promoted itself in a structured way as a 'sun and sea' tourist destination. Relying mostly on mass tourism (initially through packaged tours, and more recently, through low cost carriers), Malta annually attracts four times as many tourists as it has inhabitants.

The country achieved remarkable economic growth rates. The Commission on Growth and Development (2008) identified Malta as one of thirteen countries which registered impressive growth over a sustained period of time (Table 7).

<b>Economy</b>	<b>Period of high growth**</b>	<b>Per capita income at the beginning and 2005***</b>	
Botswana	1960–2005	210	3,800
Brazil	1950–1980	960	4,000
China	1961–2005	105	1,400
Hong Kong, China*	1960–1997	3,100	29,900
Indonesia	1966–1997	200	900
Japan*	1950–1983	3,500	39,600
Korea, Rep. of*	1960–2001	1,100	13,200
Malaysia	1967–1997	790	4,400
Malta*	1963–1994	1,100	9,600
Oman	1960–1999	950	9,000
Singapore*	1967–2002	2,200	25,400
Taiwan, China*	1965–2002	1,500	16,400
Thailand	1960–1997	330	2,400

Source: World Bank, World Development Indicators.

\*Economies that have reached industrialized countries' per capita income levels.

\*\*Period in which GDP growth was 7 percent per year or more.

\*\*\*In constant US\$ of 2000.

**Table 7: Success Stories of High, Sustained Growth**

**(Reproduced from World Bank, 2008b)**

The technical skills nurtured at the local military shipyard proved invaluable in supporting Malta's industrialisation process. The country had an abundance of non-agrarian, English-speaking, cheap labour which attracted a significant number of textile, electronic and light engineering operations. Initially, the United Kingdom was the main source of foreign direct investment, but this changed in the 1970s when Germany took over. Industrial growth led to the creation of a dual economy; a foreign-owned, internationally competitive segment which utilised relatively sophisticated imported technologies and an indigenous domestic market-oriented segment that generally relied on 'dated' technology and machinery. Gradually, the importance of manufacturing declined from some 35% to 13% of GDP. The Maltese economy is now service oriented and relies on activities such as financial services, remote gaming and the information and communication industry.

To meet the challenge of globalisation and help overcome some of the perceived limitations of small size and peripherality, forty years after independence, Malta joined the EU. The primary challenge for the country at the time was to liberalise and restructure its economy (especially indigenous operations) to meet the challenges of integration into the sophisticated European market. Bonello (2009, p. 1), the Governor of the Central Bank of Malta, argues that he favoured the EU membership because, given Malta's small size and lack of natural resources, it was 'Malta's only viable option' that guaranteed access to foreign markets. The EU membership was also perceived as being 'the solution to the prevailing economic problems...lack of discipline in public budgeting, lack of enforcement, etc' (Mizzi, 2004, p. 7).

Malta–EU relations go back to 1970, when the country entered into an association agreement with the EEC. This agreement was intended to lead to a customs union, but successive local governments were reluctant to go the full way as they feared that local enterprises would not be able to compete head-on with European enterprises (Mizzi, 2004). The association agreement with the EEC was generally a favourable one for Malta. The country not only secured financial assistance from the EEC to help it modernise the physical infrastructure, but also practically offered access to all locally manufactured goods (except textiles, clothing and food products) to its markets, without any tariff or quota barriers. Though Malta formally joined the EU in 2004, the change process began in 1990, when Malta first applied for membership. The application sent a strong signal to all the local stakeholders of government intentions, but their reactions varied between, and among, themselves. Some were sceptical about the EU's willingness to accept tiny Malta as a full EU member. Others doubted whether Malta would be prepared to make all the necessary changes for its membership. In June 1993, the European Commission published a favourable opinion ('Avis') on Malta's membership, however, it pointed out that extensive restructuring had first to be implemented.

The 1993 Avis finds that membership 'depends on a thoroughgoing overhaul of the Maltese economy's regulatory and operational systems' (Bonello, 2009, p. 1). Important reforms included the liberalisation of the financial system and the import tariff regime, gradual easing of exchange controls, partial deregulation of interest rates and introduction of value-added tax and lower direct taxation. Significant restructuring 'could only be met if we were prepared to question the way we had managed the economy in the past and resolved to make the

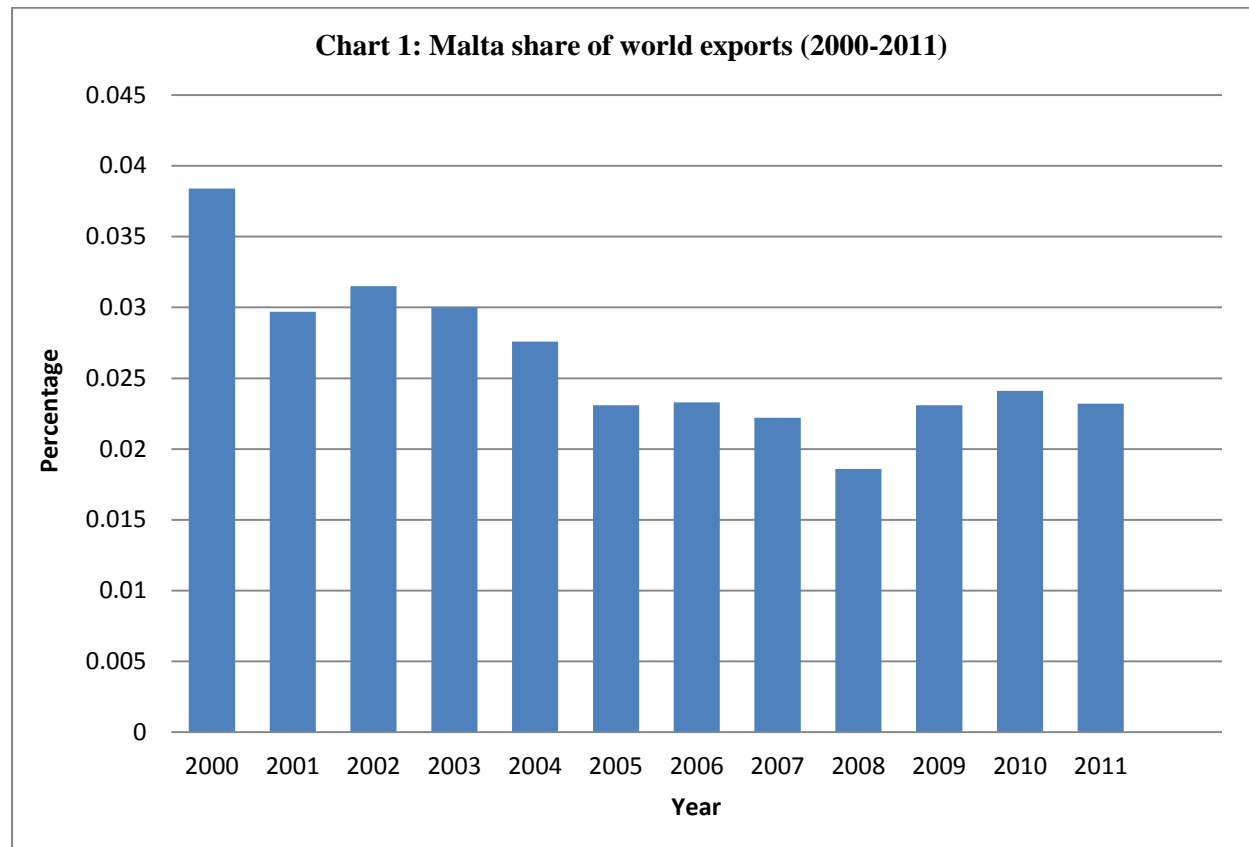
necessary changes to institutions and mind-sets, policies and work practices' (Bonello 2009, p. 1). The fact that politically there was no national consensus on the EU membership complicated the situation. In 1996, the PL came to power and decided to 'freeze' Malta's application. This naturally sent a contradictory signal to stakeholders and increased uncertainty. The 'adaptation' process at the national level started in earnest in 1999, when after a change in government Malta's application was reactivated. The European Commission updated its 1993 opinion on Malta's membership and recommended that the Council gives the go ahead to screen Malta's legislation with a view to opening negotiations.

'As from the year 2000, Malta as a candidate country started receiving technical and financial support for the transposition of the Community acquis, for participation in Community Programmes and certain Community agencies and for increasing the Maltese administrative and judicial capacity' (EU Commission, 2013). The EU membership entailed the transposition of the 'acquis communautaire' (the cumulative body of European Community laws, comprising the EC's objectives, substantive rules, policies as well as the primary and secondary legislation and case law) into local legislation. It is a pre-condition set by the EU that all countries seeking membership must first adopt, implement and enforce all the acquis. 'As well as changing national laws, this often means setting up or changing the necessary administrative or judicial bodies which oversee the legislation' (EU Commission, 2012). Geographically, Malta is the smallest state within the EU and has the second smallest population (after Luxembourg). The EU membership brought with it an obligation for Malta to join the euro. With an average trade-to-GDP ratio of 82%, Malta has the second most open economy in the Union (Bonello, 2010). The EU is Malta's major trading partner, accounting for 61% of its exports of goods and services and 70% of its imports.

The EU itself is not a homogenous entity and there are significant economic differences between its member states and regions. Malta's aspiration remains that of achieving 'superior performance' that will enable it to move closer to the standard of living enjoyed by the more advanced EU economies. Membership triggered a deep change process which is transforming not only the country's economy but also its political, social, technological, environmental and legal scenes. Today, Malta's economy is specialised in technology-driven industries which account for 71% of total exports (this is the highest in the EU). Trade specialisation in technologically advanced sectors, however, is not leading to high productivity and high

incomes. A recent study commissioned by the MCST finds that ‘[t]he competitiveness of the Manufacturing Industry is gradually eroding as manufacturing firms are faced with declining profits, lower employment levels and reduction in the overall turnover being generated in the process’ (BEAT Consulting, 2011, p. 6). Malta is in the same group of EU countries as the Czech Republic, Hungary, Poland, Slovakia and Slovenia with a trade specialisation in high technology sectors, but having a lower GDP/person than the EU average. This group ‘looks like shifting towards becoming an assembly powerhouse for the more technologically advanced countries’ within the EU (EU Commission, 2011a, p. 22). The local manufacturing sector is still ‘predominantly based on the production function with a limited focus on research and development activities’ (BEAT Consulting, 2011, p. 7). Most enterprises continue to compete as ‘price-takers’ and are failing to achieve market power through innovation and strategic marketing. The majority of Maltese exports are ‘generated by Foreign Direct Investment set up in Malta which in most cases have their marketing and sales functions located in other destinations worldwide’ (BEAT Consulting, 2011, p. 6).

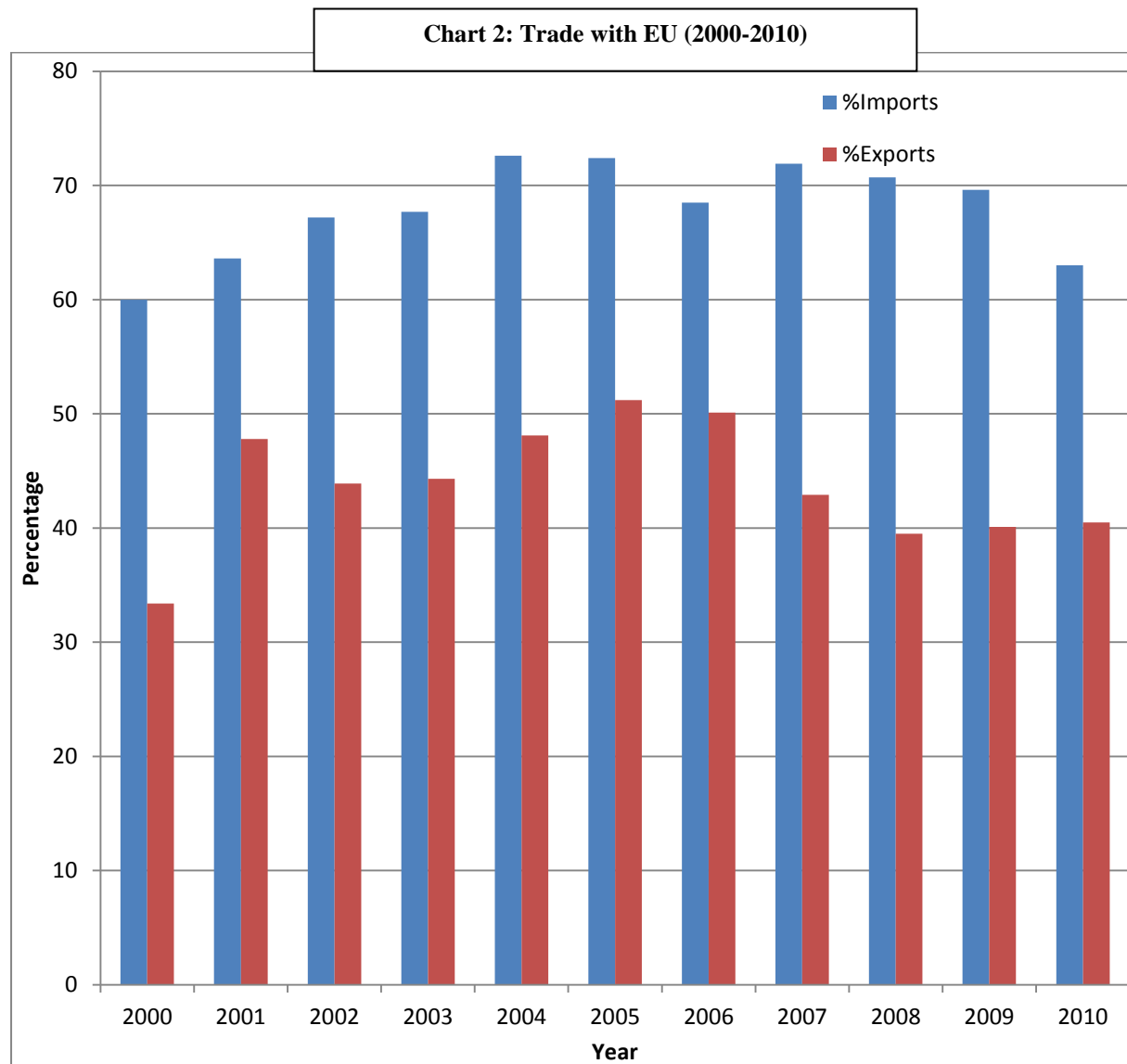
As a percentage of world exports, local exports show a significant decline since 2001 (even though there has been a small improvement from 2009 to 2010).



(Source: European Commission, AMECO database)

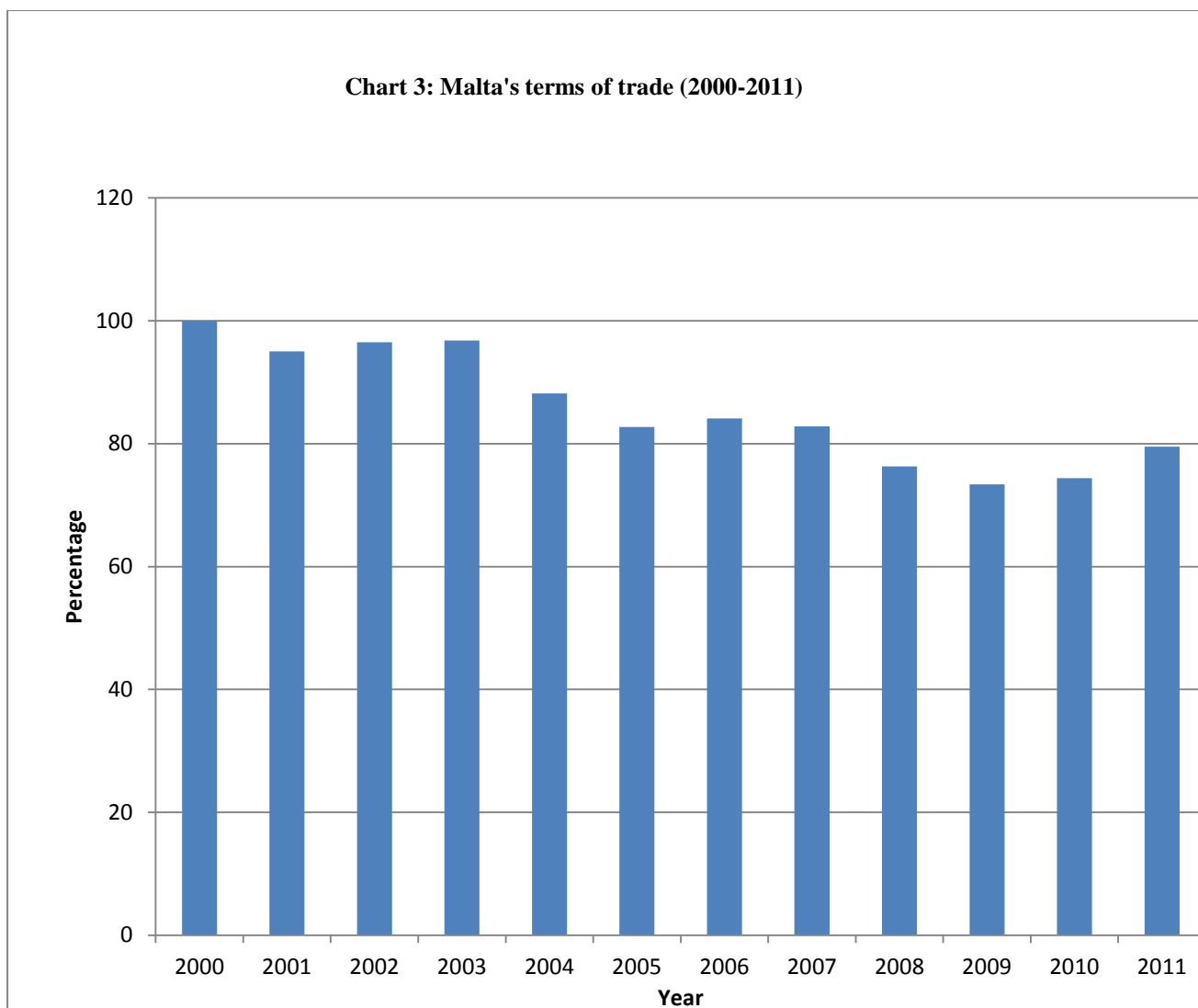


Despite EU membership, there has been little change in the direction of trade. Percentagewise, exports to the EU increased slightly in 2005–2006, but have been falling ever since. Similarly, imports from the EU peaked in 2004–2005 and have also been declining.



(Source: National Statistics Office, Malta)

The terms of trade for Malta have been declining since 2000; the trend has accelerated post-EU membership (even though in 2010, there was a small rebound).



(Source: European Commission, AMECO database)

## 5.2 EU Pharmaceutical Industry

‘The pharmaceutical industry is concerned with all aspects of the preparation and use of medicines’ (Anderson, 2005, p. 3) and is considered to be a ‘strategic’ sector for Europe (Gambardella *et al.*, 2000). It is a highly sensitive industry ‘in terms of the debate it arouses and the regulations it invites’ (Ballance *et al.*, 1992, p. 140). Health is a universal human right (WHO charter) and has become a critical political issue that impacts the local, national and global levels. ‘In an era of globalization, governments are expected to provide safety and welfare for citizens while ensuring a level playing field and boosting competitiveness for businesses’ (WHO, 2011, p. 343). ‘Good health and the opportunity to seek health care are of intrinsic value for making progress in international relations between states and between

conflicting groups within states' (Quirke, 2005, p. 1). The international harmonisation of pharmaceuticals 'was formally initiated through the creation of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use in 1989' (Zammit, 2010, p. 48).

OECD countries account for 20% of the world's population, but spend 90% of the global expenditure on health; about '80% of the world's population lives without access to essential medicines' (Quirke, 2005, p. 161). In western societies, a major concern is the over-consumption of medicines for dubious benefit (O'Donovan & Glavanis-Grantham, 2007). In Third World countries, international players such as non-governmental organisations (NGOs) and global corporations play a critical role. NGOs influence 'global health governance' through their funding priorities, since they exert considerable influence on the 'type of health programmes and initiatives that are promoted in many aid-recipient states' (Quirke, 2005, p. 58). Given the pharmaceutical industry's importance to public health, its high level of regulation, dependence on legal 'concessions' and the fact that the government is a main purchaser of its products, should lead the industry to be regarded as a 'public utility' (Marcia, 2004).

The aspirations of people for a healthier life are increasing across the world. 'The globalisation of pharmaceuticals illustrates the sheer scale and complexity of our interconnected world and its uncertain social and biological outcomes in local and national settings' (Petryna & Kleinman (2007) quoted by Zammit (2010, p. 42). Although the pharmaceutical industry has an excellent track record '(it) is a victim of its own success' (Farrugia & Savvas, 2009, p. 30) as the industry is characterised 'by a number of contradictions' (Zammit, 2010, p. 25). 'Politics and health; fundamental rights of persons, medicines and welfare; innovation and development; politics of solidarity, intellectual property, innovation and patents and world government are some of the facets in which pharmaceutical innovation and effective and equitable use of medicines are involved' (Valverde (2007) cited by Zammit (2010, p. 25).

The industry's controversial reputation arises from its independent-minded enterprises and their secretive method of operation, exceptional profitability and high level of innovation (Ballance *et al.*, 1992). The mass production of drugs dates back to 1813, with the

establishment of the first specialised pharmaceutical plant (Panda *et al.*, 2011). Over the last century, there has been a vast increase in the number of therapeutic innovations (Quirke, 2005). ‘Parallel with product innovation we clearly see major developments in process technology’ (Panda *et al.*, 2011, p. 1). The period of 1950–1970 is considered the ‘golden age’ of the drug industry. The invention of genetic engineering in 1973 opened up new research possibilities and is leading to significant growth in biotechnology. ‘This marked the start of a new era in drug R&D and also the coming of a new R&D trajectory’ (Panda *et al.*, 2011, p. 2). The life sciences are transforming drug discovery and development. ‘The advent of the so-called “molecular biology” revolution since the mid-Seventies has introduced drastic changes in the relevant knowledge base, in the processes of discovery and in the organisation of research, with the emergence of a new technological regime and new technological and organisational capabilities as a key source of competitive advantages’ (Gambardella *et al.*, 2000, p. 37).

The pharmaceutical industry is driven by complexity; the companies that succeed are simply those that can handle complexity more efficiently (Vella, 2011). The industry is obliged to act quickly and in a flexible way. ‘Complexity and speed are becoming fundamental to development. If a company does not possess the intrinsic flexibility to address complexity effectively, it will be forced out of the market’ (Research & Markets, 2006). The big divide within the pharmaceutical industry is between patented (originator) pharmaceuticals and generics. There is no one internationally accepted definition of generics, although the term generally refers to medicines that are no longer protected by patents or non-patentable (Ballance *et al.*, 1992). As per Article 10 paragraph 2 (b) of Directive 2001/83/EC, the EU defines a generic medicinal product as one having ‘the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with reference medicinal product has been demonstrated by appropriate bioavailability studies’ (Azzopardi & Zarb Adami, 2012, p. 1). Equivalent generic medicines may contain different non-active ingredients (such as colourings, starches and sugars) and they may differ in size, colour or shape, but none of these have an impact on the therapeutic effect, that is, the way they work in a patient’s body. The term ‘generic’ also includes biosimilars. Generic medicines are identified either by their International Non-proprietary Names (INNs) or their own brand name. INNs are overseen by the WHO. Understandably, producers of generic medicines tend to focus on ‘blockbuster’

drugs, many of which generate an annual turnover of more than €billion and which lose their exclusivity status. These drugs 'are the backbone of many originator companies' (Boldrin & Levine, 2007, p. 16). Pharmaceuticals is a large, high-growth, globalised, and innovation intensive industry: its fundamental sources of competitive advantages are R&D and innovative competencies, marketing and distribution capabilities (Gambardella *et al.*, 2000). Globally, the industry is undergoing enormous change characterised by increased pressures on the big players, the advent of biotech and the global expansion of the generics industry (Singh, 2006, p. 194).

Pharmaceuticals are traded in both their intermediate and finished form. Global pharmaceutical corporations sell patented medicinal chemicals and preparations to their affiliates, licensees and appointed distributors, while non-patented ingredients are sold on the open market as fine or speciality chemicals (Ballance *et al.*, 1992). The internet is fast becoming an important channel to purchase medicines as well as leading to the increased sales of counterfeit drugs and increasingly challenging state control over the distribution of medicines (Ballance *et al.*, 1992). According to Deutsche Bank (2010), the global market for pharmaceutical products is about €700 bn and has been recording an average 10% annual sales growth in the last thirty years. Global pharmaceutical markets are being shaped by two broad demographic trends: population growth and age structure. Advances in drug-based treatment research, increased investment in healthcare and consumer-driven private health coverage are all boosting the demand for pharmaceuticals. By contrast, in Third World countries, the population is relatively young and the main demand for medicines is for acute or infectious diseases. The industry is characterised by a high level of concentration, with some fifteen dominating multinational companies (Davidson & Greblov, 2005, p. 2). Market entry is difficult due to a combination of strict regulations and the need for extensive research and development, which involves time-consuming, expensive clinical trials. There are three main types of pharmaceutical producers: large integrated corporations, innovative companies and reproductive firms. 'The ethical (prescription-only) pharmaceutical industry has been one of the fastest growing, most consistently profitable, of the world's major industries' (Rickwood & Southworth, 1994, p. 1). Large pharmaceutical firms have been repeatedly accused of enjoying a substantial or excessive degree of market power (Ballance *et al.*, 1992). Zammit (2010, p. 91) remarks '[t]he industry's ability to influence legislation cannot be over-estimated'. Estimates of concentration can, however, be misleading since 'the markets for

pharmaceuticals tend to be much more fragmented than those in other industries...Industry wide estimates therefore understate the extent to which a few companies dominate certain submarkets' (Ballance *et al.*, 1992, p. 111). Panda *et al.* (2011, p. 2) explain that although the market structure 'is oligopolistic at the level of therapeutics' it is highly 'competitive for OTC and generic categories'.

EFPIA claims that it can cost €1 billion or more to develop a new medicine in the period between discovery and marketing, which is normally a duration of 12–13 years. Only around one-fifth of new products ever recover the cost of development. Only one or two of every 10,000 substances synthesised in laboratories successfully pass all stages to become marketable medicines, and from these, one in five will produce revenues that match or exceed the costs of R&D before losing patent protection (EFPIA, 2012). For bio-pharmaceuticals, the costs of R&D tend to be higher than those of traditional pharmaceuticals. Producers of originator drugs depend for their profitability on the monopolistic rights arising out of the patent system and marketing authorisation procedure. Exclusivity is the lifeblood of the industry because it means that no other company may sell the same drug for a set period (Marcia, 2004). The cost of bringing a new medicine to the market is subject to wide debate and calculations. Critics of the industry point out that R&D is a relatively small part of the budget in major pharmaceutical corporations and it is a fraction of their spending on marketing and administration. The number of new important drugs is falling despite the contribution being made by public research at academic institutions, small biotechnology companies and national healthcare institutes, all of which are funded by taxpayers' money (Marcia, 2004). As the number of blockbuster drugs began to fall, 'firms have turned to mergers and acquisitions as a means of achieving economies of scale and scope' (Quirke, 2005, p. 197), Although in the past, the size and scope of operations have tended to go hand in hand, this is now changing (EC, 2009). The industry also comprises a wide variety of SMEs which tend to be national in scope and specialise in niche activities. These companies have 'thrived through imitation and generic competition after patent expiration as well as through production and marketing in local markets and product niches' (Gambardella *et al.*, 2000, p. 37). These reproductive firms generally lack any in-house research capacity and the drugs they produce are not protected by patents (Ballance *et al.*, 1992). The generics market is fast moving and subject to volatile prices and small margins (Cassar, 2006).

Research-intensive SMEs generally spring off from the life sciences. These companies are specialised in the new biotechnologies, and their activities range from the discovery and development of new drug compounds to the development of new drug screening or research tools and technologies in fields such as genomics and bioinformatics. Many of these companies are dependent on investor capital for survival as they are still developing their first products (Biotechnology is one of the most research-intensive industries in the world.). Originator companies are increasingly resorting to ‘branded generics’, that is, ‘generic drugs that carry a big pharmaceutical name...branded generics are likely to reach up to 75 per cent of sales growth within the next 10 years’ (Branded Generics, 2011). The EC (2009) pharmaceutical enquiry finds that several generic companies are also involved in the production of prescription medicines. Generic firms also engage ‘in the development of new formulations, dosage forms and methods of delivery (so-called “line extensions” of existing products)’. They are also expanding into new areas of pharmaceutical development, such as new formulations and biosimilar medicines, and are moving onto new and fast-growing pharmaceutical markets such as China, the Middle East and Russia (Grooten, 2008). Although generic producers are mostly SMEs, there is an evident shift towards consolidation and increased concentration. A few, such as Sandoz, the generics arm of Novartis and Israel’s Teva Pharmaceutical Industries have become global players and represent the world’s top two generic firms. ‘The gap between them and smaller players keeps growing’ (Hirschler, 2005).

In today’s fast-moving world, ‘time is money’. Generics take the shortest time possible to copy, licence, produce and stockpile a drug. Any time gained gives a competitive edge in the relatively low margin industry. Jack (2005) points out that ‘The first into the market often wins and keeps the greatest share’. The bottom line in generic pharmaceuticals is all about having a strong pipeline of new products coming out (Vella, 2011). The cost structure of generic companies is fundamentally different from originator companies. On average, manufacturing costs account for 51% of turnover. The European generic medicines industry is operating under increasing cost pressures as a result of higher regulatory requirements for bioequivalence, added GMP requirements and stricter pharmacovigilance rules (EGA, 2007). The future of generics is in biosimilars, as the high prices of biopharmaceutical products is likely to lead to important cost savings. Given the high cost of developing biosimilars, ‘these cost savings are likely to be less than for chemical molecules’ (EC, 2009, p. 41). While joint

research projects and strategic alliances facilitate the exchange of knowledge, 'network externalities' are also supported by the rapid movement of scientists and technicians across firms

Innovation in the pharmaceutical industry can be divided into two distinct categories:

- Fundamental innovation which leads to the discovery of new medicines containing novel pharmaceutically active substances (NCEs)
- Incremental innovation which results from the development of existing medicinal products and may include major innovations such as the novel use of existing products in new therapeutic areas, development of a new formulation or mode of delivery, combination of previously disclosed active substances and use of a new salt or derivative of the original product.

Gambardella *et al.* (2000, p. 1) note that '[e]ver since the XIX Century, pharmaceuticals has been a stronghold of the European industry, and it still provides by far the largest contribution to the European trade balance in high-technology, R&D intensive sectors'. As a result of 'some big and many small steps in biomedical research' (The European Federation of Pharmaceutical Industries and Associations, 2008), Europeans live up to thirty years longer than they did a century ago. In accordance with the principle of subsidiarity, the delivery of healthcare services and medical care in the EU remains the prerogative of each member state. Pharmaceuticals account for 24.1% of the EU's high-tech exports. It is the sector with the highest value add per person as well as the highest ratio of R&D investment to net sales. Pharmaceuticals represent about 3.5% of total EU manufacturing value (EFPIA, 2008, p. 10). Generics account for 18% (by value) and almost 50% (by volume) of the European market. The level of generic penetration in the EU is influenced by the different public policy choices made by the member states. Generic penetration rates tend to be higher in member states, where the prescription of active substances (INNs) instead of brands is encouraged. The slow rate of acceptance in some member states is partly due to opposition from industry representatives and the medical profession (Ballance *et al.*, 1992, p. 47). EGA (2007, p. 4) remarks that 'variations in the level of generic penetration is significant, due not only to different historical and economic backgrounds, but also to the public policies employed to promote them'. Apart from budgetary considerations, generics are growing faster than



patented drugs owing to the fact that ‘a large number of top-selling medicines are currently approaching patent expiry in both the USA and Europe’ (EC, 2009, p. 38). This will open up unique opportunities for generic producers.

Table 8 outlines data prepared by EFPIA relating to the EU pharmaceutical industry.

INDUSTRY (EFPIA Total) (1)	1990	2000	2009	2010
Production	63,010	123,793	189,012	190,000 (e)
Exports (2)	23,180	90,935	249,426	270,000 (e)
Imports (2)	16,113	68,841	190,635	200,000 (e)
Trade balance	7,067	22,094	58,791	70,000 (e)
R&D expenditure	7,766	17,849	27,440	27,000 (e)
Employment (units)	500,879	536,733	640,286	640,000 (e)
R&D employment (units)	76,126	88,397	116,682	115,000 (e)
Pharmaceutical market value at ex-factory prices	41,147	86,704	149,193	152,500 (e)
Pharmaceutical market value at retail prices	64,626	140,684	217,293	222,000 (e)
Payment for pharmaceuticals by statutory health insurance systems (3)	40,807	76,909	121,228	120,000 (e)

Values in € million unless otherwise stated  
(1) Data relate to EU-27, Norway and Switzerland since 2005 (EU-15 before 2005)  
(2) Data relating to total exports and total imports include EU-27 intra-trade (double counting in some cases)  
(3) Since 1998 data relate to ambulatory care only  
Source: EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-27 trade data 1995-2010)

**Table 8: Key Data for EU Pharmaceutical Industry**  
(Reproduced from EFPIA, 2008)

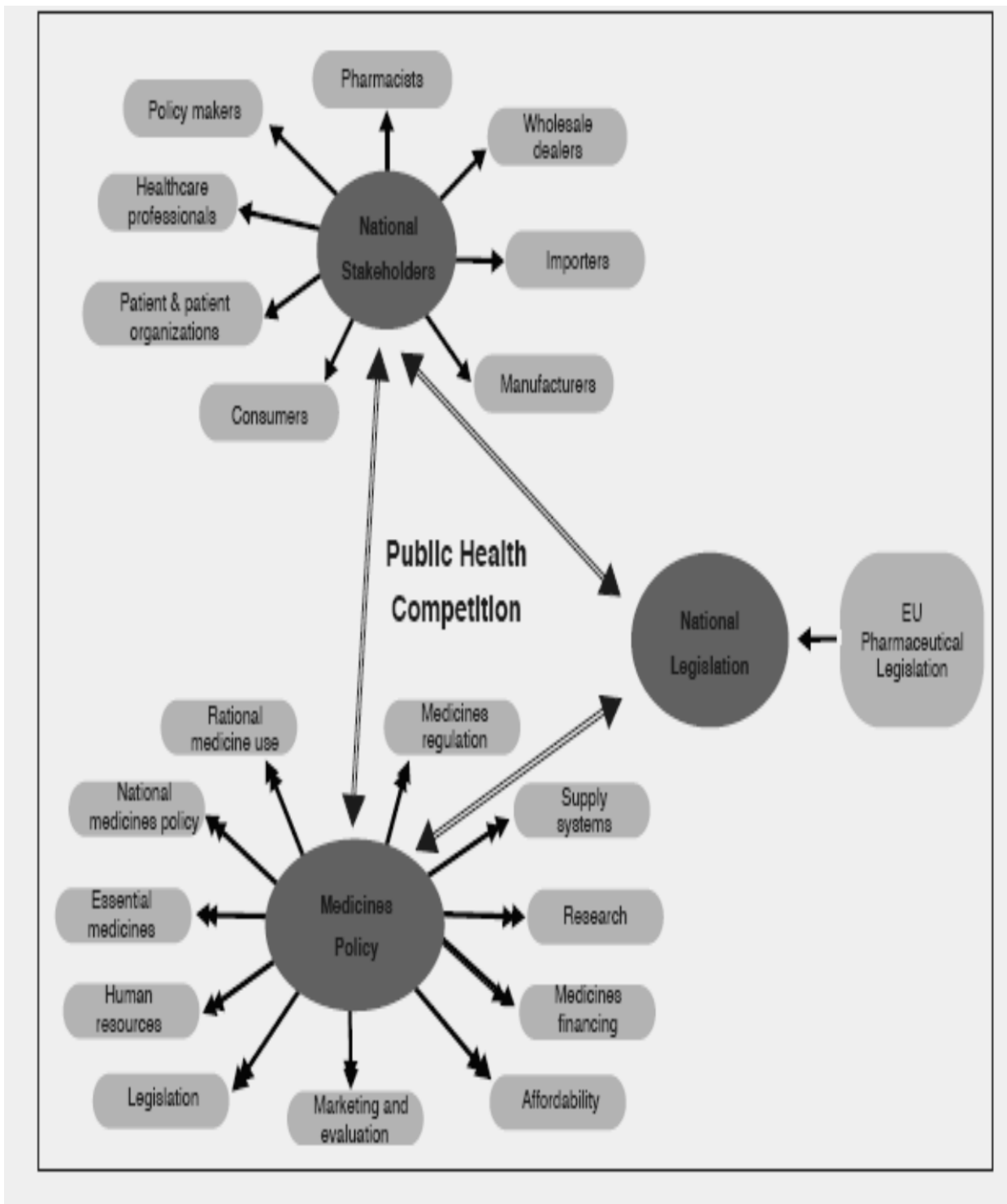
The United States accounts for almost half all health-related patents (pharmaceutical products and medical technologies) in the world. Within the EU, Denmark, the Netherlands, Sweden and Germany are technological leaders in this field (EC, 2011b). The 2008 financial crisis, the subsequent economic recession and the euro crisis have convinced the EU of the need to boost its manufacturing sector, especially through increased R&D and innovation-driven activities. It is encouraging that Europe's biotechnology sector is growing at a significant pace and now accounts for about 20% of new medicines launched on the market (EFPIA, 2009). The Europe 2020 strategy follows on the Lisbon Agenda and is intended to guide Europe's economic recovery while presenting a comprehensive agenda towards becoming a more competitive, sustainable and inclusive economy (EC, 2011b). The Innovation Union Flagship Initiative is at the core of this strategy. It outlines how Europe will tackle the 'innovation emergency' it is facing through a strategic approach that integrates research and innovation instruments and actors.

### **5.3 Societal Structures and Resources**

This research follows R-A theory in perceiving economic activity as being embedded in broader social activities and assigns importance to the nature of societal resources and structures as well as the quality of public policymaking of the open system. The overall goals of public policy in the sphere of medicines are availability, affordability and rational use. If drugs were ordinary consumer goods, 'the high level of legal regulation...would hardly be justified' (Zammit, 2010, p. 22).

Extensive regulation has significantly influenced the behaviour of pharmaceutical enterprises (Boldrin & Levine, 2007). The European Community plays an active role by legislating measures which cannot be taken by individual states. EU regulation seeks to support public health, the free movement of goods and people, compliance with legal requirements and the concepts of harmfulness and therapeutic efficacy. Unless a medicinal product is authorised, it cannot be made available to patients (Vella Bonanno & Flores, 2011, p. 346). Medicines in certain categories are authorised through a single marketing authorisation that is valid in all EU and European Economic Area countries. At the national level, pharmaceutical regulation has various components covering R&D, authorisation, production, distribution and the use of medicinal products (figure 20). Local authorities regulate within the public interest to

stimulate innovation, encourage a competitive market and protect the environment (WHO, 2011).

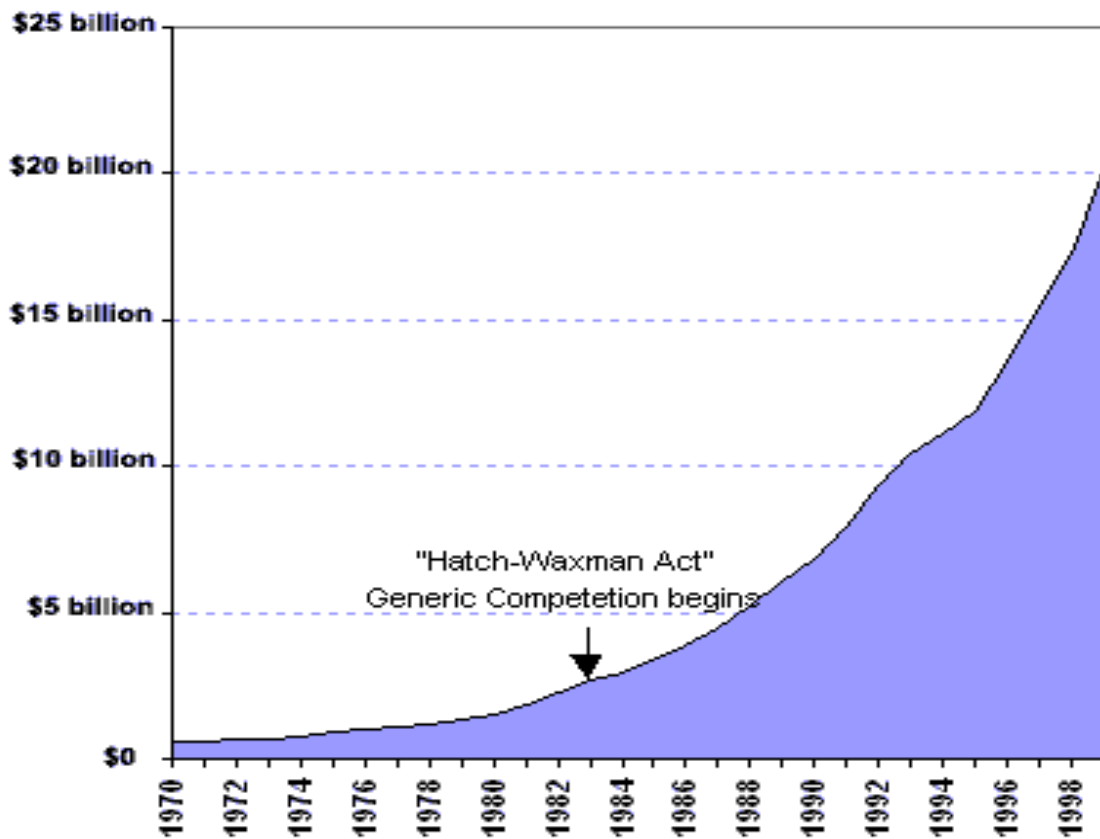


**Figure 20: Framework for Medicines Regulation within the EU**  
 (Reproduced from Vella Bonanno and Flores, 2011)

### 5.3.1 The Bolar provision

In the United States, up to 1984, experimenting on a patented pharmaceutical prior to the expiration of the patent was considered an infringement (L'Ecluse *et al.*, 2005). That year, in the *Roche v Bolar case*, the New York district court found that Bolar had not breached patent rights because of the 'de minimis' and experimental nature of its use of Roche's flurazepam HCl. This decision was subsequently reversed by the Court of Appeals. This induced the US Congress to legislate the Hatch–Waxman Act, which permits the copy (or import), use or sale offer of a patented invention within the United States, provided that this is solely 'for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products' (L'Ecluse *et al.*, 2005:113). This exemption is technically referred to as the § 271(e)(1) or the Hatch–Waxman exemption (In patent law, it is generally referred to as the 'research exemption' or 'safe harbour exemption'). The US Congress also expedited market entry by establishing the Abbreviated New Drug Application process. Generic producers were allowed to use research material already submitted to the Foods and Drugs Agency (FDA) by the manufacturer of the originator product, provided they prove bio-equivalency and the generic drug will be used for the same purpose and in the same conditions and dosage as the original patented product. In compensation, prescription drugs were granted a five-year patent term extension (SPC).

Initially, it was feared that such an exemption would lead to a drop in R&D, but results have shown otherwise. Today, even though the generic industry has over 60% (in volume) of the market, the R&D expenditure financed by pharmaceutical enterprises has been rising significantly since the 1990s (Figure 21).



**Figure 21: US R&D Expenditures Financed by Firms (1970-2000)**  
 (Reproduced from EGA, 2008)

The Hatch–Waxman exemption allowed the United States to make significant progress in the development and manufacturing of generic drugs. The EU lagged behind in this area hindered by a heavy public policymaking process, which sought to bring together too many stakeholders with conflicting interests. It was only in 1996, that the European Parliament passed a resolution on the pharmaceutical industry meant to give the production of generics a boost. This resolution was rejected by many EU member states which held that ‘such an exemption would not comply with Article 30 of the WTO’s TRIPS’ (Cassar, 2006, p. 38). The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement seeks to harmonise international rules and covers a broad range of intellectual assets, including copyright, trademarks, industrial designs and patents. The WTO (then known as GATT) members agreed that, as of 1 January 1995, they will offer a twenty-year protection period for medicine patents registered from then onwards. In exchange, the agreement affirmed the right of a country to protect its public health by ensuring ‘access to “affordable” pharmaceuticals, and to have patent rights removed in cases of “epidemic” and emergency proportions”

(Quirke, 2005, p. 69). TRIPS also provides for special transitional arrangements for least developed countries to implement new intellectual property legislation by 2016. Davies (2010, p. 165) argues that ‘The real impact of TRIPS was not the strict conditions under which TRIPS could permit generic production but that TRIPS made it prohibitively expensive for a developing country to advance its own pharmaceutical industry, because of the cost associated with the licensing system’.

In 2000, a report commissioned by the Enterprise Directorate-General of the EC entitled ‘Global Competitiveness in Pharmaceuticals - a European Perspective’ confirmed the EU’s concern over the competitiveness of the European pharmaceutical industry. The report notes that ‘the 1990s have shown an acceleration of the competitiveness of the US pharmaceutical industry as a whole in the innovation-intensive segment of the industry’ and that ‘[t]he competitive advantage of the US companies in innovation relies both on higher internal capabilities and on a higher reliance on collaboration’ (Gambardella *et al.*, 2000, pp. 83–84). The Report finds that ‘Europe as a whole is lagging behind in its ability to generate, organise, and sustain innovation processes that are increasingly expensive and organisationally complex’. In 2000, the WTO confirmed that the Bolar provision was in line with TRIPS (ruling in favour of Canada vs. EU). This ruling came at a time when a number of central and east European countries were negotiating accession into the EU membership. Many of these countries had a flourishing generics industry as they practically had no track record in intellectual property law prior to the early 1990s. ‘Although the EU-enlargement offers greater market opportunities, the implementation of harmonised intellectual property and regulatory provisions has raised particular concerns in the pharmaceutical industry. In the CEE states which have a flourishing generic industry, IP protection for pharmaceuticals has traditionally been relatively poor’ (von Uexküll, 2006). As explained, the Accession Treaty requires that new member states transpose the ‘*acquis communautaire*’ (EU legislation) into national legislation. After protracted negotiations between the Central East European (CEE) states and the EU, a compromise was reached which necessitated a comprehensive reform of the EU’s pharmaceutical legislative framework (von Uexküll, 2006).

These amendments included new rules on data exclusivity and the introduction of the Bolar provision (CMS, 2011). Under the EU law, the US Hatch–Waxman exemption is referred to as the Bolar (or Roche-Bolar) exemption, and was put into effect in 2005. In compensation,

patented medicines started to benefit from an eight-year period data exclusivity regime and an additional two years of marketing protection, which effectively extended the overall gestation period before generic manufacturers can register their products (EGA, 2008).

Other important implications of the legal changes are as follows:

- allowing the marketing of generics where originator pharmaceuticals have been withdrawn for commercial reasons
- a more efficient system for the registration of generic medicines (especially through the introduction of the European reference product and single market authorisation)
- greater harmony between newly approved generic medicines and older approved originator products
- clearer scientific and legal definitions of generic and bio similar medicines

The revised regulatory framework is meant to strengthen European competitiveness through ‘a proper balancing of interests’ (L’Ecluse *et al.*, 2005, p. 113). Cassar (2006, p. 74) remarks ‘[u]nfortunately the wording used in the Directive means that some ambiguity remains in terms of the extent and type of such development work’. Because of this, EU member states (through their national legislation or the decisions of their national courts) have different interpretations of the Bolar provision, with some adopting a much broader approach (Lovells & Whiting, 2011). EGA (2007, p. 7) regrets this lack of harmonisation and concludes that ‘the EU does not as yet constitute a safe harbour for developing generic and biosimilar medicinal products’.

#### **5.4 Other Societal Institutions**

The transposition of the EU’s directives relevant to the pharmaceutical industry into local legislation led to the Medicines Act (2003). This Act includes provisions relating to ‘good manufacturing practice, importation and parallel importation, marketing authorisations, packaging and labelling, wholesale distribution, reimbursement and selection of medicines, clinical trials, pharmacovigilance and advertising’ (Bugeja, 2008, p. 34). The Manufacture of Medicinal Products for Human Use Regulation (Art. 458.36) of the Medicines Act stipulates that, to be manufactured in Malta, a medicinal product needs to be covered by a manufacturing licence (Good Manufacturing Practice), ‘even though the medicinal /

pharmaceutical is manufactured for export-purposes only' (Cassar, 2006, p. 89). GMP certification ensures 'that the production of medicinal products is carried out at correct potency levels recommended for use in safe doses or to the correct category of patient' (Zammit, 2010, p. 23). The EU's GMP certificate assesses both process and product. 'Such activities and certification serve to confirm the quality of the medical sector in Malta and reinforces the image of the country on international markets' (Galea, 2012).

In 2008, Malta acted, for the first time, as a Reference Member State. In cases where an authorisation for a medicinal product does not yet exist in any of the EU member states, identical dossiers are submitted to all member states, for which a marketing authorisation is being sought. The reference member state prepares the draft assessment documents, which once approved, leads to authorisation in all the member states where the dossier is submitted. In 2009, Malta also became involved as a rapporteur for centralised products (Vella Bonnano & Flores, 2011). The Medicines Act (2003) delineates the role and responsibilities of the Licensing Authority, the Medicines Authority and the Medicines Review Board. The Licensing Authority (or the 'Superintendent of Public Health') has the ultimate responsibility of setting standards, taking the final decision on marketing authorisations for medicinal products and licensing manufacturers and wholesale dealers. The Medicines Authority assesses medicines, issues marketing authorisation certificates and acts as the enforcement agency in the field. Its services include conducting inspections of manufacturing plants and laboratories in accordance with EU principles and guidelines for GMP. The Authority's GMP audits are recognised throughout the EU, and it has built a reputation for efficient and timely services. 'The Medicines Authority is committed to support innovation and competitiveness through effective, efficient, proportionate and consistent regulation and provision of scientific and regulatory advice' (Vella Bonnano & Flores, 2011, p. 353). The Medicines Authority has helped local pharmaceutical companies to develop their quality/GMP perspective (Vella, 2011).

The Authority involves the private sector in consultation processes relating to the introduction of EU legislation. The Medicines Review Board is responsible for hearing all appeals against recommendations made by the Medicines Authority. In such cases, the Licensing Authority has the final decision after giving due consideration to the opinion put forward by the Review Board. In 2010, the government announced its plans through a draft



bill, that is, to incorporate the Medicines Authority into a Medicines Institute as one entity within the Malta Competition and Consumer Affairs Authority. This proposal was criticised by the Pharmaceutical Manufacturers Business Section of the local Chamber of Commerce, Enterprise and Industry, which expressed concern that the move would not be positively received by the European Medicines Agencies and the US Food and Drug Administration. ME too played an important role in the growth of the local pharmaceutical industry. During the accession negotiations with the EU, ME realised that the Bolar exemption and lack of locally registered medicinal patents could help attract foreign producers of generics to branch their operations to Malta. At the time, the Industrial Development Act (1988) was being amended to make its compliant with EU State Aid regulations. The Business Promotion Act (2001) identified pharmaceuticals as a priority sector eligible for an extensive incentive package which included various tax incentives, the provision of finance at special rates for the purchase of equipment and/or the construction of custom-built factories.

Other critical institutional developments took place in local education. The Maltese education system is slowly adapting to the needs of this growing industry and providing highly skilled employees (Kelleher, 2006). Malta enjoys a reputation for good standards of education. Over 10,000 students attend the local university, whose history goes back over four hundred years. Presently, the University has some 450 pharmacy and chemistry undergraduates. To meet industry's needs, the curriculum is updated on a regular basis. To meet a gap in the availability of the necessary expertise, some years ago, the University introduced a postgraduate diploma for Qualified Persons (warranted signatories who take responsibility for the release of medicines from the factory). Vella (2011) points out that '[t]he university courses offered here expose our graduates increasingly to both the practical and the academic side of the subject'. In 2004, MCAST, in collaboration with industry and the Malta Laboratories Association, introduced a Higher National Diploma (HND) course for laboratory technicians. The ETC, in co-ordination with ME, also seeks to ensure the availability of the required skills. ETC runs day and evening courses for assistant laboratory technicians and a course for chemical operators, specifically targeting unemployed youths (Galea & Mckenna, 2004).

## 5.5 Public Policy

The EC (2009) pharmaceutical sector report identifies three areas of public policy which are of particular importance to the industry:

- a) patents
- b) marketing authorisations
- c) pricing and 'reimbursement' of products

### 5.5.1 Patents

R-A theory considers the patent system to be a key institution that promotes social trust and facilitates economic growth by fostering efficiency and/or effectiveness of innovation, as well as a key societal resource which protects the investment made by firms. Robust intellectual property protection is the cornerstone of innovation in the pharmaceutical industry (EFPIA, 2008). Patent systems were designed to encourage and reward innovation (Wildman Palmer & Soames, 2009). It is widely acknowledged that patents are a fundamental incentive to innovative activities in pharmaceuticals and biotechnology (Gambardella *et al.*, 2000). However, it is only since the 1960s that patents assumed critical importance for pharmaceuticals (Quirke, 2005). A patent is a legal title protecting an invention, which can be a product or a process, granting its holder the right to prevent third parties from making, using, offering the sale of, selling or importing the product without the patent holder's prior consent (WTO, 2012). An EC (2009) sector report on pharmaceuticals finds that a single product may have a number of patents. There is also a degree of competition between originator medicines for the same therapeutic use. The information contained in the patent application, in return for the protection extended, is published and becomes public knowledge. This allows third parties (including competitors) to seek to improve the originally patented product and obtain a patent on the improvement.

Patent rights are not designed to fence off the holder from competition. 'The patent system is thus designed to foster innovation, not only by the patent owner, but also by competitors' (EC, 2009, p. 169). Since the 1990s, there has been a trend towards increased protection for pharmaceuticals (EGA, 2007) as shown in Figure 22:

<i>Pharmaceutical Properties Eligible for Patenting*</i>	
1980s	1990s
<ul style="list-style-type: none"> <li>■ Primary uses</li> <li>■ Processes and intermediates</li> <li>■ Bulk forms</li> <li>■ Simple formulations</li> <li>■ Composition of matter</li> </ul>	<ul style="list-style-type: none"> <li>■ Primary uses</li> <li>■ Processes and Intermediates</li> <li>■ Bulk forms</li> <li>■ Simple formulations</li> <li>■ Composition of matter</li> <li>■ Expansive numbers of uses</li> <li>■ Methods of treatment</li> <li>■ Mechanism of action</li> <li>■ Packaging</li> <li>■ Delivery profiles</li> <li>■ Dosing regimen</li> <li>■ Dosing range</li> <li>■ Dosing route</li> <li>■ Combinations</li> <li>■ Screening methods</li> <li>■ Chemistry methods</li> <li>■ Biological target</li> <li>■ Field of use</li> </ul>

**Figure 22: Increase in Protection for Originator Medicines  
(Reproduced from EGA, 2007)**

Pharmaceutical patent holders practise ‘total product’ or ‘lifecycle maximisation’ strategies by seeking to obtain as many patents as possible during the development and marketing cycle and extend them for new uses of established products. Prior to the European Patent Convention in 1973, applications for patents across Europe had to be separately made in each country (Cassar, 2006, p. 79). Patents in the EU can now be obtained either by filing an application at each national patent office or a single application at the European Patent Office (EPO). The EPO was established in 1977 as an inter-governmental organisation. Although all the EU countries are signatories (Malta joined in March 2007), the EPO is independent of the European Community. A EC (2009, p. 461) pharmaceutical sector inquiry report notes that ‘[a]ll stakeholders expressed strong support for the urgent creation of a single Community patent and a unified and specialised patent litigation system in Europe’. In 2012, the European Council agreed on the unitary patent and the setting up of the European patent court, which will complement the work of the EPO in granting and administering patents.

Once the period of protection expires, no authorisation from the original patent holder is required for anyone to commercially exploit the invention. In the case of pharmaceuticals,

this paves the way for the market entry of generic medicines, which are free (provided that they get marketing authorisation) to enter the market with ‘copied’ versions of the original drug.

#### **5.5.1.1 Supplementary Protection Certificates**

Towards the end of the 1980s, the European pharmaceutical industry argued that the effective protection period for a patented medicine was about ten years, or half of the targeted harmonised period for patents (twenty years). The effective patent protection period is significantly less due to the time ‘lost’ between the discovery and approval of a new drug (Boldrin & Levine, 2007). In 1993, the EU emulated the United States and introduced the Supplementary Protection Certificate (SPC) (Council Regulation (EEC) No. 1768/92). The SPC extends the patent right for a maximum of five years to compensate for the reduced protection period. This results in about fifteen years of market exclusivity for patented pharmaceuticals (EFPIA, 2008). The application for an SPC must be lodged in each EU Member State within six months of the date on which marketing authorisation is granted. This requirement is meant to create legal certainty for potential generic competitors, since it allows them to know expiry period for the protection of the medicinal product.

According to Galea and McKenna (2004, p. 63), ‘[t]here are two reasons of overriding importance for the recent expansion of the generic pharmaceuticals sector in Malta, namely: the inclusion of the Bolar provisions in the country’s patent legislation and the very limited number of patents that have been registered to date in Malta’. As a former British colony, Malta’s commercial law closely follows the UK model, offering extensive protection to patent proprietors. Malta’s intellectual property laws date back to the 1960s, making Malta among the earliest of the EU member states in this regard (Galea & McKenna, 2004). The failure to locally register medicinal patents was the most important differentiating factor in attracting generics producers to Malta. Given the smallness of Malta’s domestic market, historically, the ‘well-heeled brand name manufacturers overlooked our islands and did not register their innovative medicines (nor New Chemical Entities - NCEs) with our patents office’ (Galea & McKenna, 2004, p. 65). Given that patent registration cannot take place retroactively (the novelty criterion allows one year from the date of first filing to protect an innovation), there exists a significant list of internationally patented medicines, medicinal ingredients and production processes, which are not covered by a Malta patent.

Warr (2012) explains that, prior to 1994, intellectual property in Malta was mostly about the registration of trademarks rather than patents. At the time, Malta was participating in the Uruguay Round of negotiations at GATT. The global trade agency in 1995 entered into an agreement with WIPO, as part of its drive on TRIPS. Because of these developments, a separate unit for intellectual property was set up locally within the Ministry of Trade. At the time, Malta was still considered a developing country and was given a five-year derogation to implement the obligations arising out of TRIPS and bring in line intellectual property legislation and policies. ‘Given that there was no harmonised international patent law, the local IP department had been advised to shape the changes in a way which would be most beneficial to the local economy. This is when we realised the potential benefits of introducing the Bolar exemption, and it was subsequently incorporated in the Patents and Designs Act of 2002’ (Warr, 2012). As part of these arrangements Malta also introduced the SPC. Malta does not have any case law to fully perceive the extent of its Bolar provision. ‘This is primarily because there has never been to date a patent trial to fully explore the boundaries set out by our provision’ (Cassar, 2006, p. 73).

It is notable that under Article 10(6), only generic marketing authorisation applicants within the EU are able to benefit from the exemption, so that the same research conducted solely for a marketing authorisation outside the EU would not be covered (Cassar, 2006). The changed operating environment in Malta led to an explosion in locally registered patents. The majority (85%) of all locally registered patents during 2000–2010 were in pharmaceuticals (table below). This growth in the number of registered patents continued until 2007. Malta then acceded to the European Patent Convention and Treaty, and it became possible to cover Malta by applying with the European Patent Office in Munich (Anchor Corporate Services, 2012).

Table 9: Malta Patent Filings (2000-2011)						
	TOTAL	FOREIGN no.	LOCAL no.	% FOREIGN	PHARMA no.	% PHARMA
2000	116	93	23	80	69	59
2001	133	107	26	80	83	62
2002	202	180	22	89	109	54
2003	297	275	22	93	197	66
2004	471	452	19	96	416	88
2005	659	648	11	98	641	97
2006	810	802	8	99	790	98
2007	178	170	8	96	165	93
2008	23	17	6	74	18	78
2009	30	21	9	70	20	67
2010	19	7	12	37	2	11
2011	16	4	8	0	0	0
<b>TOTAL</b>	<b>2,954</b>	<b>2,776</b>	<b>174</b>	<b>94</b>	<b>2,510</b>	<b>85</b>

(Source of Data: National IP Office of Malta, 2012)

Warr (2012), the Director General of the Commerce Department and Comptroller of Industrial Property, explains that local IP legislation does not permit stockpiling. Stock-piling is a practice that generic drug companies undertake, whereby they build up an inventory of patented drugs in the six month period leading to the expiration of the patent so that they are ready to go to market as soon as the patent expires. However, Galea and McKenna (2004, p. 65) note ‘the local Patents Act includes an early working clause but not a stockpiling provision and is, in other words, in line with the WTO judgment’. Cassar (2004, p. 76) concludes that ‘[s]tockpiling is not specifically implanted in Maltese law...if the law does not forbid it, then for all intents and purposes it is there’.

### 5.5.2 Marketing Authorisation

Marketing authorisation (MA) procedures verify if the medicines are safe, effective and of good quality. MAs are issued on the basis of scientific criteria of the medicinal product concerned as well as detailed results of clinical tests and clinical trials. ‘MA procedures are regulated by EU law, set out in Regulation (EEC) 2309/93 and Directive 2001/83/EC (Medicinal Products Directive)’ (Cassar, 2006, p. 20). To obtain an MA, there is a centralised

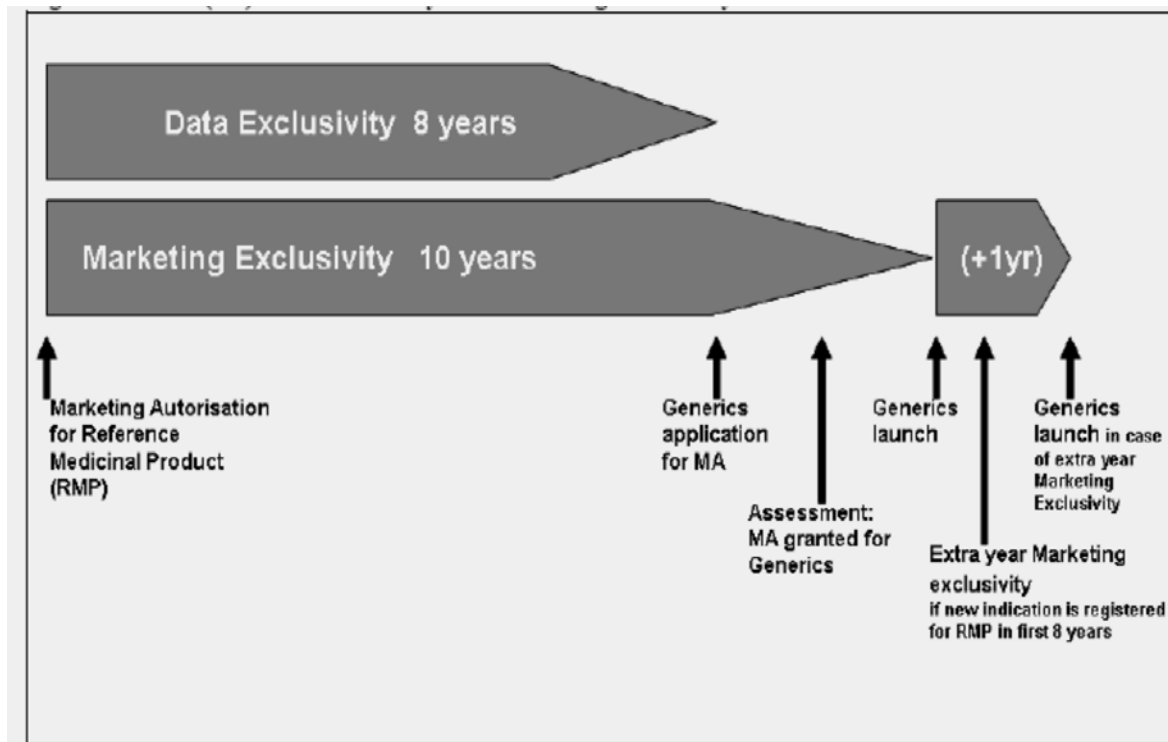
EU application procedure as well as a national one. The centralised procedure (which is also available for generics) involves a single application, evaluation and authorisation. Once an MA is granted under the centralised procedure, the medicinal product may be put on the market in all EU member states. A national application may also be valid in other EU member states through mutual recognition arrangements. The MA has an initial duration of five years and may be renewed on the basis of a re-evaluation of the risk-benefit balance upon application by the holder at least six months before the expiry of the five-year period.

In the case of an MA for a generic product, it is possible for the applicant to file a so-called ‘abridged’ application, whereby the applicant is exempted from the requirement to prove safety and efficacy through preclinical tests and clinical trials. Such abridged applications are only permitted once the originator company’s data relating to the pre-clinical tests and clinical trials is no longer protected.

#### **5.5.2.1 Data exclusivity**

Data exclusivity relates to the regulatory data protection, whereby an innovative pharmaceutical company can keep information submitted confidential to obtain marketing approval for a medicinal product. Data exclusivity is a separate and additional provision to patent protection for the originator medicine. It was introduced in 1987 to compensate for insufficient product patent protection in some countries. Data exclusivity implies that MA bodies are not allowed to process an abridged application to market a generic drug before a certain period of time has elapsed, since the first marketing authorisation for the originator product was granted. Data exclusivity rules were harmonised within data exclusivity periods ranging from six to ten years (von Uexküll, 2012). The EU data exclusivity period was set at eight years (EU Directive 2004/27/EC) and has been effective since 2005. The implication is that generics may not be placed on the market until ten years after the original; this provides a two-year window during which bioequivalence testing may be carried out. A further one year of protection for the originator drug is available if authorisation is obtained for a new therapeutic indication that brings significant clinical benefits in comparison with existing therapies.

This system is commonly referred to as the 8 + 2 (+ 1) formula (Figure 23). Prior to its EU membership, Malta’s legislation provided for a six-year data exclusivity period. In its membership negotiations, Malta requested a fifteen-year derogation, but this was not granted. Malta adopted the EU exclusivity formula with effect from 2006.



**Figure 23: EU’s Data and Marketing Exclusivity Formula**  
(Reproduced from European Commission, 2009)

‘EU accession brought with it what has been called a cumbersome bureaucratic registration process’ (Bugeja, 2008, p. 5). Until 2002, Malta had 7020 products placed on the market and it was sufficient for an importer to present a CPP issued by the WHO. The EU does not recognise the CPP and stipulates that all medicines sold domestically must have a local marketing authorisation. Malta obtained a derogation (up to 2006) whereby medicines could be sold through a provisional marketing authorisation issued by the Medicines Authority. However, from 2005, the decentralised procedure (the recognition by national authorities of an assessment performed by another EU member state for medicinal products which have not received a marketing authorisation at the time of application) could also be used to boost the range of medicines locally available (Bugeja, 2008).



Following EU membership, the number of drugs on the Maltese market fell to 1,500 by 2007. In 2006, both Cyprus and Malta put pressure on the EU to amend Directive 2004/27 (which governs the decentralised procedure) to allow public healthcare goods authorised in another EU state to be sold on their markets, also known as the ‘Cyprus Provision’ (Vella Bonnano, 2012). Table 10 presents the number of marketing authorisations for medicinal products locally issued from 2004 to 2007.

Period	Type of authorization or medicinal product list	Number
May 2004	Derogation List / WHO CPP <sup>a</sup>	1823 different active ingredients
		7020 medicinal products
		5162 medicinal products from EU
		3750 medicinal products on the private market
Up to December 2004	PMA <sup>b</sup>	2200 medicinal products
Year 2005	MRP <sup>c</sup>	6% (108 out of 1770 applications)
	DCP <sup>d</sup>	5% (1 out of 22 applications)
January to May 2006	MRP	10% (22 out of 211 applications)
	DCP	5% (7 out of 134 applications)
May 2006	PMA	2230 medicinal products
	MA <sup>e</sup>	570 medicinal products
November 2006	126a list <sup>f</sup>	1299 under process
		1376 medicinal products
Up to March 2007	126a authorisations <sup>g</sup>	776 active ingredients
		7 authorisations
	MA	103 applications under process
		1437 from PMA-MA process
		148 from MRP process
		19 from line extensions (PMA-MA)
		1 national
MRP/DCP	172 under process	
Unlicensed <sup>h</sup>	132 medicinal products	

a. World Health Organisation Certificate of Pharmaceutical Product;  
b. Provisional Marketing Authorisation;  
c. Mutual Recognition Procedure;  
d. Decentralised Procedure;  
e. Marketing Authorisation;  
f. list of medicinal products with no authorisation and therefore medicinal products not marketed in Malta. N.B. Some were being imported directly by the Government Pharmaceutical Services through Article 20 of Medicines Act, 2003;  
g. authorisation through Article 126a of Directive 2001/83 as amended by Directive 2004/27/EC;  
h. authorisation for the use of products which are not registered in Malta in line with DH Circular 270/06 Guidelines for the supply of medicinal products for human use through processes which are not covered by the Medicines Act, 2003 and its subsidiary legislation.

**Table 10: Authorisations issued for Medicinal Products in Malta (2004-2007)**  
**(Reproduced from Bugeja, 2008)**

Galea and Mckenna (2004, p. 67) point out that '[m]arketing authorisation granted by any EU member state serves to ensure ease of penetration into South American and North African markets'. To verify that the pharmaceutical products meet EU standards, many non-European countries (including Malta's neighbours in North Africa) requested a free sales certificate. This certificate was issued by the local Medicines Authority as well. 'Such a certificate usually suffices in having a medicine sold in these countries' (Galea, 2012). A business opportunity arising from Malta's EU membership relates to the issuing of marketing authorisations for English-speaking countries by the local Medicines Authority (Galea, 2012). Given that the Medicines Authority enjoys mutual recognition with most EU countries and handles relatively few applications, a dossier can be registered in Malta rather than in the United Kingdom or the Netherlands perhaps. In these countries, registration can be a relatively lengthy process due to the amount of applications handled.

### **5.5.3 Pricing and Reimbursements**

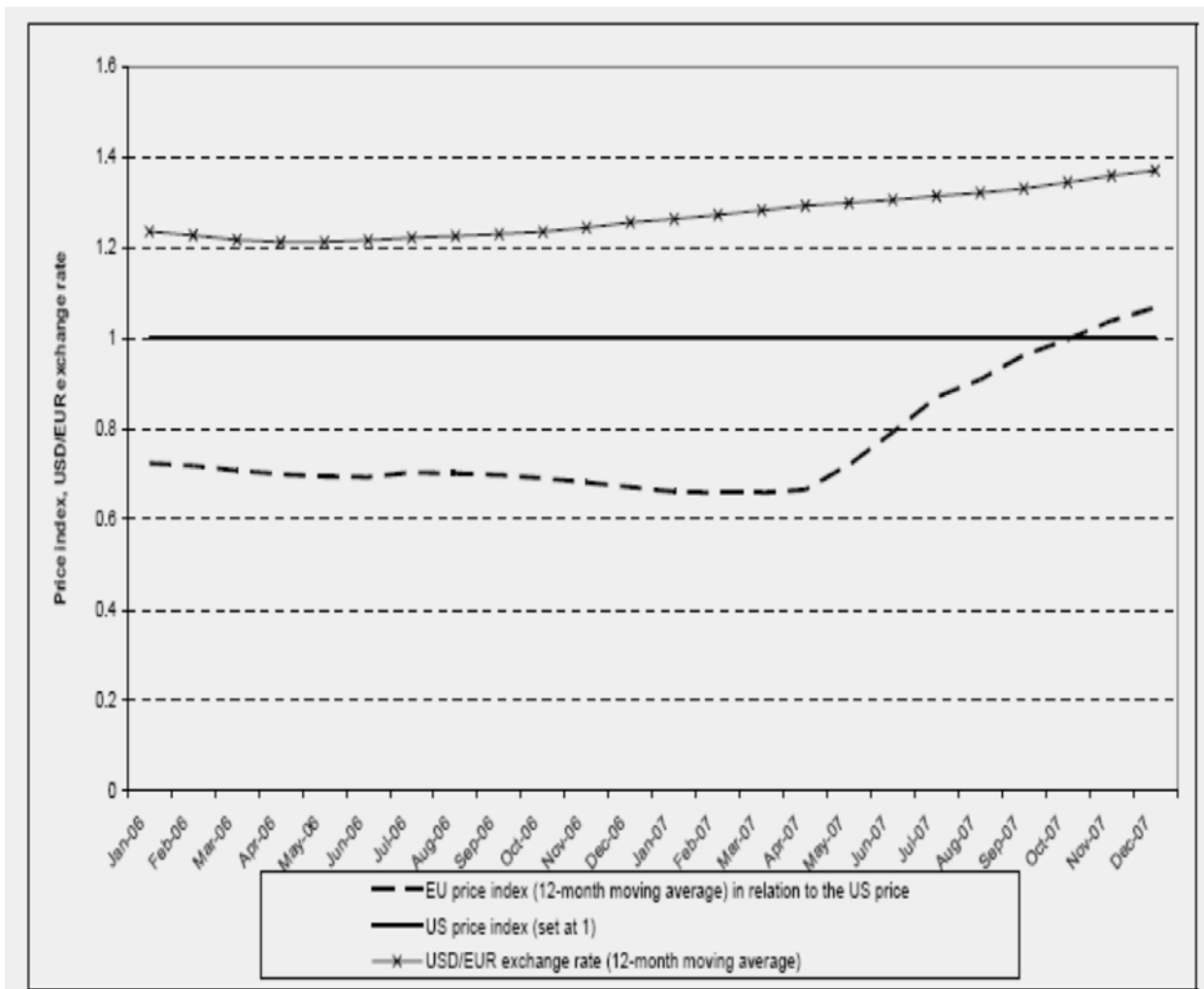
Price controls are the most prevalent form of regulatory intervention on the global pharmaceutical market (Ballance *et al.*, 1992). The cost of patented medicines is a problem for not only governments but also the general public, especially in Third World countries. The demand side of the pharmaceutical sector is unique, as it is characterised by a complex interrelationship between patients, doctors, hospitals, insurance providers and reimbursement systems. Although patients are the ultimate consumers of medicine, they often rely on a doctor's expertise and recommendations. The average annual EU spending on pharmaceutical products is €430 per capita, but 'there exist significant differences between and within countries' (EC, 2009, p. 46).

Each EU member state follows different policies and schemes, adapted to its own economic and health needs. A number of member states apply policies supporting the sale of generic medicines by obliging pharmacists to dispense the cheapest product (EC, 2009). The norm, however, is for pharmacists to dispense medicines prescribed by the doctor, and they have little say in the medicine given to the patient. Because of these factors, and the fact that a large proportion of prescription medicines are provided under public healthcare or insurance schemes, the price sensitivity of medicines is rather limited (EC, 2009). While 'policymakers are generally sympathetic to the industry's arguments that increases in prices and profits are

essential if research to develop cures for major diseases is to continue' (Boldrin & Levine, 2007, p. 139), governments are under pressure to contain their expenditure on health.

Once the protection period is over, 'generic' drugs enter the market and the price of a 'prescription' drug significantly falls. Generic medicines are cheaper because they have a lower cost-base arising from lower investments in product development. Generics help cut the costs of public healthcare, and their growing popularity has generated increased competition and lower prices (Hirschler, 2005; Gambardella *et al.*, 2000; EC, 2009). In OECD countries, spending on pharmaceuticals has been increasing faster than total healthcare spending, with pharmaceutical spending in 2006 accounting for 17% of the health budget in the OECD. Generics have come to play a key role in ensuring the affordability and sustainability of healthcare systems throughout Europe (EGA, 2007, p. 2). Many governments resort to some sort of reference pricing for medicines. EGA (2007) claims that reference pricing creates artificial and inappropriate prices for medicines, leading to inefficiencies in the supply chain. Linking the price of generic medicines to a constant percentage of the originator product (e.g. 25–50% lower than the originator) is deemed as being anti-competitive and endangers the security of supply of generics. 'Such linkage enables originators to force generic medicines competitors off the market by constantly lowering prices to the point where generic medicines (forced to sell at a fixed percentage below the originator) can no longer afford to enter onto-or to stay on-the market' (EGA, 2007, p. 6).

The EC (2009, p. 40) sector enquiry finds '[t]he ultimate price level of generic products depends on many factors including among others the degree of competition'. Average ex-factory prices of generics are lower in Europe than in the United States (EGA, 2007). Figure 24 shows that during 2005–2007, the EU ex-factory price index was on average 15% below the US benchmark.



**Figure 24: EU-US Price Comparison of Generics**  
 (Reproduced from EU Commission, 2009)

The impact of EU accession on the prices of medicines in Malta has been quite strong, with many of them increasing ‘drastically as mark-ups for the wholesale dealer and pharmacists were no longer regulated’ (Bugeja, 2008, p. 37). On paper, the EU membership should have facilitated parallel trading and increased competition. Local consumers did not enjoy lower prices from such activities, since generally speaking, any resulting benefits were kept by importers and/or pharmacists (retailers). Wholesale dealers play a dominant role in the Maltese market, and whenever they feel threatened by parallel imports, they stop delivery of other ‘key’ drugs in their product portfolio. A number of wholesale dealers also own pharmacies, and this enforces their hold on the local market. In 2007, the government set up a Medicines Committee to verify the market prices of medicinal products (Farrugia & Savvas, 2009). Reference pricing was introduced, whereby local medicinal prices are compared to the

average price prevailing in a basket of countries made up of three categories: high, medium and low priced.

The medical profession in Malta is not required by law to prescribe drugs by their international non-proprietary name (INN). Nevertheless, pharmacists can legally offer generic alternatives to the medicines prescribed, ‘unless the doctor specifically indicates on the prescription that no substitution is allowed’ (Azzopardi & Zarb Adami 2012, p. 4). Farrugia and Savvas (2009, p. 34) argue that low generic prices compared to those of originator medicines are unlikely to be sustainable in a small island state such as Malta, unless the market penetration is appreciable: ‘this can only be achieved through strong generic promotion and a campaign to engender positive public/prescriber opinions of generics’.

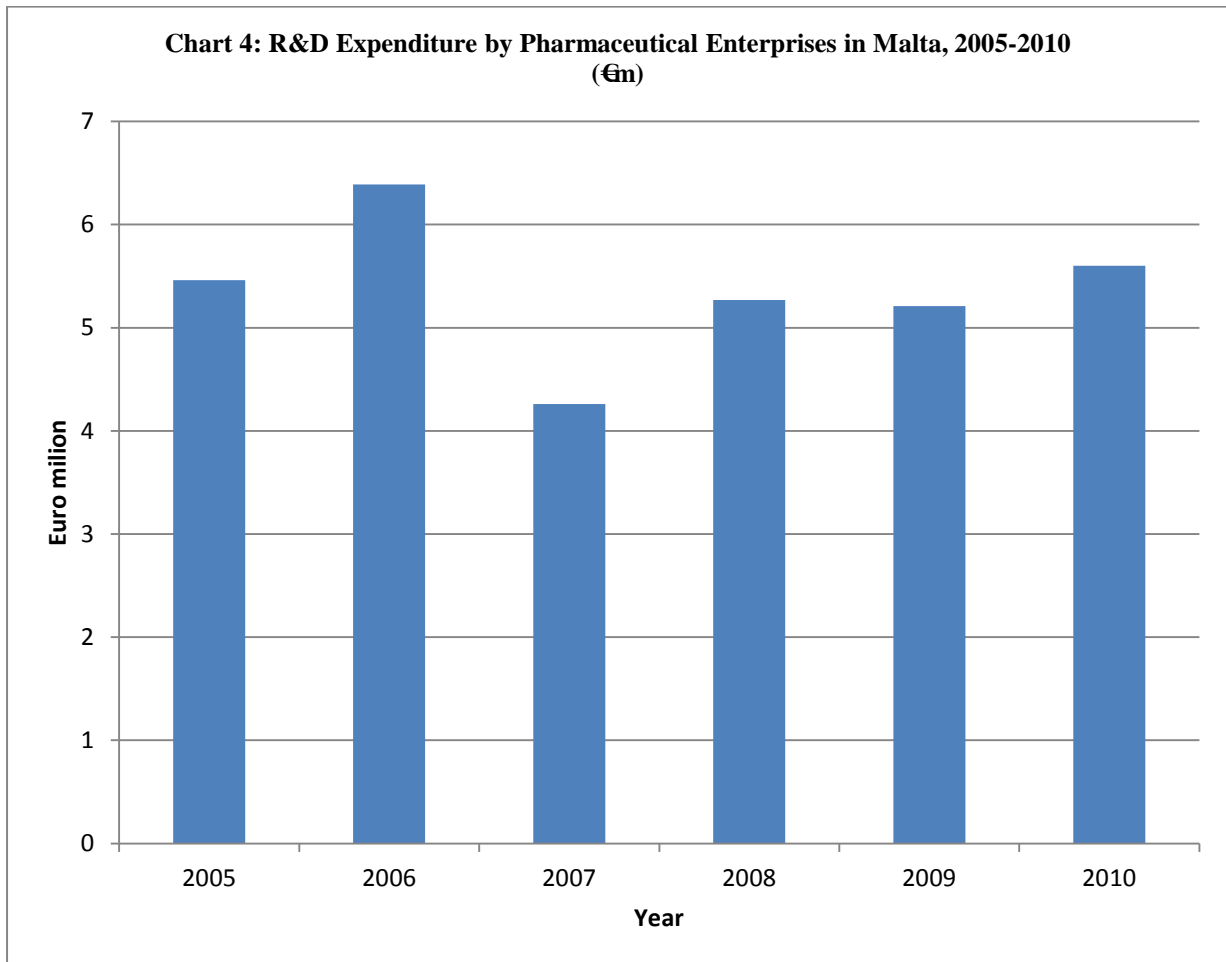
<b>Company Name</b>	<b>Product</b>	<b>Employees</b>
<b>Actavis Ltd.</b>	Generics	559
<b>Arrow Pharm Malta Ltd.</b>	Generics	298
<b>Amino Chemicals Ltd.</b>	Active Pharma Ingredients	53
<b>Siegfried Generics Malta Ltd.</b>	Generics	53
<b>Combino Pharm Ltd.</b>	Generics	41
<b>Medichem Malta Ltd.</b>	Active Pharma Ingredients	30
<b>APL Swift Services(Aurobindo)</b>	Generics	17
<b>Starpharma Ltd.</b>	Generics	12
<b>Institute of Cellular Pharmacology</b>	R&D and plant extracts	11
<b>Solea Pharma Ltd.</b>	Active Pharma Ingredients	10
<b>Pharmadox Healthcare Ltd.</b>	Generics (Repackaging)	10
<b>Pharmacare Premium Ltd.</b>	Generics	9
<b>Alpha Farma Ltd.</b>	Generics (Repackaging)	7

**Table 11: Enterprises in the Maltese Pharmaceutical Sector (Manufacturing)**

(Source: Malta Enterprise, 2012)

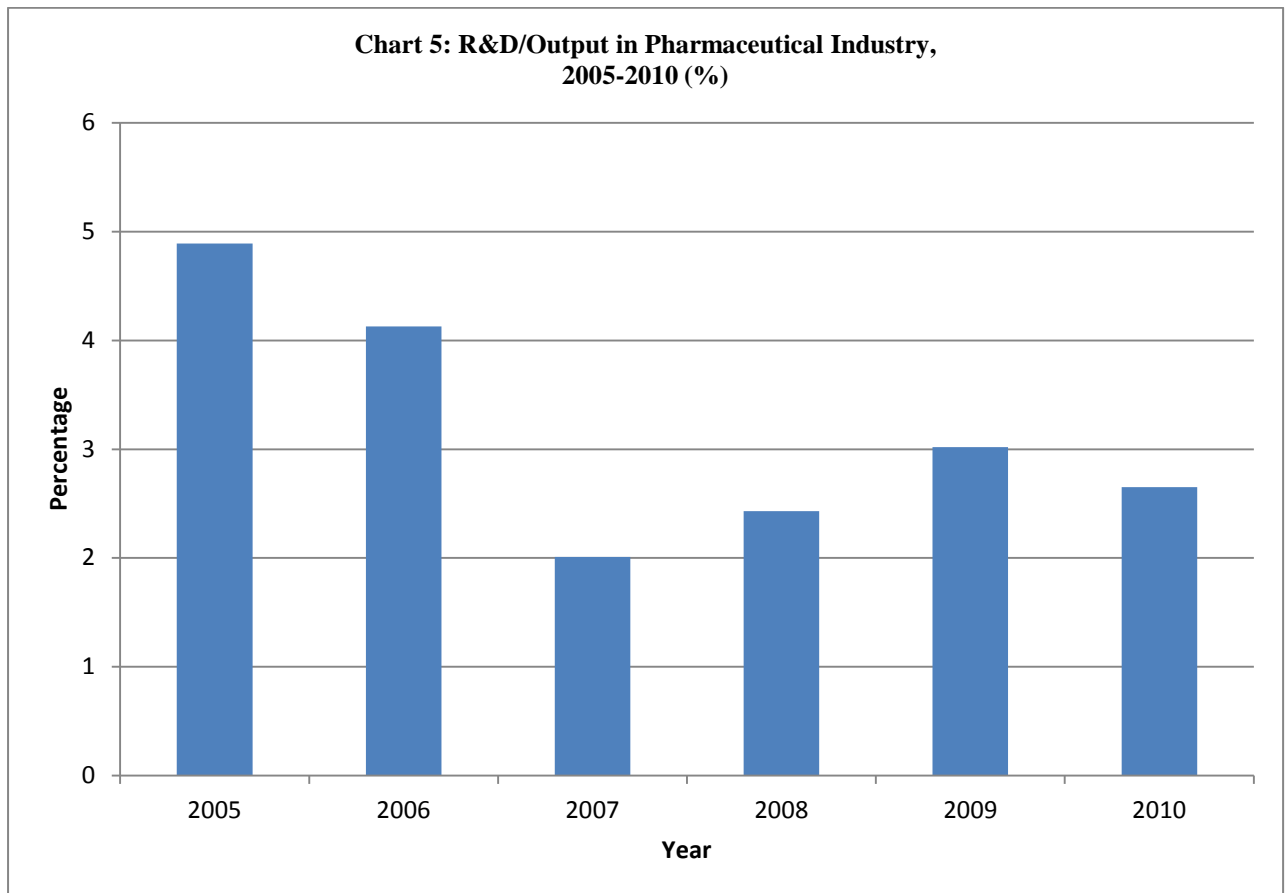
Table 11 lists all the manufacturing enterprises operating in the Maltese pharmaceutical sector. After a period of significant growth upon Malta's EU membership, the number of these manufacturers has not increased. There are also two producers of medical gases and two manufacturers of active pharmaceutical ingredients (APIs) which are GMP licensed. (Since 2013, API producers are obliged to be GMP certified).

Chart 4 below shows expenditure on R&D by the local pharmaceutical sector.



(Source: National Statistics Office, Malta)

Chart 5 relates R&D expenditure to output for 2005–2010.



(Source: National Statistics Office, Malta)

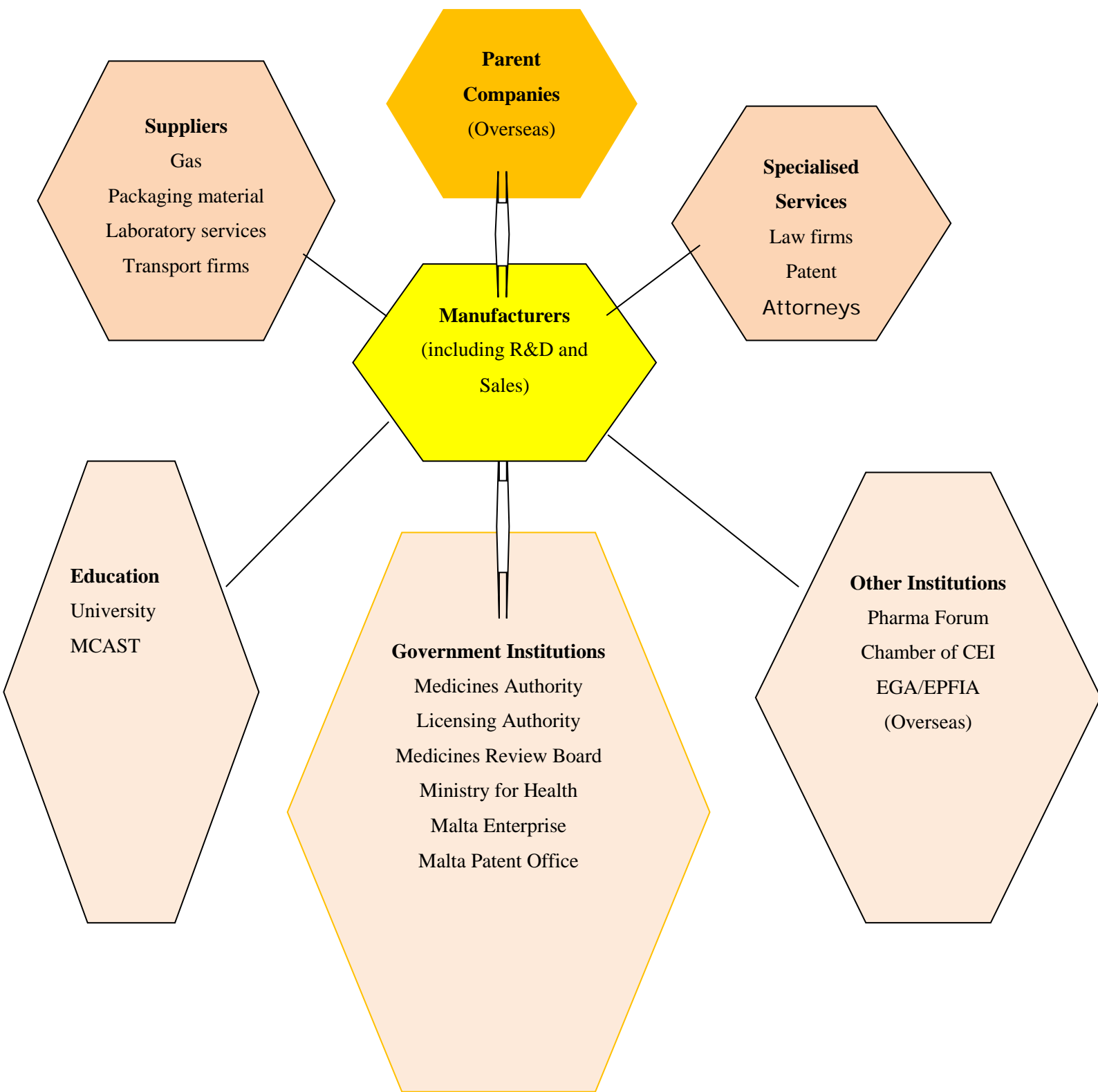
The data show that while the level of R&D in the pharmaceutical sector has been significant (especially when compared to other sectors of the Maltese economy), the amounts being invested relative to output are on the decline. Moreover, in 2013, Actavis gave notice that because of the Group’s global restructuring, it would be closing its R&D unit. This is expected to further reduce the amount of R&D in Malta.

As BEAT Consulting notes with regard to local manufacturing operations, pharmaceutical enterprises also suffer from the same deficiencies of subsidiaries depending on their overseas parent company. These enterprises are essentially ‘production units’ and for them, operational effectiveness and cost control are critical considerations. This, despite the fact that a small number of local pharmaceutical operators have set up sales units responsible for African, Middle Eastern and other markets. The width and depth of the local sector is quite limited, especially when compared to other European pharmaceutical centres. Mackay (2011,

p. 68) points out that '[t]he predominant problem encountered by the local generic drug manufacturers relates to the unavailability of third party storage facilities for storing pharmaceutical waste until this is exported'. Waste resulting from the processing of active pharmaceutical ingredients (APIs) has to be exported and is sent to Switzerland to be treated. This is rather expensive, especially since the route across Italy has to be monitored by satellite. Galea (2012) points out that the provision of good quality water has been a primary problem for the industry in Malta.

Figure 25 shows the present composition of the pharmaceutical sector in Malta:



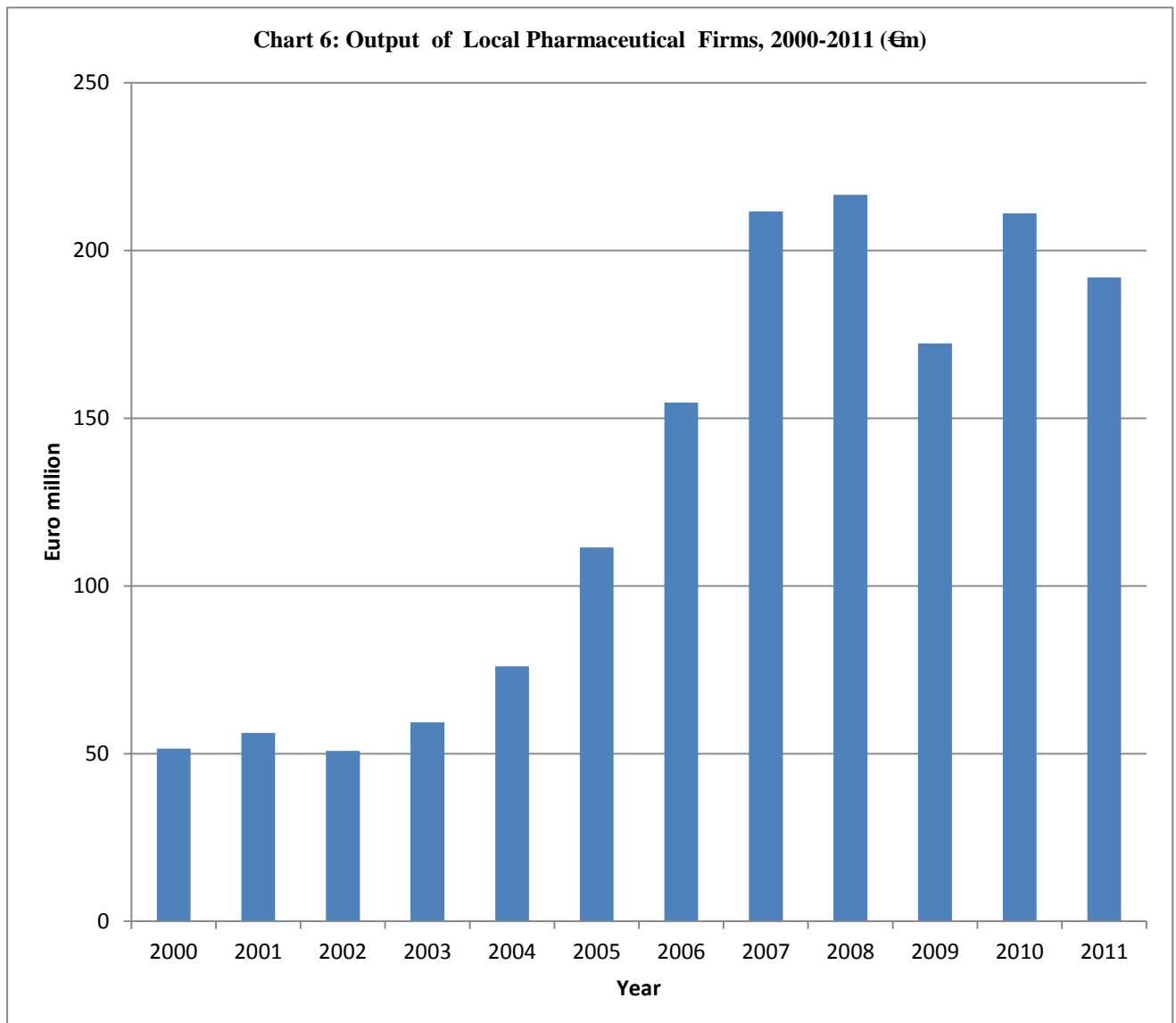


**Figure 25: Composition of the Pharmaceutical Industry in Malta**

## 5.6 Sector Performance

The data presented below was obtained from the NSO, because no sector studies or published data specific to the Maltese pharmaceutical sector are available. The sector's output during 2000–2011 is shown in Chart 6. There is a steady increase in turnover up to 2008, when output peaked at €216.6 m. This represents an increase of 423% over an eight-year period. In 2009, we see a significant dip and since then, the industry has not fully recovered.

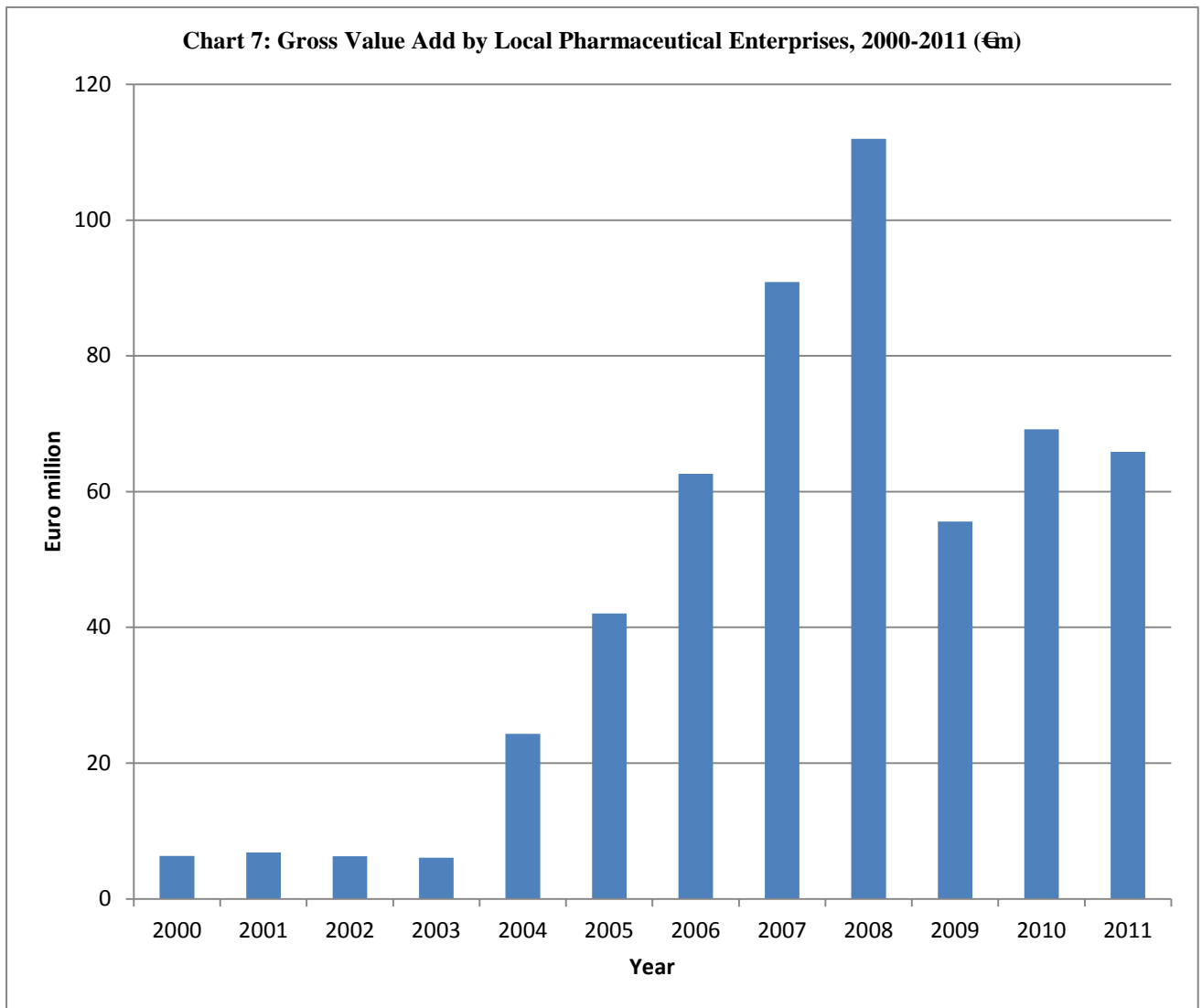
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(Source: National Statistics Office, Malta)

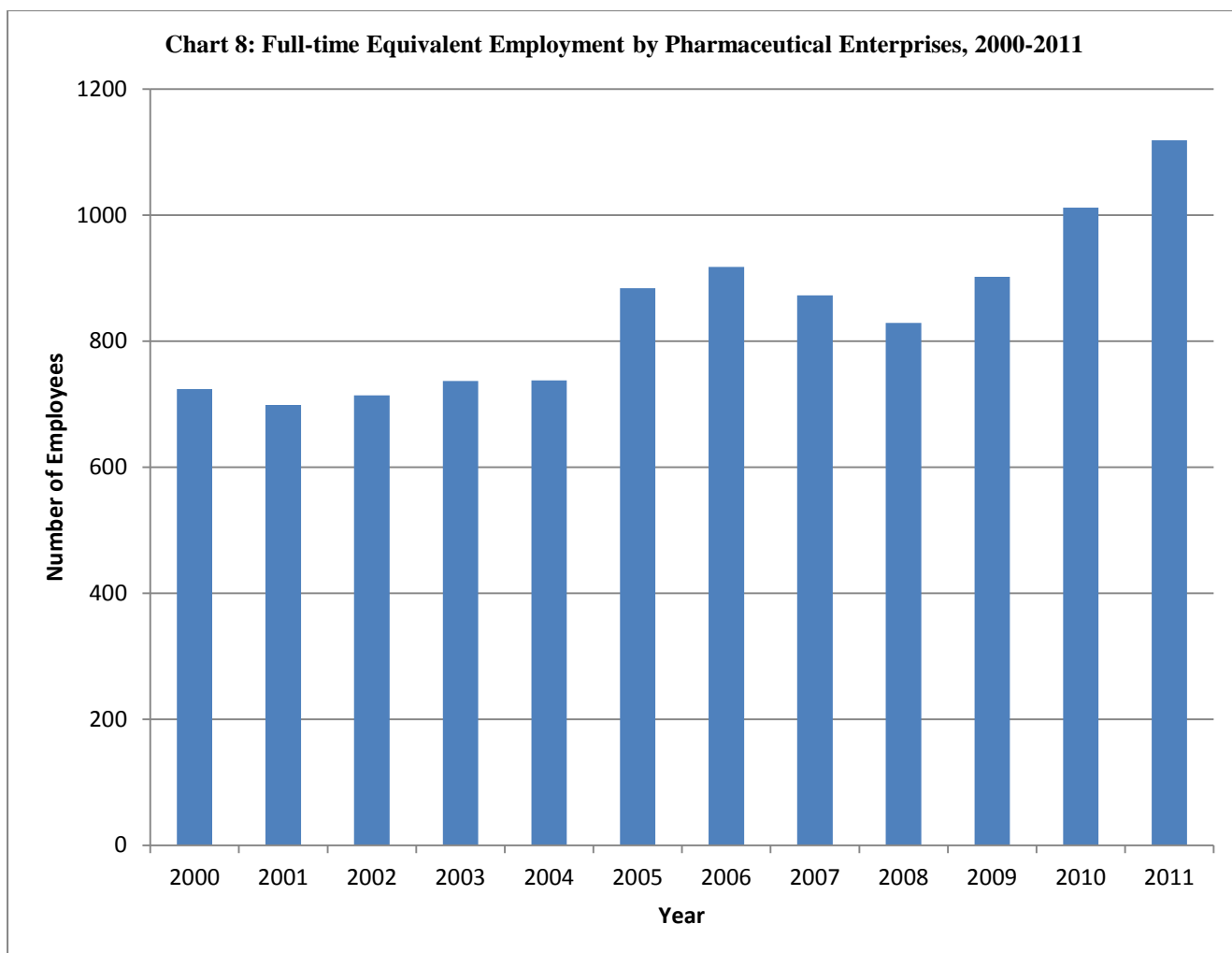
In terms of gross value added (Chart 7), there was a similar steady increase in the 2004–2008 period, which was then followed by a significant drop. The increase from €6,312 (2000) to

€12,002 (2008) represents a remarkable improvement. Subsequently, gross value added also fell to €65,859 (2011). This is partly because of a shift from manufacturing towards partial-manufacturing and repackaging operations.



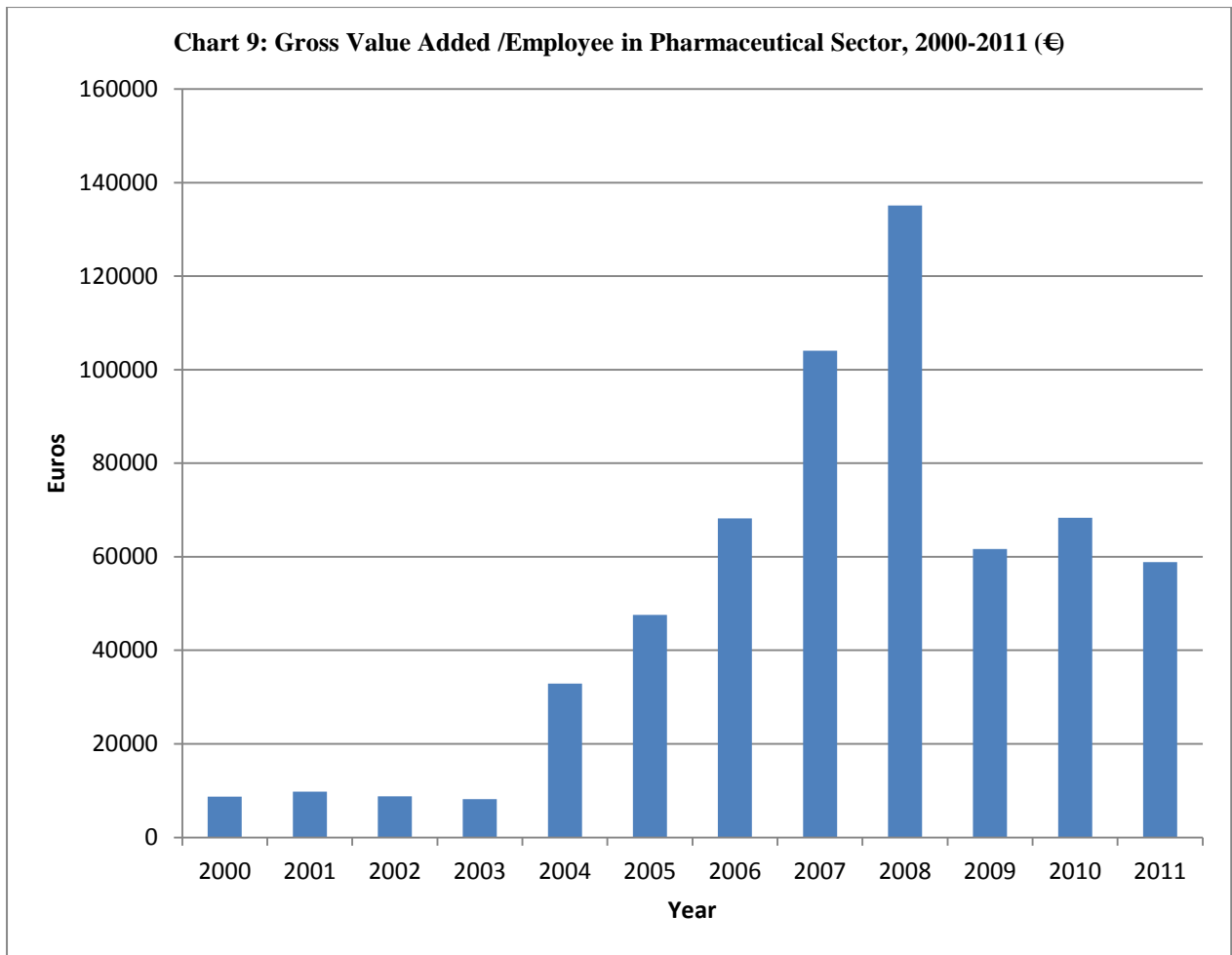
(Source: National Statistics Office, Malta)

Pharmaceuticals are not a labour-intensive industry. This is evident in Chart 8, which shows that while turnover almost quadrupled between 2000 and 2011, the number of employees increased from 724 to just 1019.



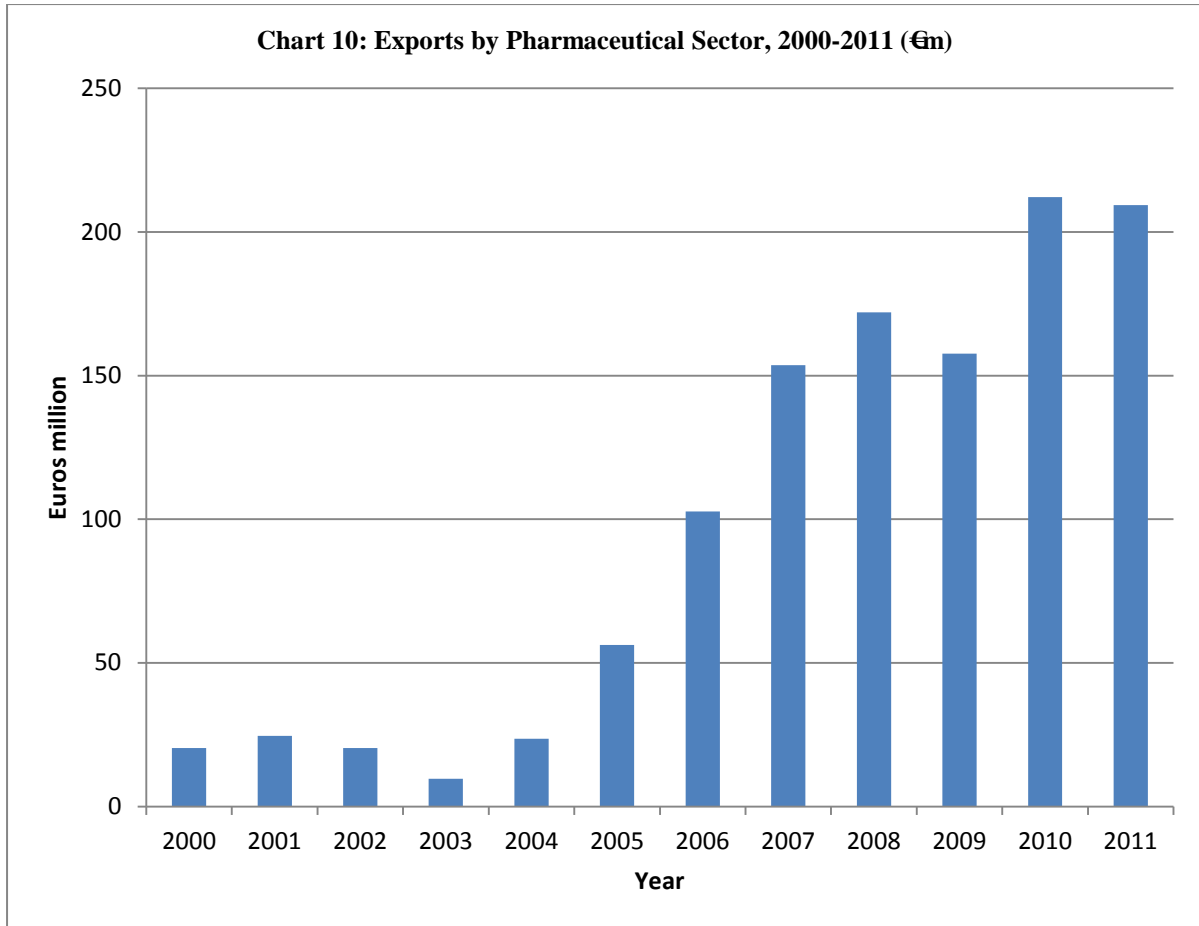
**Source: National Statistics Office (Malta)**

Combining charts 7 and 8, we get the gross value added per employee (Chart 9) for the local pharmaceutical industry. Once again, 2008 is the peak year with gross value per employee reaching a high of €35,105. This was a significant improvement compared to where the industry stood in 2000, when the relative figure was just €8,718. Nevertheless, by 2011, gross value per employee had fallen to €8,864, that is, 56% less compared to 2008.



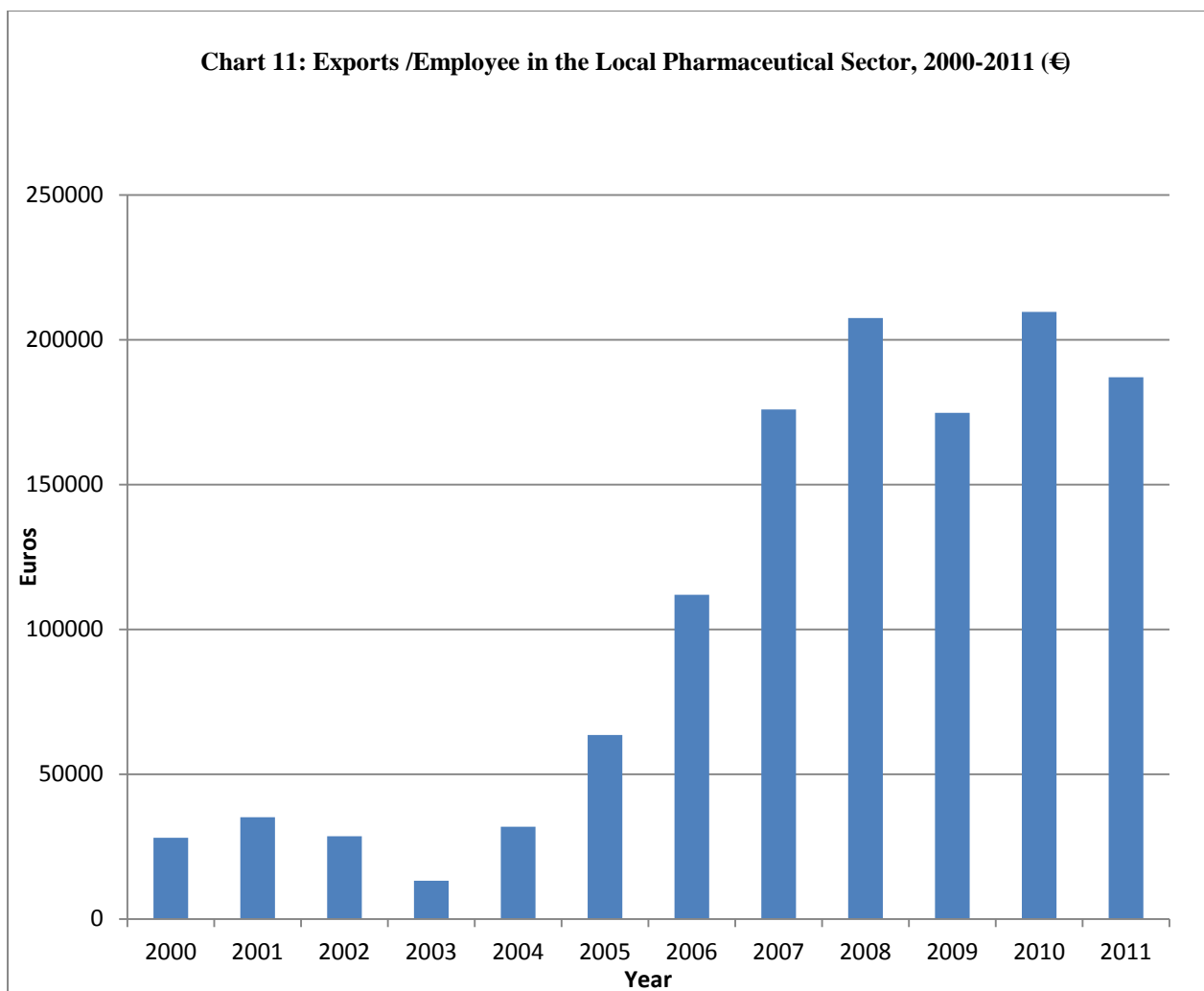
(Source: National Statistics Office, Malta)

Chart 10 shows exports by the local pharmaceutical industry for 2000–2011. In this instance, it appears that there is steady growth with small declines in 2003, 2009, and 2011. Exports peak in 2010 at €12 m, which is an almost tenfold increase over 2000.



(Source: National Statistics Office, Malta)

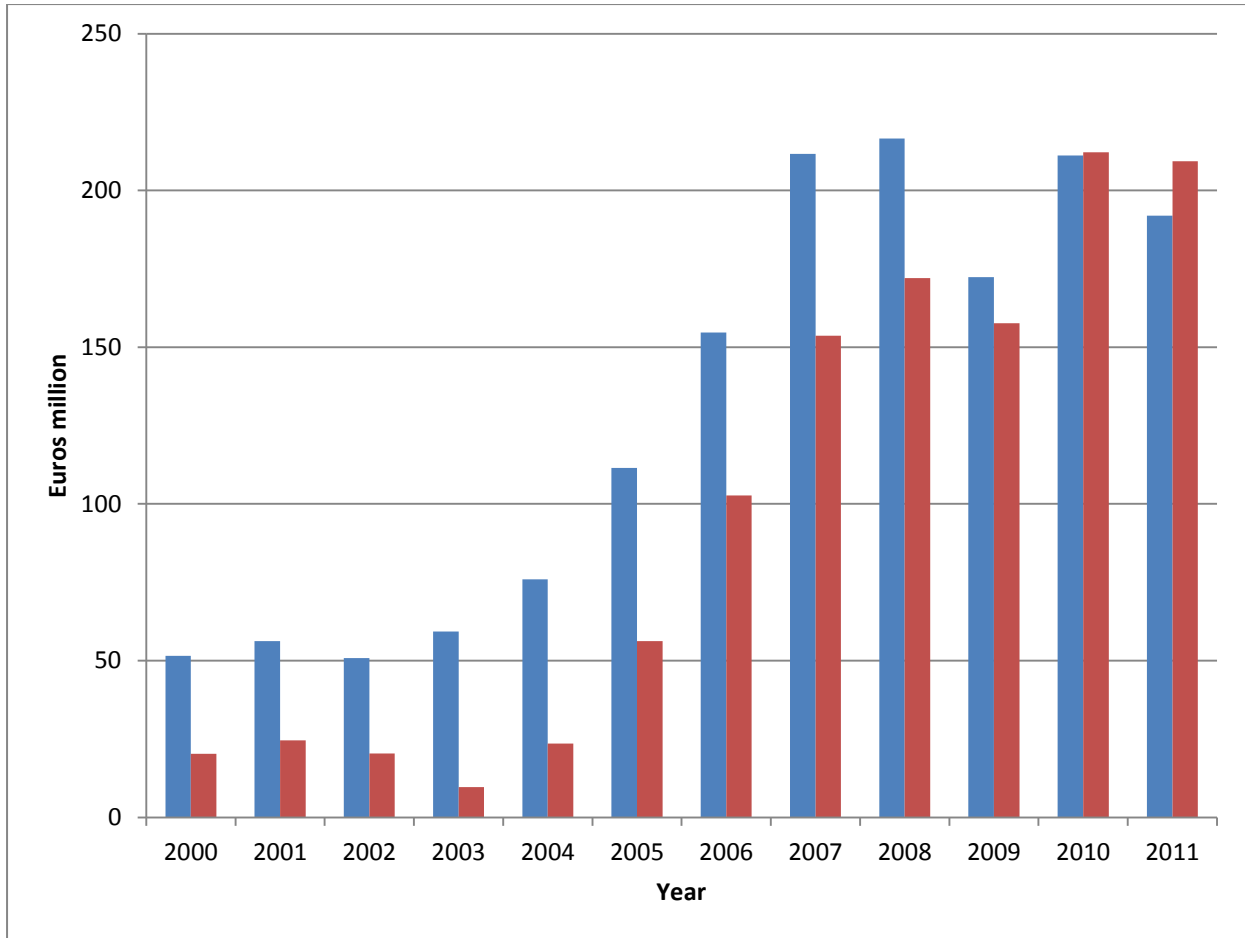
The value of exports per employee (Chart 11) presents a similar picture as in Chart 5, where it peaked in 2010 (€209,677 per employee). This represents a 740% increase over 2000.



(Source: National Statistics Office, Malta)

Chart 12 shows the level of exports compared to output. Interestingly, in 2003, the level of exports fell drastically compared to output. This was probably due to stockpiling as the local pharmaceutical industry prepared itself for Malta's entry in the EU from 2004. Exports have been consistently less than output, except in the last two years.

**Chart 12: Output (B) & Exports(R) by Local Pharmaceutical Sector. 2000-2011. (€m)**



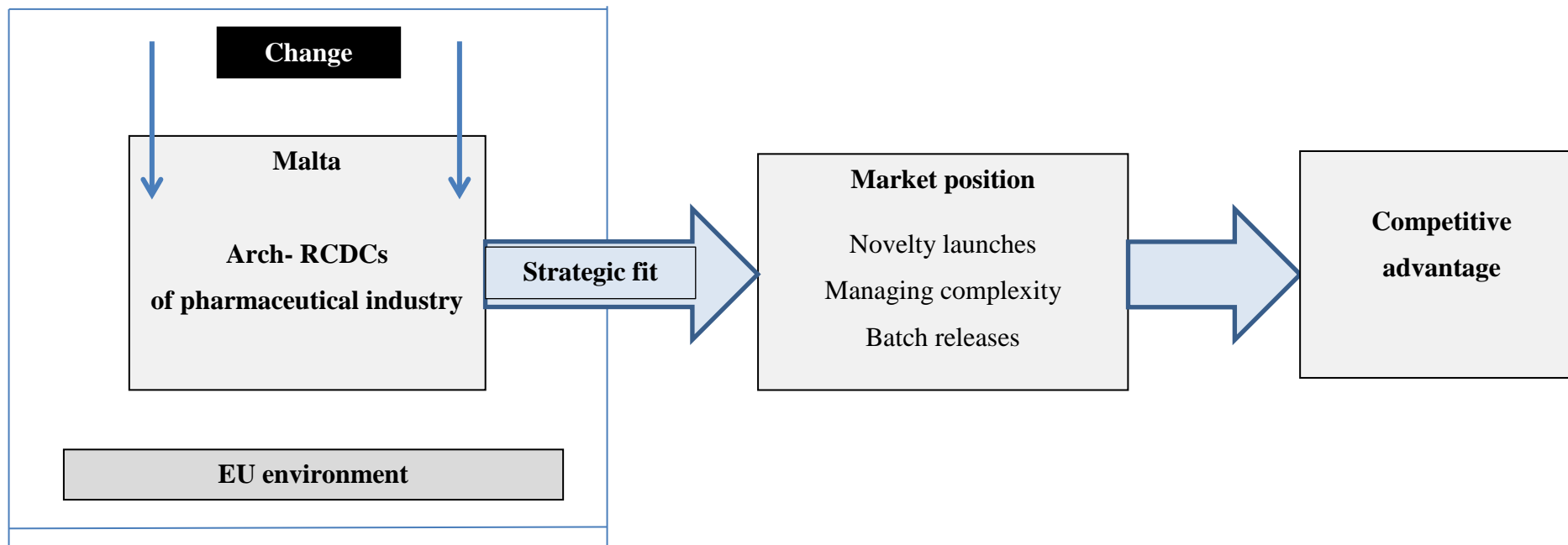
(Source: National Statistics Office, Malta)

## 5.7 The Field Research

The field research followed the theoretical framework presented in Figure 14 to evaluate the relevance of the identified arch-RCDCs in shaping the competitive advantage of the Maltese pharmaceutical industry. Figure 26 illustrates the field findings.



Figure 26: Competitive Advantage of the Maltese Pharmaceutical Industry



The field research finds that, except for one company (ICP), all other local pharmaceutical enterprises produce generics. Nine of these companies are subsidiaries of international companies, while four others (including ICP) are Maltese owned. The 'indigenous' companies have close working relationships, or some form of strategic alliance, with foreign-owned firms either operating in Malta or overseas. While opening doors to a huge single market, EU membership brings with it additional operating costs for local pharmaceutical enterprises. These costs arise mainly from legal obligations related to the environment (especially waste management) as well as health and safety. Mangion (Medichem) notes that '[E]U membership brings with it additional obligations and costs, especially with regards to the protection of the environment'. These costs tend to have a bigger impact on smaller enterprises.

Although practically every local pharmaceutical enterprise seems to have its own particular operating rationale, local enterprises can be grouped in the following categories:

1. API production

Malta lacks any chemical synthesis or fermentation process. Most generic APIs are sourced in Asia in semi-finished form and are then 'polished' in Malta and re-exported. Exports are normally intended for both 'regulated' markets (such as the United States, Canada and Japan) as well as non-regulated ones (such as Latin America and Africa).

2. Solid dosage forms

Generally, these are produced from generic APIs imported either from the EU or Asia. These forms (normally tablets) are exported either in bulk or packaged, using own brands and those of third parties (under some form of contracting arrangements). These third parties are mostly generics companies, but at times, consist of originator firms.

3. Packaging operations

Generics are imported in bulk from Asia to be packaged in primary and/or secondary packaging. These drugs are analytically tested before a batch is released. A marketing authorisation has to be obtained before these medicines are exported whether to the EU or non-EU markets. The importation of generics is at most times conducted on a 'parallel trade'

basis (mostly from former East European countries) with bulk or primary packaged medicines being repacked into 'customised' secondary packaging, using own or third party brands. This last type of operation tends to cater to expensive, high-end drugs intended for North African and the Middle Eastern markets.

#### 4. Institute of Cellular Pharmacology Ltd.

ICP is a story of its own. The company produces vegetal extracts for human and animal use on an industrial scale for pharmaceutical and related industries. It conducts its own R&D and applies for patents on a regular basis (at least one every four months). ICP is the only R&D-based pharmaceutical operation in Malta. (R&D activities of most other local operators focus more on quality assurance rather than molecule or process development).

The next section outlines the main findings of the field research in the light of the illustrative list of questions asked during the interviews with top management of local pharmaceutical enterprises.

Question one: impact of EU membership on the Maltese pharmaceutical industry.

Interviewees generally agree that EU membership deeply impacts the local pharmaceutical industry in a number of ways. Saliba (ICP) states that '[E]U membership has a broad and deep impact on Maltese society and economy. Membership created extensive ripple effects; just like throwing a big stone in a bath'. Mangion (Medichem) argues that '[w]hile it is true that EU membership facilitates the growth of the local pharmaceutical industry, the experience of countries such as Iceland and Switzerland shows that the industry could have thrived even if Malta stayed out of the EU'. Allegrucci (Combino) agrees and points out that '[M]alta's potential as a launching base for pharmaceutical would have been discovered in any case. EU membership merely facilitates this discovery'. This is possibly true, but most interviewees agree that EU is a certificate of consistency, reliability and quality for suppliers, distributors and consumers and it is not easy for a small country like Malta to build such a reputation. Mangion (Medichem) adds that 'EU membership 'per se' is not so important, what really makes a difference for Maltese companies is patent law'. Saliba (ICP) opines that '[s]tandards are driven by customers not by EU or other regulators'. The key features of the

impact of EU membership on the local pharmaceutical industry resulting from the interviewees are that membership,

- a. Offers unhindered access to a huge (more than five hundred million persons), affluent market. The single market enables Maltese producers to operate as inside-players and technically they compete on a level playing field with producers from other EU member states
- b. Facilitates access to third markets. 'The EU pharmaceutical industry has a first class reputation all over the world. The fact that Maltese producers form an integral part of the European industry opens doors in the rest of the world' (Debono, Alpha)
- c. Brings price stability as Malta is also a member of the Eurozone. 'Price stability is important as it helps us improve our financial planning. Being part of the Eurozone eliminates a lot of fluctuations in the exchange rate market' (Vella, Actavis)
- d. Attracts foreign direct investment into the local pharmaceutical industry as evidenced by the increase in the number of local operators since Malta joined the EU in 2004
- e. Facilitates the sourcing of expertise and skilled personnel from other EU countries, 'We are able to attract manpower from other member states, such as Spain and Italy, whose economies are not performing so well, as workers have the comfort of remaining within the single market'.

Question two: impact of EU membership on the local operating environment for pharmaceutical enterprises.

Debono (Alpha) opines that '[m]embership led to a qualitative leap in the operating environment. The GMP is generally better regarded than the FDA'. Mangion (Medichem) agrees and adds that 'GMP is very well respected all over the world; the only exception possibly being the USA. Even Canada has a higher regard for the GMP than the FDA'. Obtaining GMP certification is not subject to EU membership but it is impossible to operate within the EU without GMP. (For example, ICP was already GMP certified prior to Malta joining the EU). Allegrucci (Combino) points out that 'EU membership imparts a sense of assurance among foreign buyers.....the operating environment and resulting exports from Malta are of the highest standard'. Schembri (Aurobindo) remarks that '[t]he EU stands for high standards and a high level of regulatory compliance. Member states often offer mutual recognition and this is very important for producers of pharmaceuticals'. Saliba (ICP) proposes a different perspective, noting that the biggest impact of EU membership is on Malta's tertiary sector, '[t]here existed a big gap in subjects relevant to the pharmaceutical industry, between the local university and those in the UK. This gap has now been practically

closed'. On the domestic market, according to Debono (Alpha) EU membership led to '[g]reater choice, increased competition and lower prices' and that '[c]hanging over to the EU proved to be a cumbersome process for local importers many of which represented Swiss producers'. He adds that although Swiss pharmaceuticals did not need re-testing or re-analysis, they still required batch release. Initially, the number of pharmaceutical products on the domestic market declined from some 7,000 to 1,700 medicines (Table 10) but eventually they started to rise again due to the 'Cyprus provision' (products having a marketing authorisation by an EU member state were allowed to be sold on the local market) and the setting up of EPO.

Question three: impact of EU membership on Maltese pharmaceutical firms.

This question ties with the previous two questions as the impact of EU membership on local firms cannot be separated from the impact on the industry as well as its operating environment. Vella (Actavis) explains that his company '[c]ame to Malta for a number of reasons. At the time Iceland was already facing a shortage of skills and a steep increase in costs. Probably, the company would not have acquired Delta had it not been convinced about Malta's commitment to join the Community. Actavis needed a production base within the EU'. Galea Kenely (Starpharma) states that '[o]ur company was set up in 2002 specifically to tap the opportunities arising from EU membership'. In a similar vein, Giromini (Siegfried) notes that 'Siegfried came to Malta in 2004 due to the country's membership in the EU and the fact that the country is considered to be 'patent free'. Since then we have invested a lot in state of the art equipment which very few companies, even in the EU itself, can match.'

Mangion (Medichem) points out that 'EU membership for our company is not critical as we do not sell to EU countries. In my opinion, what is vital for us is international patent law'. He adds that EU membership brings with it a lot of obligations and additional costs, with EU legislation often being 'myopic'. He complains that the EU is too bureaucratic and the costs related to environmental protection are 'prohibitive'. Saliba (ICP) once again offers a different perspective explaining that '[i]n our industry an enterprise's operating standards are set by our customers and not by the EU. Customers carry out operational audits on a regular basis and GMP or FDA compared to these audits are child play.' Farrugia (Chamber of

Commerce) notes that ‘[t]he impact of EU membership is probably greater on local authorities than on operations of the companies themselves’.

Seychell (Pharmadox) notes another advantage that Malta obtained whereby no VAT is charged on imported pharmaceuticals, This derogation was negotiated with the EU and is on an indefinite basis. This concession ‘implies that local manufacturers do not have to pay VAT on the import of materials. For a small enterprise like ours this is important because it eases the pressure on our cash flow.’ Seychell (Pharmadox) continues that ‘[i]t is equally important that Malta has zero-duty on the importation of active ingredients and other materials provided the final products are re-exported to markets outside the EU’.

Question four: primary challenges currently facing the industry compared to those faced upon membership?

In 2004, local industry was generally confident that it would be able to meet the stringent operating standards set by the EU. What pre-occupied Maltese pharmaceutical companies was the potential competition from former ex-Soviet countries which were joining the EU at the same time as Malta. There was also some concern about the lack of technical know-how and expertise. At the time, the pharmaceutical industry in Malta was growing very fast and ‘[t]his was putting a lot of pressure on the availability of personnel, such as qualified persons and quality analysts’ (Vella, Actavis). Saliba (ICP) points out that ‘[a]t the time, companies like Actavis, were engaging graduates to do the work of technicians’. The industry was also unhappy with the existing physical and institutional infrastructure. Schembri (Aurobindo) states that service providers were not geared for the specific needs of the pharmaceutical industry, ‘[i]t was hard for construction companies to abide by the high standards demanded by the industry’.

Ten years later, the concern with competition from East European operators remains. ‘Really we do not compete directly with Asia. Our competition comes mostly from East Europe, now including also Croatia and Serbia’ (Vella, Actavis). Through various measures have been taken to increase the local supply of personnel at all levels of the industry, the availability of human resources remains a problem. Vella (Actavis) speaks about ‘[a] dichotomy between Malta’s industrial strategy and its education system’. Both Saliba (ICP) and Allegrucci

(Combino) opine that people are one of the unique selling points (USPs) of the pharmaceutical industry in Malta. Allegrucci (Combino) remarks that '[s]ecuring the right personnel, whether operators, technicians or graduates remains a problem. Luckily, the EU serves as a safety valve and presently we are sourcing a lot of manpower from Spain. But this tends to raise the cost of labour'. Vella (Actavis) complains about rising labour costs and claims that this is undermining the competitiveness of the industry. Allegrucci (Combino) does not agree, noting that '[t]he share of labour costs in total costs in our industry is minimal'. Schembri (Aurobindo) points out that 'Maltese workers are not well prepared for the pharmaceutical industry. Government needs to take a more holistic approach to the manpower needs of industry'. Martin (Crystal) criticises the turnover among operators noting that '[l]ocal employees are often ready to change jobs even for a marginal increase in wages'. Another issue raised by Vella (Actavis) relates to the brain drain. He states that more Maltese employees, after gaining experience in the industry, are migrating to other countries, '[i]n Europe as well as far away countries such as Australia'.

Local service providers catering for the industry have risen to the occasion, '[t]ransport providers in particular have come a long way. They now operate internationally, playing a regional role'(Schembri, Aurobindo). The physical infrastructure supporting the pharmaceutical industry is still far from satisfactory. 'The airport lacks the necessary facilities to handle pharmaceuticals' (Schembri, Aurobindo). There are also problems in disposing with toxic materials (which are transported all the way to Switzerland) as well as with the quality of municipal water.

Most interviewees praise the efficiency of the Medicines Authority whose contribution they deem critical for the development of the pharmaceutical industry. Schembri (Aurobindo) opines that the '[t]he Medicines Authority is well respected as it has an excellent track record'. Debono (Alpha) states that 'The level of expertise about our industry in the public sector is poor, except for the Medicines Authority'. Vella (Actavis) agrees that there exists limited knowledge about pharmaceuticals in the public sector and so does Farrugia (Chamber of Commerce) who states that '[t]he poor level of knowledge in the public sector is evident in the way that medicines are procured by the government'.

Schembri (Aurobindo) points out that '[M]E can do a lot more but unfortunately it lacks the necessary technical knowledge'. Seychell (Pharmadox) finds that 'ME has two standards in granting assistance one for local players and one for foreign ones'. Allegrucci (Combino) does not agree as in his opinion 'ME does a very good job. It has been instrumental in getting our company to come to Malta'. Galea Kenely (Starpharma) complains that '[d]ifferent institutions have different standards and these vary significantly'. She speaks of 'regulation overkill' pointing to the policies relating to the construction industry (Malta Environment and Planning Authority), waste management (Wasteserv) and health and safety (Occupational Health and Safety Authority). Giromini (Siegfried) laments that with regards to waste management, 'MEPA and other institutions continue to churn out studies, but no concrete action is taken'.

Another important challenge which the pharmaceutical industry in Malta is currently facing relates to patent law itself. A growing number of foreign patent-holders attempt to register them in Malta retrospectively. Given that the country lacks the necessary expertise to professionally assess such requests, they often manage to register them. Local companies are then obliged to appeal these patents. This in itself is a pretty straight forward task as the necessary evidence is relatively easily available from overseas, but it costs money and is time-consuming. The local pharmaceutical industry is lobbying for changes in Maltese patent law and requesting the setting up of a patents tribunal.

Question five: to what extent are local pharmaceutical enterprises dependent on costs for their competitiveness?

There is general agreement among pharmaceutical companies operating in Malta that they compete primarily on costs. Vella (Actavis) explains that '[g]enerics are very price sensitive and cost-control is critical for the success of our industry'. He explains that in Malta, pharmaceutical companies have high overheads and fixed costs relative to the volumes produced, '[t]his is why we tend to specialise in short-runs that carry a premium price'. Martin (Crystal) states that '[o]ur operation in Malta is fully dependent on minimising costs. But the costs here in Malta are lower than those of our parent company in Spain'. Allegrucci (Combino) remarks that '[a]lthough production costs in Asia are lower than in Malta, so is the productivity of their workers. Malta offsets its higher costs through higher productivity,



by offering easier access to EU markets, especially in carrying out quality assurance as well as in obtaining batch release and marketing authorisation'. Giromini (Siegfried) notes that his company's operating costs in Malta are practically at par to those in India. He attributes this to '[t]he investment made in state-of-the-art equipment, strict process control and the quality of our human resources'. As will be explained in question seven, there are a few local pharmaceutical operators who are able to influence the price they fetch for their products, so that while cost-control is important for them, it is not the only element underpinning their competitiveness.

Question six: what can be done to increase the value-added of local pharmaceutical firms?

Given the production-orientation of most local pharmaceutical companies, it is to be expected that a good number of them emphasise the role of technology in raising value added. A higher value added is closely associated with increased output at the same, or lower, costs. Seychell (Pharmadox) points out that to improve value added '[w]e need to keep up with changes in the market by consistently updating and upgrading our technology'. Vella (Actavis) states that '[t]o increase the value added of our Malta operation we depend on the technology given to us by the parent company and moving towards the higher end of the product spectrum'. The need to go for speciality medicines is emphasised also by Mangion (Medichem) who notes that '[t]he solution is to go for speciality medicines targeting 'niche' market opportunities, such as using heroin and opiates for medicinal purposes. We need to have short-runs, be flexible and be able to respond quickly to customer requests'. Schembri (Pharadox) explains that '[s]hort runs and niche products enable us to charge a premium price'.

Other interviewees emphasise the importance of staying close to customers. Debono (Alpha) opines '[w]e can enhance our value added by improving our disposition to accommodate clients and be flexible'. He adds that this can be achieved through just-in-time delivery and being ready to deliver small consignments, thereby minimising the money tied in stocks by clients. Galea Kenely (Starpharma) opines that '[o]ur company has to stay in touch with clients so as to 'foresee problems' and be able to offer timely support'. She adds that Starpharma has to offer a '[c]ustomised service which is complete and based on patent specialisation'. Seychell (Pharmadox) agrees with this saying that '[w]e have to become a

one-stop shop and be able to offer a complete service to customers exploiting the patent-free status of Malta as long as it lasts’.

Question seven: the extent to which Maltese pharmaceutical enterprises are price setters.

Vella (Actavis) states that ‘[w]e absolutely have no control over the prices we charge. That is entirely in the hands of the parent company’. Allegrucci (Combino) and Giromini (Siegfried) agree, with the latter pointing out ‘[T]he Malta operation is just a cost-centre. All pricing decisions are taken by our Head Office in Switzerland’. Debono (Alpha) remarks that ‘[g]iven the competition we have, it is practically impossible to charge premium prices’. For local operators serving as a mere production base cost-control is critical as they are not in a position to fetch higher prices (except by going for niche products requiring shorter runs and fast delivery). Local operators that specialise in ‘patent launches’ have more room where to manoeuvre and seem to have enough market power to influence the prices they charge. Mangion (Medichem) notes that ‘[w]e operate in a patent-free zone and if a contractor wants to use our services and expertise, he has to pay for it’. This is shared by Schembri (Aurobindo) who states ‘[o]ur company does exploit its advantageous position arising from the country’s patent-free status and it does have a degree of leverage on the prices it charges’. Seychell (Pharmadox) explains that in the case of launching a new generic ‘[t]ime is of essence. We stock-pile the product and then ship out as fast as we can, sometimes even using chartered flights, to ensure fast pipeline filling. We have developed a specialisation in such launches and get paid well for it’. Saliba of ICP, the only operator in Malta not producing generics says that his company ‘[c]harges a significant mark-up. This is the advantage of doing our own research. Research is expensive but rewarding’.

Question eight: the influence of Maltese companies on EU policy-making.

The view of the pharmaceutical industry in Malta is that, with the exception of Actavis, it has practically no say on what gets decided in the EU. ‘Actavis is one of the largest producers of generics in the world and it is well-represented in Brussels. In a way Actavis serves as the voice of the local generics industry within the EU’ (Galea Kenely, Starpharma). Local operators generally perceive the EGA as being effective in its lobbying. Saliba (ICP) points out that ‘Maltese operators have no say in EU policymaking, and as far as I am concerned

even the EFPIA is ineffective'. Giromini (Siegfried) opines that in any case 'EU policymakers are far removed from the real needs of the pharmaceutical industry'.

Question nine: do local pharmaceutical firms collaborate and network?

Giromini (Siegfried) replies that '[M]altese pharmaceutical operators operate in silos. We are more interested in networking with foreign companies than among ourselves. We do not seem to trust each other. We have not even been able to procure a joint electricity backup system'. Vella (Actavis) notes that '[t]here is an element of collaboration, especially within the Chamber of Commerce; but this is mostly a lobby group'. He adds 'our umbilical cord is with our parent company. We make sure to attend for all the important networking events such as the World Drug Manufacturing Summit'. Seychell (Pharmadox) finds that collaboration within the Chamber of Commerce is weak as most members are importers and wholesalers of pharmaceuticals and not manufacturers. The Chamber has three sections representing pharmaceuticals: manufacturers, pharmacists and healthcare (mostly wholesalers). Seychell adds that his company has a close working relationship with Aurobindo. Allegrucci (Combino) points out that his company has a close working relationship with Siegfried. Saliba (ICP) opines 'Malta has a very small community and here people get to know each other at university, in the village and so on. In cases of need we do support each other. There is more collaboration taking place than meets the eye'. Maltese operators 'are not really competing among themselves. They only compete in securing the right human resources given that the supply is limited'. Martin (Crystal) while admitting that there is little collaboration with other operators notes that '[w]e work very closely with local suppliers, especially those supplying equipment and materials'.

Question ten: the major assets/competencies of local enterprises.

The pharmaceutical industry in Malta considers its employees as one of its major assets. Schembri (Combino) praises the work ethic of the Maltese, especially their productivity and flexibility. He explains that his company has manufacturing plants in such diverse places as France and India, and points out that '[p]ractically 80% of the problems we face in our overseas plants arise out of poor communications. In Malta our employees have a good command of English as they tend to be multi-lingual and are well-disposed to work with

foreigners'. Workers are praised for their willingness to learn and good communication skills. These employee' traits can be considered as part of a 'bundle of competencies' which are exploited to cater for the specific needs of the pharmaceutical industry. Galea (Malta Enterprise) explains that a good number of employees working in the pharmaceutical industry where previously engaged in other manufacturing sectors, such as clothing and electronics. 'They were given specific training by ETC so that they would be able to work in the pharmaceutical industry'. Giromini (Siegfried) makes a distinction between flexibility and adaptability of local workers, '[f]lexibility is a mechanical process, whereas adaptability results from a disposition to meet customer needs'. Another feature which is emphasised by Zammit (Actavis) is what he refers to as 'managing complexity'. This '[e]ntails a capability to produce cost-effectively a broad mix of products'. This feature is closely related to the concept of flexibility, being able to produce niche products and fast response. Zammit (Actavis) explains that '[l]ocal production costs are higher than in the other fourteen plants of our company across the world which, achieve lower costs due to standardisation; we are renowned for our flexibility and adaptability'. It is not unusual for the company's Malta plant to make ten changeovers in a production line within a week. Debono (Alpha) and Galea Kenely (Starpharma) both emphasise the importance of their companies staying close to the market. The former emphasises the need of '[i]mproving our disposition to accommodate clients and be flexible' while the latter stresses that '[o]ur company has to stay in touch with clients so as to 'foresee problems' and be able to offer timely support'. Both of these statements point towards the importance of market sensing (including market orientation).

Question eleven: the future of the pharmaceutical industry in Malta.

Vella (Actavis) states that '[t]he consumption of generics is expected to continue to grow with the market for pharmaceuticals becoming increasingly competitive'. He adds that an ageing population in Western societies, the increased cost of healthcare and additional budgetary constraints of governments are leading to a changed market scenario. The cost of new medicines is generally becoming prohibitive due to increased regulation and this is paving the way for generics. As a result a number of originator companies are moving into generics generally through acquisitions and vice-versa. Schembri (Aurobindo) notes that '[p]rocurement patterns in the EU are changing very fast. Customers are placing smaller orders and expect quick deliveries so as not tie up money in stocks'. Debono points out that

‘[a] new cycle is emerging in the pharmaceutical industry built around biosimilars and lower prices. This is partly being driven by an ageing population’. He adds that South American countries like Argentina and Brazil are very strong in biosimilars due to the legacy of a significant German community after World War II ‘Malta could become an important stepping stone for these countries into the EU’. Giromini (Siegfried) opines that it is impossible for the local industry to move into originator products, ‘[i]t is like moving from driving a motor cycle to formula one racing’. Saliba (ICP) warns that the Life Sciences project is likely to be a ‘white elephant’ and that if Malta is not careful ‘[t]he pharmaceutical industry will have the same fate as textiles’. Table 12 presents the key findings from the field interviews categorised by topics emerging from the illustrative list of questions (Annex 1)

Questions	Topic	Key Findings
1+2+3	EU membership impact on local pharmaceuticals	Significant especially on public institutions. Enhanced reputation facilitated access to global markets. Attracted FDI, improved price stability and eased sourcing of expertise and manpower. Higher operating costs.
4	Challenges for the industry	2004: competition from East Europe, lack of know-how and skills, support of local service providers 2014: first two concerns remain. Limited knowledge in public sector about the industry (except for Medicines Authority). Improved physical infrastructure not enough. Satisfactory improvement by service providers
5+7	Competing on costs and influence on prices	Depends on nature of operations. 'Subcontractors' fully dependent on costs compensating higher fixed costs through 'premium' products. 'Patent launchers' who have a degree of market power and ICP enjoy good mark-ups.
6	Improved value added	Primarily through technology up-grades and niche products for 'subcontractors'. Offering a complete solution to customers for 'patent launchers'.
8	Impact on EU policies	Practically non-existent except for Actavis
9	Collaboration and Networking	Negligible relative to potential. Mostly confined to joint lobbying efforts.
10	Assets/Competencies	Human resources deemed primary asset: good communications, flexible and willing to learn. Ability to 'manage complexity' and a customer focus
11	Future of industry in Malta	Overall positive especially through a growing global market for generics and biosimilars

**Table 12: Key findings as per illustrative list of interview questions**

The next sections present the research findings categorised by the arch-RCDCs as per theoretical framework proposed in Figure 14 and as referred to in figure 26 .

### **5.7.1 Market sensing**

The field research shows that, in the case of the pharmaceutical industry in Malta, market sensing is of critical importance at the national, industry and enterprise level. The EU membership led to an upgrading of the country's operating environment in terms of policies and institutions. The EU's 'acquis communautaire' is among the most sophisticated in the world, and the membership enables Malta to consistently upgrade its legislation and supporting societal structures relating to the pharmaceutical industry. The transposition of EU legislation into Maltese law by itself did not guarantee the transfer of the necessary knowledge as well as its proper implementation. As explained above a number of interviewees lamented that the local public sector still lacks a proper understanding of the industry's specific needs. Also, although the EU's 'acquis communautaire' is constantly being upgraded to reflect developments in the global scenario, these changes do not necessarily reflect the specific needs of local operators who deem that they are not in a position to influence EU's policies. Actavis is the only exception.

EU membership has been a critical catalyst in creating the 'right' legislative and institutional operating environment and has been instrumental in fostering a high reputation which enhances the market positioning of local pharmaceutical operators. Membership opens the doors to European and global pharmaceutical markets, enabling local pharmaceutical firms to benefit from the EU's extensive network of trade agreements. ME also plays an important market-sensing role by monitoring global developments and staying close to the pharmaceutical market. This is essential for ME in seeking to convince foreign investors to branch their operations to the country. (During the field research, it also emerged that two other foreign companies have on-going negotiations with ME to open subsidiaries in Malta). ME needs to remain close to developments in the pharmaceutical industry to be in a stronger position in securing from the government the financial and other resources necessary to service the on-going needs of the industry (including the continued development of the infrastructure). ME is completing the construction of a Life Sciences Park, which is expected

to help create a new dimension to the activities presently undertaken by the pharmaceutical industry in Malta.

The research also shows the importance of the National IP Office at the Commerce Department within the Ministry for the Economy, Investment and Small Business. While the staff at this office are deemed by the research interviewees as being helpful, they lament that it lacks the necessary resources to research patent applications internationally and to assess them accordingly. This research has already referred to the request by the local pharmaceutical industry to change Maltese patent law and the setting up of a patents tribunal so as to enable local operators to challenge pharmaceuticals registered retrospectively. This is a delaying tactic by originator companies to protect their market position and delay its being challenged by generics. At the enterprise level, market sensing is generally channelled through the overseas parent company. This umbilical cord is critical in keeping the local operation in touch with international market developments. Many interviewees confirm that although they do attend specialised fairs and visit overseas clients regularly, the actual price negotiations are handled directly by the parent company. This is confirmed by Vella (Actavis), '[w]e absolutely have no control over the prices we charge. That is entirely in the hands of the parent company' and Giromini (Siegfried), '[T]he Malta operation is just a cost-centre. All pricing decisions are taken by our Head Office in Switzerland' Few local top managers are expected to 'scan' the market to identify changing customer needs, except in those instances where the local operation also serves as a 'regional' sales office.

Nevertheless, a 'unique' form of market sensing capability is evolving among other local operators who are building a competence in scanning the 'patent' world to identify medicines whose patent will be expiring in the near future. This type of market sensing leads to the identification of market opportunities through a thorough understanding of the 'lifecycle' of medicinal patents.

### **5.7.2 Change Management**

Although Malta's decision to join the EU was a highly controversial and protracted one, once the PN was returned to power in the 2003 general elections, the PL accepted the people's verdict on the EU membership as being final. Since then, the local political class has practically been united in its commitment to EU membership and this sends a strong message



to local society as well as potential foreign investors. This commitment greatly facilitated the economic restructuring and transformation processes necessary to secure EU membership. The government was the primary driver of the change process triggered by this membership and provided the necessary leadership to ensure that restructuring takes place without too many hiccups. The opposition took a back seat in fear of being accused of still being anti-EU membership. As far as the social partners were concerned, they too accepted the inevitability of membership and this conditioned their mind-set and attitudes to change. The pharmaceutical industry in Malta pays relatively good wages and salaries and this helped it to be accepted and be held in high esteem by local workers.

There has, therefore, been societal consensus to promote and support the pharmaceutical industry. Given the government's positive attitude to the generics industry, the EGA twice held major conferences in Malta in 2005 and 2012 . Busuttil, a Maltese member of the European Parliament, reiterated the government's commitment to the generics industry which '[h]as shown a commitment to Malta and to the Maltese workforce and I will reciprocate by supporting this industry's interests in Brussels' (The Times, 2006). The PN government consistently projected the growth of the pharmaceutical industry as reflecting its capability to win the trust and confidence of overseas investors and attract to Malta a sophisticated manufacturing activity. An aura of high technology and high value-added was built around the industry at a time when many lower-end manufacturing enterprises were closing down or transferring production to lower cost destinations. Saliba (ICP) notes that '[i]n its membership negotiations with the EU, the government had to take a key decision: whether to opt for an environment that favoured originator companies or generics'. He adds that the general public was not made aware of the implications of this decision, and Actavis was powerful because it had a large workforce. Consequently, the government simply went along with the advice and requirements of Actavis and this created the platform for additional generics to set up shop in Malta.

As mentioned earlier on this chapter, the transposition of the EU's directives helped change the operating environment of the local pharmaceutical industry by inducing the setting up of new structures such as the Medicines Authority. This institution acts as a supervisor of the local pharmaceutical industry and has become an important stakeholder. The Authority is the link between the local pharmaceutical industry and sector developments within the EU. ME's

role has already been highlighted, especially with regards to its strategic efforts to attract pharmaceutical firms to Malta. Pharmaceuticals are classified as a priority sector within the Business Promotion Act which regulates the granting of government assistance to enterprise. Another critical role which ME plays is in getting the industry's stakeholders together to identify and address the specific needs of the industry. One example of this has been the work done by ME to enhance the factory-building know-how of local contractors. These were generally used to building standard factories and needed to upgrade their competencies to be better able to build the more sophisticated buildings required by the pharmaceutical industry. ME also brokers meetings between the industry and other local authorities, as was the case with education. Galea(ME) notes that '[M]E's efforts have been instrumental in sensitising the local academic and employment institutions with respect to the opportunities that the pharmaceutical industry offers and in encouraging them to launch new courses tailor-made for the industry'. Changes were also made in the curriculum of existing courses to adapt them to the needs of industry. The transformation process was not always a smooth one and challenges did arise. For example, while the chemistry department (which forms part of the Faculty of Sciences) whole heartedly welcomed the opportunity to introduce various courses to address the specific requirements of the pharmaceutical industry, the pharmacy department (which forms part of the Faculty of Medicines) struggled to re-orient itself. It was only recently that the pharmacy department introduced two undergraduate degrees, pharmaceutical technology and pharmaceutical science, intended for the specific needs of the industry.

The situation was rendered more complex through personality clashes, which in a small community tend to be more deeply felt. Generally, there has been no real objection by other local business interests or social groups to the development of the pharmaceutical industry in the country. The industry is pre-dominantly export oriented and not perceived as a threat. Bugeja (2008, p. 35) notes that the impact of regulatory change arising from the EU membership '[w]as multifaceted, triggering reactions from all the main stakeholders'. The primary contention that surfaced arose out of considerations relating to sales on the domestic market. Prior to the EU membership, '[l]ocal importers and wholesale dealers were particularly worried about the impact of parallel trading on their business' (Vella Bonnano, Medicines Authority). These enterprises represent a powerful interest group. Individually, they act as exclusive local representatives and distributors of numerous originator drugs and established brands and have significant market power arising from their exclusive product

portfolio and dominion over the local market. At the time, the wholesale dealers took advantage of their position to manipulate and control market prices. A controversy broke out over the requirement stipulated by EU regulations that the labels of medicines sold on a domestic market have to be in the language of the country. In the case of Malta, this implied that all medicines had to be re-labelled to have a label in Maltese. Importers saw this as an unnecessary expense and the issue was only solved when the government and the EU Commission agreed to allow labelling in English (Malta's other official language).

'[T]he EU membership brought with it a breath of fresh air into the local pharmaceutical sector and medicines market' (Vella Bonanno, Medicines Authority). The change brought about by the EU membership at the enterprise level affected mostly Actavis as at the time it already had a sizeable operation in Malta. The Icelandic top management of the company had seen EU membership as a unique opportunity to tap the lucrative EU market and move away the Malta operation away from the Third World markets it used to cater for. Internally within Actavis itself there was little resistance from the management towards this re-orientation, '[e]ven though some managers were disappointed that the enterprise was losing its semi-philanthropic orientation by no longer producing cheap medicines for poor countries' (Zammit, Actavis).

### **5.7.3 Knowledge Capacity**

The Medicines Act (2003) incorporates the directives of the EUs 'acquis communautaire'. This Act includes provisions relating to 'good manufacturing practice, importation and parallel importation, marketing authorisations, packaging and labelling, wholesale distribution, reimbursement and selection of medicines, clinical trials, pharmacovigilance and advertising' (Bugeja, 2008, p. 34). The Manufacture of Medicinal Products for Human Use Regulation (Art. 458.36) of the Medicines Act stipulates that, to be manufactured in Malta, a medicinal product needs to be covered by a manufacturing licence (Good Manufacturing Practice-GMP) 'even though the medicinal / pharmaceutical is manufactured for export-purposes only' (Cassar, 2006, p. 89). A GMP certification ensures 'that the production of medicinal products is carried out at correct potency levels recommended for use in safe doses or to the correct category of patient' (Zammit, 2010, p. 23). The EU's GMP certificate assesses both process and product. 'Such activities and certification serve to confirm the quality of the medical sector in Malta and re-enforces the image of the country on international markets' (Galea,

Malta Enterprise). Agius (2011) remarks the pharmaceutical industry 'is a very complex industry, so you also can't just wake up one day and decide that you are going to play an important role, it takes years and years'. Gambardella *et al.* (2000, p. 81) state 'the development of competencies and innovative capabilities is a long, cumulative and difficult process that does not respond immediately and smoothly to economic incentives'.

Malta boasts a tradition in pharmacy which goes back at least to the sixteenth century to the days of the Knights of St. John. This created a degree of knowledge about pharmaceuticals but the industrial production of pharmaceuticals in the country started only in the mid-1970s, with the setting up of Pharmamed. Eventually, in the early 1990s, the industry got its first (and last) indigenous research-driven company (ICP Ltd.). Pharmamed in its first stage operated at the basic level of the industry and obtained most of its know-how and technology transfer from its Dutch management. The company not only survived but was transformed and grew, proving that Malta had the essential knowledge and competencies to run a generics pharmaceutical operation. Grioli (Pharmamed) states that '[t]he company at the time did not have the knowledge and resources necessary to embark on the production of originator drugs'. It is only when Delta brought Pharmamed did the company start on a qualitative improvement in its operations, even though it remains focused on generics. Pharmamed, and especially Actavis when it took over the company, proved to be the cradle of the generics industry in Malta. When later on, other pharmaceutical companies set up shop, they found sufficient knowledge and a skills base which they could build upon. By the time that Malta was on its way to EU membership, the country had a pool of experienced managers and engineers (most of whom had been employed in other industries) which was available at relatively low costs (the cost of specialised personnel in Malta is even more competitive than for less skilled employees).

The inflow of FDI in pharmaceuticals that followed Malta's EU membership quickened the transfer of knowledge and this compensated for any limitations that existed. In particular, FDI is instrumental in securing the right technology for the manufacturing and related activities (including quality assurance) of generics. Malta gradually built a competitive advantage in short-run production and other niches. Zammit (Actavis) points out that '[w]e had become specialists in packaging operations. Our employees used to liaise with foreign manufacturers of machinery so as to improve their equipment'. This shows the capability of

the Maltese not only to quickly absorb technology but also to adapt and develop it to serve their needs. An important consideration that emerged from the field research is that knowledge capacity relates to developments not only within the private sector but also within the public sector. This is essential as it conditions the ability of the public sector to efficiently and effectively support the development of the pharmaceutical industry. Indeed, as noted earlier in this chapter a significant number of interviewees complain that the local public sector lacked the desired depth of knowledge about their industry and this is often reflected in the way that public officers react to their requirements. While there is a lot of truth in this, it has to be appreciated that absorbing and adopting the entire 'acquis communautaire' in such a short time is a daunting task for any public sector. The knowledge incorporated in such directives needs time to be digested (especially for a small country like Malta which has limited resources and had to transpose a hefty acquis meant for the needs of much bigger and more advanced societies). The challenge of keeping up with extensive legislative adjustments is an on-going one and comes at a cost for a small country seeking economic integration with a much bigger economic area. A country like Malta has to consistently strive to remain on track, even though a lot of these adjustments are costly and may be alien to its specific needs.

Knowledge capacity also includes the capability of service providers to meet the needs and standards demanded by the pharmaceutical industry. This research has already noted that some interviewees commented on the learning curve of service providers such as suppliers of testing equipment and materials, transport and waste collectors and construction companies. These service providers have been able to upgrade their operations and presently provide satisfactory support to the pharmaceutical industry. Another important consideration emerging from the field research is that the absorption capacity tends to be partly conditioned by the nature of the strategic development of the industry. The growth of the pharmaceutical industry in Malta is more the result of an 'emergent' strategy than of a 'deliberate' one. An important implication of this is that the country's institutions and structures were not prepared to cater for the specific needs of the industry. This is evident from the experience of local education and training institutions, which adjusted to the industry's needs in a reactive rather than proactive manner. It was only thanks to the flexibility and initiative shown by the chemistry department at the local university, which was quick to react and introduce new modules and courses, that the required graduates became locally available. In fact, had this

department not acted as fast it did to introduce a post-graduate course leading to certification of qualified persons, the industry would have continued to suffer from a shortage of personnel who are essential for the running of a pharmaceutical enterprise, because without their certification, pharmaceuticals cannot be released from a factory. Additionally, in 2005, the government realised that there was a need to incentivise the enrolment of more tertiary students into science-based faculties. This induced government to change the stipends system in such a way that it favoured the study of science subjects. This had a positive effect and the intake of students for chemistry and related subjects significantly increased, thereby increasing the supply of manpower to the industry, which at times has to resort to poaching so as to secure the right personnel.

The primary change agent in education and training has been Actavis which has consistently been insisting on ever-higher standards rather than some strategic exercise. Over the years, Actavis has continued to demand better qualified students and this helps to meet the growing demand for qualified personnel by the pharmaceutical industry. As noted above, pharmaceutical operators who did not find the right personnel locally were obliged to get them from overseas, either internally from other branches of their group and/or from other EU countries. Despite the measures taken to increase the local supply of personnel at all levels of the pharmaceutical industry, the availability of human resources is still a problem as evidenced by Allegrucci (Combino) statement, '[s]ecuring the right personnel, whether operators, technicians or graduates remains a problem'.

The fact that the country's national laboratory does not even qualify for GMP reflects the short-comings that persist in Malta in servicing the growth of the pharmaceutical industry. Vella (Actavis) notes that a new phenomenon related to knowledge capacity is emerging. 'Individual development is now outpacing the evolution of local enterprises. This is leading to a situation where a number of well-trained employees prefer to pursue their career overseas as they realise that the way that the industry is operating in Malta offers limited opportunities for career advancement'. This 'brain-drain' could eventually limit the further development of the industry.

Actavis closing down its R&D unit in Malta as part of the rationalisation process following the take-over by Watson does not augur well for the pharmaceutical industry in the country.

Actavis had built a significant R&D capacity, which at its peak (2007) engaged 45 employees. The unit worked on product development up to the dossier stage, with the parent company subsequently deciding whether to sell the dossier to another manufacturer or develop the product itself. Zammit (Actavis) states that '[l]ocal R&D favours local manufacturing as there is already a familiarity and know-how of what the product entails'. Vella (Actavis) agrees, pointing out that '[h]aving our development centre situated so close to our manufacturing facility, allows the development centre to interface very closely with the manufacturing process. This gives us a unique advantage because when one is developing a new product it is also a lot about the manufacturing capability'. Schembri (Aurobindo) remarks that '[m]any of these employees who lost their jobs from Actavis are finding it difficult to take up alternative employment with other local companies, not only due to the salary but also because of the 'title' of the jobs being offered such as scientific officer as against lab analyst'. The setting up of a Life Sciences Park may help solve this problem. Schembri adds that in the meantime, '[i]t is important for the local university to introduce post-doctoral courses to engage specialised personnel in research activities before they are lost to the local pharmaceutical industry'.

The field research uncovered another source of knowledge, which is proving invaluable to the specialisation of the local pharmaceutical industry: law. The legal profession has a long track record in Malta and this knowledge is being exploited to assess the legal standing of patented medicines to determine how imminent their expiry is (and in which markets) to embark on the development of their generics equivalent. At the national level, one of the spill overs of the EU membership is the increased awareness about the role of R&D in driving innovation, which is 'widely recognised as the main engine of prosperity and the key to higher living standards' (Montfort & Mallia 2007, p. 14). Little innovation has been taking place in Malta on the basis of structured programmes (Montfort & Mallia, 2007), and the country does not perform well in the Innovation Scoreboard, which benchmarks 34 European countries (BEAT Consulting, 2011). Malta's R&D intensity is far below the EU average (EU Commission, 2011a) and the country has set a national R&D target of just 0.67% of GDP by 2020, arguing that it suffers from structural disadvantages (market size, structure and location, and absorption capacity). Malta's limited R&D is partly a result of its fragmented economic activities and the pre-dominance of micro enterprises, which operate in isolation and have little links with larger foreign-owned enterprises or among themselves. In the period 2000-

2011, of a total of 2954 patents filed locally 2510 (85%) were submitted by the pharmaceutical industry (Table 9). Of these 2796 (94%) were submitted by foreign companies which indicates that in most cases these patents did not arise from local research but were merely being registered in Malta. The number of patent registrations fell dramatically in 2010 and 2011, when probably many foreign operators started to register their patents with the European Patent Office. The low level of R & D taking place within the local pharmaceutical industry emerges from the fact that whereas around Malta's accession into the EU the research spend relative to output was around 5% (2005) by 2010 this had fallen to less than 3%.

According to Farrugia (Chamber of Commerce), '[M]alta is still in its infancy in terms of R&D'. Instigated by the EU, the MCST recently completed a Research and Innovation Strategy for 2014–2020. This strategic process brings together the Chamber of Commerce, the University, ME and MCST. This R&D strategy will be financed through structural funds made available by the EU. To ensure a more cost-effective use of funds, the Commission is insisting that countries adopt an approach known as 'smart specialisation'. This favours a strategy that builds on the strengths of a member state to tap into opportunities rather than addressing weaknesses to reduce threats. As part of the process, MCST has undertaken a comprehensive exercise to determine existing capacities for further Research and Innovation (gauged through such factors as human resources, infrastructure and research and innovation) within the local economy. Surprisingly, pharmaceuticals are not included in the 'smart specialisation' programme. Castillo (MCST) explains that '[T]he strategy is meant to be a dynamic process and may change should developments justify it'. The reason for this exclusion is that MCST (as shown by this research) has found that little 'real' research takes place within local pharmaceutical enterprises. Castillo (MCST) adds '[m]ost R&D activities in the local pharmaceutical industry are oriented towards quality assurance, rather than product or process development'. Moreover, any Research and Innovation activities within local pharmaceutical enterprises are often determined by the parent company overseas with the local unit having little or no say.

#### **5.7.4 Alliance Capability**

During Malta's accession negotiations with the EU, MEUSAC was set up to coordinate some 130 organisations representing various groups from civil society. 'In this way, the EU



accession was considered not solely as a foreign policy issue but something that encompassed the whole society' (Schembri Aurobindo). MEUSAC managed 'to introduce an unprecedented level of consultation into Malta's political system' (Aytaç and Kıratlı, 2008, p. 23). MEUSAC was reactivated in 2008, with the specific scope of engaging civil society in the EU consultation and decision-making process to gauge 'the impact proposed EU measures could have on Malta, its institutions, its specific sectors and ordinary citizens' (MEUSAC, 2013). Mizzi (2004, p. 2) remarks that 'it is only with enhanced coordination and co-operation amongst the social partners in Malta that the full economic and political benefits of Malta's EU membership can be exploited'. This is Malta's own form of 'democratic corporatism' and has been in place since the early 1990s. The MCESD is an advisory council, which brings together government and the social partners, is meant to promote social dialogue and formulate recommendations to government on matters of importance to the Maltese society. The fact that trade unions and the employers' organisations sit together with the government to discuss issues of national relevance has resulted in practically no industrial unrest (especially in the manufacturing sector) over the last two decades.

The MCESD is often mocked as being a mere 'talking shop' and a rubber stamp for government policy. It is also criticised for having failed to reach, over the last eight years, agreement on a social pact. Gambardella *et al.* (2000, p. 2) point out '[t]he competitiveness of the industry cannot be assessed by looking only at the individual firms, but also at the broader set of institutions, infrastructures, and policies that influence the actions of companies, and – even more important – at the dynamic interactions between these levels of analysis'. These actors are linked together through a web of different relationships, which include almost pure market transactions, 'command and control' administrative rules, competition, collaboration, and all sorts of 'intermediate forms' (Gambardella *et al.*, 2000, p. 2). Modern economic thinking emphasises that firms need to collaborate and be part of a 'network' or 'cluster' rather than operate as stand-alone units. The pharmaceutical industry relies heavily on inter-linkages. The Maltese pharmaceutical industry (as with local industry in general) lacks the business sophistication that arises from inter-linkages and networking on a local level. As has been explained earlier in this chapter such a disposition to work together is generally lacking. Local pharmaceutical firms work with their overseas parent company (or other affiliates) rather than with each other. While, as has been noted, FDI has the merit of helping local

operations in remaining close to the markets and in facilitating the transfer of knowledge and technology, it also prevents them from cooperating with other local enterprises.

This research shows that very few local pharmaceutical companies collaborate with one another, even though Saliba (ICP) claims that ‘There is more collaboration taking place than meets the eye’. Giromini (Siegfried) notes that ‘Maltese pharmaceutical operators operate in silos. We are more interested in networking with foreign companies than among ourselves. We do not seem to trust each other’. As already mentioned in this chapter various interviewees note the role of the Chamber of Commerce in getting local operators in the pharmaceutical industry together. Seychell (Pharmadox) finds that collaboration within the Chamber of Commerce is weak as most members are importers and wholesalers of pharmaceuticals and not manufacturers. ME too realises the importance of collaboration and set up a ‘Generics Manufacturers Forum’, which brings together local pharmaceutical firms. ‘Key supporting agencies such as the Medicines Authority, Health Department, Utility Services are invited to attend the forum on an “ad hoc” basis’ (Galea & McKenna, 2004, p. 69). However, this Forum also serves more as a lobby group rather than an institution meant to foster collaboration between the sector’s enterprises.

Given the geophysical smallness of Malta, one would expect that local pharmaceutical enterprises have a unique opportunity to get to know each other well and explore possibilities of collaboration. As Saliba (ICP) puts it ‘Malta has a very small community and here people get to know each other at university, in the village and so on’. This even more so given as Galea Kenely (Starpharma) points out ‘Maltese operators are not really competing among themselves’. Seychell (Pharmadox) finds that living in a small community does not necessarily lead to increased collaboration, ‘[p]eople know each other and many are suspicious of the credentials of a person entering into a line of business such as pharmaceuticals. According to Saliba (ICP) however ‘[t]here is more collaboration taking place than meets the eye’. Zammit (Actavis) agrees stating that ‘[t]here is a lot of peer contact when we meet overseas during some trade fair or conference. Discussions are informal but a lot of information and experiences are shared’.

The local pharmaceutical industry has created few linkages through sub-contracting arrangements even though as Martin (Crystal) states ‘[w]e work very closely with local

suppliers'. Vella (Actavis) claims that '[w]e are definitely keen to pursue opportunities to leverage the local set-up. For example, printed matter is very important to our business so we are sourcing a good amount of it locally...we will only use local clusters when the cost, quality and service meet our expectations'. Although some contracting work is being conducted, there is little sharing of services and practically no joint initiatives. BEAT Consulting (2011, p. 11) find that '[s]uch linkages should be extended to include both intra- and inter-sectoral linkages, comprising industry participants from a local indigenous industry and locally established foreign direct investors operating in synergy through an effective technology transfer mechanism'. The 2010 Innovation Union Scoreboard ranks Malta thirtieth out of thirty-four countries in terms of the intensity of innovative SMEs collaborating with each other.

Debono (Alpha) points out that '[o]ur government needs to listen to all representatives of our industry and not just to foreign operators'. Schembri (Aurobindo) believes that the social partners, including the political parties, should undergo a reality check about the state of the industry in Malta, '[i]t is about time we start thinking strategically about the future of pharmaceuticals in our country'

### **5.7.5 Other RCDCs**

As already mentioned in this chapter, one of the resources that many overseas investors operating in Malta mention is the competence of the local workforce to communicate with foreigners, especially its ability to speak English. At times, this sounds clichéd but in reality, the local population has a long tradition of working with expatriates and this facilitates communication. Schembri (Aurobindo) notes that this is in sharp contrast with his company's experience in other countries, '[p]ractically 80% of the problems we face in our overseas plants arise out of poor communications'. Local manufacturers praise the work ethic, flexibility and productivity of the Maltese. Although these capabilities can be considered as a separate RCDC yet in reality they are also a characteristic of strategic flexibility which is not just the final outcome of the system but also a separate competence in its own right which is 'learnt' through experience.

Another reason which various interviewees (foreign ones) refer to is Malta's attractive tax system. Through the operation of the tax refund system, Malta offers one of the lowest effective tax rates in the EU. Malta operates a full imputation system that eliminates the economic double taxation of company profits. Maltese resident companies are subject to tax in Malta at the corporate tax rate of 35%, however, upon the distribution of dividends, the shareholders are entitled to a refund of the Malta tax charge (generally, 6/7th of 35% = 30%). The combination of the tax incentives, together with the tax refund system, generally results in an effective tax of zero to a maximum of 5%. Although such a 'resource' appears to be important, it is not considered as critical for the pharmaceutical industry in Malta. Tax incentives may improve profitability, but even without them, the pharmaceutical industry would have still thrived in Malta.

### **5.7.6 Strategic Flexibility**

The stimulus emerging from EU membership enabled the local economy to embark on new opportunities or grow existing ones that generally compensated for those economic activities, which membership itself (and/or globalisation) rendered uncompetitive. Pharmaceuticals are one such opportunity (others being, for example, financial services and internet gaming) which Malta has seized in the past decade. Practically, all the interviewees deem flexibility as a fundamental advantage of operating from Malta and many of them believe that flexibility is part of the local mind-set. Particularly interesting is the point made by Giromini (Siegfried) who praised the adaptability rather than just the flexibility of Maltese workers to emphasise that this is not purely a 'mechanical' but a conscious disposition to meet customer needs. It has already been noted that the flexibility and productivity of the local workforce in the pharmaceutical industry can be considered as an integral part of strategic flexibility. This arch-competence was built along the years and had helped local industries such as textiles and electronics to thrive before. When these industries moved to lower cost countries, some of their workers were re-trained and engaged by the pharmaceutical industry. Galea (Malta Enterprise) confirms that these workers '[w]ere given specific training by ETC so that they would be able to work in the pharmaceutical industry'. This flexibility is evidenced also by the way that local education institutions, especially the Chemistry Department at the UoM and MCAST adapted their curricula to meet the emerging needs of the pharmaceutical industry.

The capability of 'managing complexity' too is closely to that of strategic flexibility. This ability of the local pharmaceutical industry to produce a relative broad mix of products, specialising in short runs and fast delivery is a characteristic of 'near-shore' locations which make good for their higher costs by focusing on niche products and services. Zammit (Actavis) explains that '[l]ocal production costs are higher than in the other fourteen plants of our company across the world which, achieve lower costs due to standardisation; we are renowned for our flexibility and adaptability'. This means that the local operation competes with the Group's other manufacturing plants not on costs but on flexibility. Containing costs is important but not critical as the local operation is not expected to reap cost advantages from long runs and economies of scale. Short runs require frequent change overs and the time required in foregone production tends to be very expensive. This is especially so for bigger producers, since the downtime required to change from one SKU to another can vary from sixteen to twenty-four hours. Zammit (Actavis) concludes that '[a]lthough Malta has higher "conversion costs" than all the other plants of our company on a worldwide basis, it is unbeatable at changing from one product to another'.

Strategic flexibility is closely linked to market sensing and a customer-focus. 'Customer satisfaction represents a key business driver for Actavis thus providing its clients with an optimal service level. This is being achieved through the maximization of our operational flexibility' (Actavis, 2012a). Debono (Alpha) stresses the need of '[i]mproving our disposition to accommodate clients and be flexible' while Galea Kenely (Starpharma) notes that '[o]ur company has to stay in touch with clients so as to 'foresee problems' and be able to offer timely support'. The international market scenario for pharmaceuticals is changing at a rapid pace. Biopharmaceuticals are becoming increasingly popular. Continued fiscal constraints in Western countries are forcing governments to save money on healthcare so as to cope with ever-growing needs. Many governments are asking for smaller batches, especially of more expensive pharmaceuticals, to keep the cost of stocks as low as possible. Over the last decade, the EU membership has enabled the local pharmaceutical industry to grow and re-position itself on global markets. The industry changed its marketing moving away from dependence on aid-financed pharmaceuticals meant for poor countries to the development of generics meant for EU and global markets. This re-positioning of the pharmaceutical industry led to an impressive improvement in its turnover and value added. This shift over recent years ran in parallel to another 'structural' shift within the local

pharmaceutical industry itself, away from manufacturing to partial manufacturing and re-packaging operations. This shift negatively impacts gross value added and raises questions on the undercurrents within the local pharmaceutical industry and their impact on its longer-term competitiveness.

While it may be argued that such shifts reflect the very capability of the local pharmaceutical industry to adapt to changing global dynamics, they raise questions as to whether Malta is destined to serve as an assembly powerhouse for more technologically advanced countries in this sector also? Most interviewees agree that the basic rationale for the pharmaceutical industry in Malta is not to be found in R&D but in exploiting opportunities created by patent law and in producing ‘niche’ pharmaceuticals. The fact that few medical patents were registered in Malta prior to the EU membership (due to its small domestic market) opened an opportunity window to work on developing their generic equivalent before the actual expiry of the patent, as envisaged under the Bolar exemption. This enables a number of local pharmaceutical companies to specialise in what is referred to as ‘patent’ or ‘novelty’ launches, whereby generics are air-freighted on the eve of expiry of a patent to permit the earliest possible pipeline filling. This brings ‘first-mover’ benefits which arise from the capability of an enterprise to capture a significant market position by being first on the market. It is to be noted that a patent generally does not expire on the same date in every country and this enables Maltese suppliers (or their clients) to move from one market to the other to exploit in full this ‘first-mover’ advantage.

‘Patent launches’ often result in a competitive advantage which lasts for about six months. It is likely that within this period, competitor products enter the market and any price advantage will be significantly reduced, if not completely eliminated. A typical local operator does between thirty and forty new launches in a year. Many of these operators talk about becoming a ‘one-stop’ shop, offering a customised, complete and flexible service. Apart from all the necessary certification and regulatory procedures, local companies are able to prepare and file house documents (a mandatory five years) as well as sample retention (required for the lifetime of the product). Local operators are building expertise in ‘patent opportunities’ and carry extensive research to determine which patents will expire, when and where. This specialisation in ‘regulation’ has been facilitated by the fact that English, the language of the pharmaceutical industry, is also an official language of Malta. Perceiving the opportunity,

and moving flexibly and fast to become ‘first movers’ in a particular market upon the expiry of a patent underlines the competitive advantage of the local pharmaceutical industry. The pharmaceutical industry in Malta manifests significant strategic flexibility as it continues to morph to adapt to global changes, both at the industry and enterprise levels. This strategic flexibility does not necessarily lead (in the short term) to superior performance, as evidenced by its falling value added.

Table 13 shows the key findings of this research with regards to the arch-RCDCs identified in the alternative framework for the superior economic performance of small states.

Arch-RCDC	National Level	Industry Level	Enterprise Level
Market Sensing	Impact of EU membership on Malta's public policy & societal resources. Access to EU & global markets	Transposition of EU legislation relating to pharmaceuticals. Inflow of FDI key for market sensing	Parent (or alliance with foreign partners) dependent. Patent specialisation leads to market sensing, Visits to international fairs & conferences
Change Management	Commitment of local political parties to EU membership post 2003 elections	Industry essentially export-oriented and posed little threat to powerful importers group. Medicines Authority key driver of change with support from other local institutions (ME, education etc)	No real resistance within enterprises to change process given the commitment of top management. This is true also for Actavis the leader of the industry.
Knowledge Capacity	Minimal R&D activities	Long tradition in pharmacy and law. FDI main channel for importing know-how. Build-up of knowledge in public sector slower. Lack of a deliberate policy reflected in struggle to improve supply of HR and upgrading infrastructure	Actavis served as the cradle of the industry. Local operators dependent on parent company, except for 'patent launchers' which exploit legal knowledge
Alliance Capability	Malta's own form of democratic corporatism-MCESD & MEUSAC	Little beyond some joint lobbying. Some inter-linkages with local suppliers.	Local operators are stand-alone units with close collaboration with foreign partners (mostly parent companies)



Other RCDCs?	Taxation?	Adaptability and productivity of local workforce (strategic flexibility?)	
Strategic Flexibility	EU membership (and globalisation) required deep economic restructuring. The country quick to adapt and renovate	Significant growth and upgrading of the local pharmaceutical industry. Flexibility and fast response underpin its competitiveness in ever-changing EU and global markets	Continued transformation of local pharmaceutical enterprises to adjust and tap opportunities arising from changing market conditions

**Table 13: Key Findings as per Alternative Theoretical Framework for Small States' SEP**

*The findings of the research confirm Malta's credentials as an 'open system' and highlighted the impact of EU legislation on the development of societal institutions and public policy related to the Maltese pharmaceutical industry. The sector performance shows that after that the Maltese pharmaceutical industry registered high growth in the immediate period following EU accession. This growth has been slowing down especially in terms of output and gross value added. At the same time the level of exports has continued to rise reflecting a continued restructuring of the industry. The findings of the field research also show that Malta has built a competitive advantage in generics. While EU membership was of utmost importance in creating the right operating environment for generics, what proved to be fundamental for the growth that followed was international patent law. FDI also played a critical role in the development of the pharmaceutical industry. Malta's market sensing in this case study was boosted by EU membership at the sector level and by FDI at the enterprise level. In terms of change management, at the national level EU membership accepted by practically all of society and given the export-orientation of the Maltese pharmaceutical industry there was little resistance to its continued growth. Even at an enterprise level there was full commitment by top management to make the best out of the opportunities that EU membership offered.*

*At the time of the EU membership, Actavis incorporated much of the local pharmaceutical manufacturing knowledge base. This base rapidly expanded through the inflow of significant FDI. The relevant EU directives were included in the Medicines Act (2003) which set the stage for the industry's expansion and increased awareness (and knowledge) about the industry within the public sector. The lack of a deliberate strategy resulted in some institutions, and in particular education, being unprepared for the specific needs of the pharmaceutical industry. The propensity of societal organisations, including enterprises, to work together (as well as with external agents) to achieve common goals is captured in 'alliance capability'. The research shows that the Maltese lack a culture of working together but compensate for it by a high propensity to collaborate with foreigners. As a result, there are practically no inter-linkages at the industry level, with the umbilical cord for enterprises being attached to their parent company. Malta's own type of 'democratic corporatism' is evidenced within its MCESD. All interviewees agreed on the importance of flexibility for the local pharmaceutical industry. This has enabled enterprises to specialise in short runs and*

*fast delivery. This ability to manage complexity enables local enterprises to avoid competing just on costs. This competitive advantage is further enhanced through 'novelty launches' as well as 'batch release' of imported medicines (mostly from Asia) unto EU markets. The continued restructuring of the pharmaceutical industry in Malta reflects this consistent search for new opportunities, which if success ultimately manifests itself as strategic flexibility.*

## 6. Discussion and Conclusion

*The final chapter revisits the research problem in the light of the main findings of the thesis and includes an extensive discussion on how these relate to the superior performance of small states. Some conclusive considerations are then made with regard to this experience, along with broader implications for policymakers and entrepreneurs in small states. Specific answers to the research questions are given and an outline of the contribution of the research is made.*

The lack of an agreed definition has not helped in understanding the key issues facing small states (Neumann & Gstohl, 2006). Easterly and Kraay (2000) note that the theoretical study of small states has been plagued by definition problems. Prevailing models of the state, sovereignty and economic systems, themselves ‘contribute only in a limited way to our understanding of the internal dynamics and external relations of micro-states’ (Warrington, 1994a, p. 128). This research indicates that small is a polymorphous construct (Thorhallsson & Wivel, 2006), a comparative term (Sanders, 2005) and that irrespective of the criterion used, it will always be subjective and arbitrary (Thorhallsson & Wivel, 2006). Bailes (2011, p. 2) observes that ‘a state is “small” when it feels and acts small’. Warrington (1997a) sees ‘micro-states’ as a complex association of a demographic, geographic or economic scale with political autonomy.

Matters are further complicated by the fact that ‘the borders between such categories as ‘micro state’, ‘small state’ and ‘middle power’ are usually blurred and arbitrary’ (Neumann & Gstohl, 2004, p. 6). The point at which a boundary is drawn around the category ‘micro-state’ is an entirely arbitrary matter determined by an implicit but generally held assumption about the ‘ordinary’ size of states (Warrington, 1994b). Issues arising out of ‘smallness’ have many times been intertwined and confused with those arising out of geophysical considerations (especially location and ‘islandness’), statehood (including sovereignty and jurisdiction) and the level of economic development (Neumann & Gstohl, 2006). Hache (1998, p. 49) notes that ‘Islandness is often treated as the critical determinant factor rather than small size per se, primarily because most small states are also island or archipelagic’. There is general consensus that many of the issues encountered by small island states are similar to those of smallness in general (Read, 2002). Newitt (1992, p. 16) asserts ‘[n]ot all small states are

islands and not all island states are small; but the problem of “smallness” is given an added dimension in the case of an island’.

Small states are faced with two forms of economic challenges: the first are inherent and largely fixed (arising from peripherality, smallness and islandness), while the second are contingent, emanating mainly from governance practices (Prasad, 2008). Armstrong and Read (2003, p. 111) argue that the key economic growth challenges facing small states are primarily because of their size and not their topography: ‘Islands, land-locked and littoral small states therefore need to be regarded taxonomically as separate and distinct sub-sets of small states in general, with the island and land-locked sub-sets possessing specific additional problems arising from their isolation’. Generally, the size of population is taken as a proxy for a range of other economic characteristics, all of which are deemed to bestow particular vulnerabilities on small states (Heron, 2008). Both the World Bank and Commonwealth Secretariat use the ‘population principle’ to categorise states (Misra, 2004). Small states have been defined from 1 million to 20 million and over, with different cut-points in between (Tonurist, 2010). In the 1950s and 1960s, a small state was perceived as having from 10 to 15 million people. By the 1980s, this had fallen to 5 million and by the 1990s, it had dropped to 1–1.5 million. Crowards (2002) suggests that the threshold levels were modified downwards to avoid classifying most states as small. The World Bank (2008a, p. 5) suggests that ‘the size of countries can be ranked along a continuous scale’. Members of the WTO, in the context of their on-going debate on small economies, associate smallness with a country’s share of world trade. UNCTAD (2007) classifies 92 countries as being ‘structurally weak, vulnerable and small economies’ and it too uses a country’s share of world trade as one of the proxies for small size. UNCTAD notes that by itself, a country’s share of world trade ignores the importance and potential of the ‘non-tradable’ segment of its economy and proposes that it may be more relevant to consider relative prices that a small state fetches for its exports.

Due to the lack of an adequate definition of a small state, this research had to formulate its own parameters of what constitutes ‘smallness’. It proposes the concept of an ‘open system’ which essentially brings together two elements: the relative lack of economic power and a population which is less than 1.5 million.

A second key consideration in the study of small states is whether this is still relevant in a globalised world (characterised by a relative decline in the supremacy of the nation-state) and a post-industrial economy (which is not so dependent on mass production and mass markets). Historically, small states were looked upon favourably. Greek philosophers emphasised the benefits of small and homogeneous polities. 'Aristotle argued that a polity should be no larger than a size in which everybody knows personally everybody else' (Alesina, 2003, p. 303). The experience of small European 'illustrates a traditional paradox in international relations concerning the strength of the weak' (Katzenstein, 1985, p. 21). The success of some small states in achieving economic growth has stimulated interest in them (Armstrong & Read, 2003b, p. 99), and they should be treated as a special case of development paradigms (Karunasekera, 1994).

There is no consensus on what is special about small states. Some argue that nothing is special in being small, while others claim that size is an important factor. Other analysts suggest that what matters most is isolation (The World Bank, 2008a). Read (2002) concludes that location rather than smallness or isolation per se should be considered. Alesina and Spolaore (2003) perceive the ideal 'size' of a state as a trade-off between the benefits of size and costs of heterogeneity. The benefits of size relate to economies of scale in the provision of public goods and policies, larger domestic markets, interregional insurance and redistribution. The costs stem from significant differences in cultural, religious, linguistic or economic factors that may lead to different individual choices with regard to public goods and policies. A big state can spread the cost of producing public goods across more people, thus reducing the cost per capita; however, the larger the nation is, the less homogeneous its population becomes, giving rise to more complex interests and conflicts.

As globalisation advances, the benefit of having a large domestic market diminishes, with the trade-off between size and homogeneity shifting in favour of the latter. The risks arising from small state instability are probably the most important factor militating against their development (Wint, 2002). Diversification is viewed as a strategy to reduce risk (Thomas & Pang, 2007). The search for diversification in small states affects the mind-set of individuals as well as households (Guilmoto & Sandron, 2001). Aubert and Chen (2008, p. 179) propose that the small island mentality emphasises 'economic survival, and along with this survival instinct, a pragmatic attitude of doing whatever it takes to stay economically competitive'.

‘Occupational multiplicity’, common in small islands, is a natural survival strategy and a characteristic of areas where employment opportunities are scarce, precarious and seasonal. ‘The involvement in diverse activities enables an intensive use of scarce management skills and provides a measure of security, or fall back, in the event of failure’ (Baldacchino, 1998, p. 274). Streeten (1998) criticises small states for harping on their handicaps and vulnerability to get increased aid flows and more advantageous trade concessions. Vulnerability to external forces is, according to Warrington (1997a p. 102). ‘both a bleak reality and a useful device for gaining leverage with external partners’.

Autonomy is a valuable, adaptable asset that can pay handsome dividends if used astutely; a microstate’s ‘governing wits’ may well compensate for the economic, demographic, cultural and political disadvantages that are legitimately associated with small scale (Warrington, 1997b, p. 105). Small states have been assisted by international organisations, notably UNCTAD, the Commonwealth Secretariat and the UNDP, in proving that they deserve special consideration (Fairbairn, 2007, p. 133). Between 1993 and 2004, the per capita aid received by small states (US \$210) was almost 17 times that received by all developing countries (US \$12). Also, whereas official development assistance is almost 15 percent of gross national income in small states, it accounts for only one percent for other developing countries (Favoro & Peretz, 2008, p. 275). That small states seek to capitalise on their perceived weaknesses to further their trade prospects is widely accepted. Yet, they also face a number of structural disadvantages. As Jones and Birkbeck (2011, p. 1) point out, ‘[s]mall states live with a paradox when it comes to trade negotiations. They depend on international trade to a greater extent than any other group of countries, yet they have the weakest voice when it comes to influencing the rules that govern trade’.

Small states have little to offer negotiating partners through market access concessions, their institutional negotiating capacity is limited as they have few trade negotiators and inadequate budgets and they may at times be subjected to coercive threats by more powerful states. Some small states have joined, or are considering joining, supra-national regional blocs to address some of their ‘size’ limitations. Quoting Michael McVey, a UNWTO consultant, Scheyvens and Momsen (2008, p. 495) say that ‘[s]mall island communities tend to have an exaggerated sense of independence and self-importance’ and that it is unrealistic of small island states to expect to control their own destinies.

The concept of 'governed interdependence' (Weiss, 2000) is also of relevance to an open system. Proximity is not only geophysical but also 'relational' as most social players tend to know each other well. 'Relational' proximity arises from the greater and faster impact of decisions and actions by one social player on the rest of society. This tends to impact the distribution of power, which as shall be argued later when discussing impacts on how an open system reacts to external change. Developing an 'alliance capability' (including a disposition to work together and network) is perhaps the biggest cultural challenge facing an open system'. Given these proximity considerations, the politico-socio-economic framework of an 'open system' has to be seen holistically, as this makes it bigger than the sum of its components. In today's intensely competitive and globalised world, 'alliance capability' is an arch-RCDC which reflects the propensity of the units of an open system to work together in pursuit of their goals. Strategic alliances enable an open system and its various sub-systems to create and share key externalities which are unique 'societal resources' and hence, difficult for international competitors to imitate. But, as this research's case study finds, the scope of such alliances in an open system are not limited to local players but includes their teaming up with others overseas.

'Alliance capability' creates an additional dimension to other RCDCs by stimulating trust, reducing uncertainty and improving the speed and quality of decision-making. The literature on small states typically argues that in the era of 'globalisation', it still makes sense to analyse the 'smallness' of states. Differences between small and large countries are real, even though researchers have contradicted each other as to whether 'small states differ from larger states on economic, social and political factors' (Bräutigam & Woolcock, 2002, p. 187). The study of small states is an exercise in diversity. While small states differ from one another, they share enough characteristics to make their separate study academically interesting and of practical interest. Small states are 'simply too numerous and-sometimes individually, but certainly collectively-too important to ignore' (Neumann & Gstohl, 2006, p. 3). This research finds that understanding 'smallness' is important not so much to find ways to 'offset' their perceived vulnerability, but rather because small states face similar challenges in achieving a superior economic performance.



Globalisation and post-industrialisation create new opportunities and threats for small states. The changing scenarios call for a new mind-set by politicians and policymakers; one which emphasises creative thinking and a can-do attitude rather than vulnerability as was the case in the industrial era. It is unfortunate that a large part of small state studies has been conditioned by the weak, powerless perspective emanating from international relations. Equating 'smallness' with 'vulnerability' was natural at a time when mainstream economics projected industrialisation, with its dependence on urbanisation, big populations and large-scale manufacturing, as the primary path towards economic development. The vulnerability approach has been criticised for perpetuating a 'dependency' culture which negatively impacts the developmental efforts of small states. Discourse on fragility and vulnerability suggests that small societies cannot do without assistance from outsiders and this adversely affects the self-esteem of small states and stifles their initiative (Scheyvens & Momsen, 2008). The vulnerability mindset inflicts 'lasting damage on people's images of themselves and on their ability to act with relative autonomy in their endeavours to survive reasonably well within the international system' (Hau'ofa, 1994, p. 152). Later, the pursuit of resilience to offset vulnerability started to be seen as the primary challenge facing small states. The resilience school assumes that the origin of vulnerabilities is exogenous and mostly determined by international economic conditions, whereas the capacity to adapt is internal and dominated by socio-psychological traits (Baldacchino & Bertram, 2009).

Resilience studies stop short of explaining why some countries manage to have better governance and policymaking capabilities than others. They adopt a static approach as small states rarely have a preferred, steady-state position to which they want to return after 'turbulence'. The dynamism of real life obliges a small state to consistently seek to develop its economy to offer a better way of life to its citizens. The vulnerability paradigm is condemned as being a version of structural determinism. 'The presumption that constraints of small size and geographical separateness render small economies particularly economically "vulnerable" is both conceptually and empirically unsatisfactory. Conceptually, there are advantages as well as disadvantages to being small and isolated' (Baldacchino & Bertram, 2009, p. 146).

This research literature review highlights a number of key considerations:

- Practically all approaches confirm the importance of specialisation. The key questions which emerge relate to the ‘nature’ that this specialisation should take, how it can be achieved by a small state and what type of terms of trade will it generate.
- The shift from comparative to competitive advantage. This suggests that in today’s globalised environment, specialisation does not necessarily result from inherited resources but from created ones.
- The need to distinguish between economic growth and development, with the latter being closely associated with the capacity to ‘sustain’ competitive advantage.
- There is no single definition of a small state or a small economy and new perspectives and emerging economic scenarios call for a re-definition of ‘smallness’.
- The importance of good governance. While the government is still expected to play a primary role, an increasingly complex operating environment calls for a higher propensity to ‘work together’ with the other social partners.
- Increasingly dynamic environments call for theoretical explanations that go beyond a static and equilibrium-seeking analysis.

Katzenstein (1985, p. 79) notes that ‘[t]he industrial adjustment strategy of the small European states stresses specialisation in export markets’. Given the smallness of domestic markets, it is logical to expect that ‘industrial’ specialisation be export-oriented. However, this tells us little about the ‘nature’ that this specialisation should take. Exports have to face international trade rules and the dynamics of international markets. Specialisation in an open system is a complex phenomenon. Specialisation leads to increased knowledge and innovation and determines the ability of an open system to engage in higher value activities, thereby improving productivity. High-tech activities are not synonymous to high-value added. Politicians and policymakers are fascinated by hi-tech ventures and tend to ignore the potential of conventional ones. What matters is not the economic sectors in which a country competes, but how it competes (Porter, 1998). In an open system this inevitably relates to the quality of human resources available. Lifelong learning and on-going training programmes are essential if an open system is to anticipate/adapt to the change emerging from global markets. The demands of the global economy require that strategies incorporate human

resource development into larger economic strategies (The Asia Pacific Economic Co-operation, 2011)

Another popular misconception regarding value added is that it results automatically from bigger factories, increased automation and longer production runs. In the post-industrial era, value creation results from innovation and strategic marketing, which add extra value for customers. 'Niche' activities appear to be more appropriate for an open system. Niche marketing involves designing and producing goods and services meant for specific, often secondary, market segments. These activities are profitable due to the benefits of 'focus' (as per Porter's generic strategies) and specialisation. The strategies generally demand a level of business sophistication which is not easily available in an open system. The contribution of 'specialisation' in a small economy changes along the economic development path. The lack of 'economies of scale' has to be off-set through 'economies of scope'. At the factor-driven stage, the primary impact of specialisation is in creating additional value through vertical and horizontal diversification.

At the efficiency-driven stage, its main contribution is in building absorption capacity, including technical know-how, which enhances operational effectiveness. At the innovation-driven stage, specialisation generates knowledge (including technological know-how and marketing) which enables enterprises to carve unique market positions and reap higher returns. Another key consideration that is often overlooked by small state studies relates to risk minimisation. In an open system, this is an equally desirable public policy objective as high economic growth. The growth and development path of small states faces greater risk because of their size (UNCTAD, 1988). According to Wint (2002), the risks arising from small state openness is probably the most important factor militating against their development.

Given the limited number of economic activities that can be undertaken in an open system, concentrating on a 'narrow' set of economic activities implies that, should things go wrong in a particular sector, this will have an unduly high impact on the rest of the economy. This, for example, has been the experience of small states such as Mauritius, whose economy was unduly dependent on the clothing sector. When this sector collapsed due to a number of factors, including changes in global textile trade rules, the country suffered a severe setback,

which affected the standard of living of many people. Guilmoto and Sandron (2001, p. 137) state that the '[l]ack of proper information and perceived high risk induce small states to prioritise diversification rather than specialisation which may prove too onerous in a time of crisis'. Diversification implies a trade-off with specialisation. The danger with too much diversification is that it may lead to too many low-value economic activities with no linkages or synergy. Having such a 'fragmented' economy, producing a broad array of goods and services, is no blueprint for an open system competing on global markets.

Strategic management is critical for an open system. As Deloitte Consulting (2008) notes, it involves finding the right balance between 'profit' maximisation and 'risk' minimisation. Given the importance of these two objectives, the solution for an open system is to try to seek 'diversification within specialisation' (This is not to be confused with flexible specialisation which is essentially a production structure involving a number of smaller units.). Such an economic strategy entails specialising in a few sectors while ensuring that there is a sufficient range of diversified activities within each sector. Equally important is the development of inter-linkages between the economic sectors themselves. Given that an open system generally has limited possibilities of vertical integration, it needs to promote 'horizontal' integration. If an open system wishes to develop, for example, its agriculture and tourism sectors, it should ensure that the agricultural produce is diversified and feeds the local tourist industry, rather than cater to export markets. A further critical deliberation relates to 'market power'. By definition, an open system has insignificant, or no market power, on international markets.

R-A theory perceives market power as arising from the 'unique resource assortment' of the enterprise/state, which enables it to command an 'advantageous' market position either in terms of lower costs, higher customer value or both. Business studies conceive market power as arising from 'supply' and/or 'demand' factors. Supply factors generally relate to advantages due to 'natural' monopolies, resources and competencies, economies of scale, technological (process) sophistication and product innovation. Demand advantages arise mainly through strategy and the manipulation of market structures. In economics, 'market power' is normally associated with the performance of enterprises; but countries too are able to exert power on international markets as they use trade policies to enhance their own welfare (Tasdogan *et al.*, 2005). Armstrong and Read (2002, p. 436) note that having market power seems to be 'the minimum criterion for a large country rather than a means to classify

small states as a distinct group'. The point made by Armstrong and Read is more practical than theoretical and their reservations can be overcome by conceiving 'market power' as a dynamic concept along a continuum rather than a static one determined by some threshold below, which a country has no 'market power' at all. International economics perceives 'market power' as being reflected in the 'terms of trade' of a country. The terms of trade are the ratio of export prices relative to import prices. It indicates how much a country can obtain in imports per unit of its exports. An increase in purchasing power from a rise in the terms of trade is obtained by comparing real GDP with real gross domestic income (GDI).

For any given pattern of real output and expenditure, a rise in the terms of trade will directly impact the trade balance and current account position. Assuming no changes in quantities, higher export prices will generate an increase in export earnings and thus, an equivalent shift in the trade balance. Brissimis and Kosma (2005) remark that the impact of the exchange rate (which at a national level is a type of 'price of prices') on a firm's market power remains largely unexplored. When the exchange rate changes, a firm may choose to pass the cost shock fully onto its selling price (complete pass-through) or absorb the cost shock and keep its selling price unchanged (no pass-through), or some combination of the two.

Katzenstein (1985) finds that large industrial states tend to export the costs of such changes, while small European states tend to absorb them. By definition, an open system lacks a significant degree of market power. It is, of course, possible for a small state to achieve a high degree of market power. (Luxembourg, with its specialisation in financial services, is a clear example. Vatican City, despite its physical and demographic smallness, is one of the most influential and well-off states in the world). There is no appropriate measure which captures the market power of different countries in a meaningful way. (The terms of trade indicates how a country is doing over a period of time and does not directly compare the performance of different countries). Ideally, such a measure should also differentiate between 'temporary' and 'sustainable' market power.

There are hypothetically three sources of national market power on the global market and these arise from,

1. Portfolio investment held overseas in a particular industry. This type of market power though important tends to be limited and of little value from a decision-making viewpoint.
2. The level of exports and degree to which a state (and its enterprises) can influence prices (an enterprise through its 'ex-factory' prices and the state through the exchange rate).
3. Knowledge and capital transfers. This is the most 'sophisticated' and sustainable form of market power, and is usually in the form of FDI, franchising, licensing and management contracts.

The global market is generally characterised by oligopolistic structures that generate various forms of 'market power' (Sweezy, 1999). Although there have been attempts by some developing economies to achieve market power through branding (such as Jaffa oranges and Chiquita bananas) or 'cartelisation' of primary products (OPEC in the 1970s), their success has been limited and short-lived. An open system at the factor-driven stage is generally unable to influence the price of its exports. Small states dependent on the export of primary products are very sensitive to fluctuations in their earnings and their fortunes vary with demand in the world markets. Historically, the prices of primary exports are on a downward trend relative to those of manufactured exports.

At the efficiency-driven stage, an open system is still a 'price-taker'. At this stage, it will retain a greater share of the value being created, through higher wages and possibly increased taxation. Efficiency-driven economies tend to push their exports through operational effectiveness and lower costs. It is only at the innovation-driven stage that significant business sophistication enables enterprises to influence, if not determine, the prices they fetch for their goods and services. (When this happens, one of the defining characteristics of an open system is lost and that economy although 'small' would have achieved a high level of market power). High dependence on the international business of an open system makes the strategic management of its interface with the rest of the world critical. Openness can be as much a blessing or a curse. Rodrick (1999) points out that

- Openness by itself is not a reliable mechanism to generate sustained economic growth  
Openness is likely to exert pressures that widen income and wealth disparities within countries

- Openness leaves countries vulnerable to external shocks that can trigger domestic conflicts and political upheavals.

Economic integration has been indicated as a possible path for a small state to offset the limitations of its size. But economic integration is no easy solution and it too needs to be properly managed to benefit a small state. Small states which opt for economic integration need to ensure that membership benefits their competitiveness and economic development. The pragmatism and focus which such a strategic choice demands is not easily forthcoming from political leaders of small states who usually prefer grander schemes. The primary research finds that the impact of the EU membership on Malta is similar to that of a big pebble thrown in a small pond—there were multiple ripple effects which at times re-enforced, and at others, worked against one another. Economic integration comes at a price as it reduces the flexibility of an open system and has to learn to live with directives not tailor-made to its requirements. Given the increased uncertainty created by political, economic, social, technological and environmental changes, ‘policymakers in the 21st century need to adopt a proactive mind-set rather than a reactive cognitive one’ (Chareonwangsak & Kitthananan, 2009, p. 3).

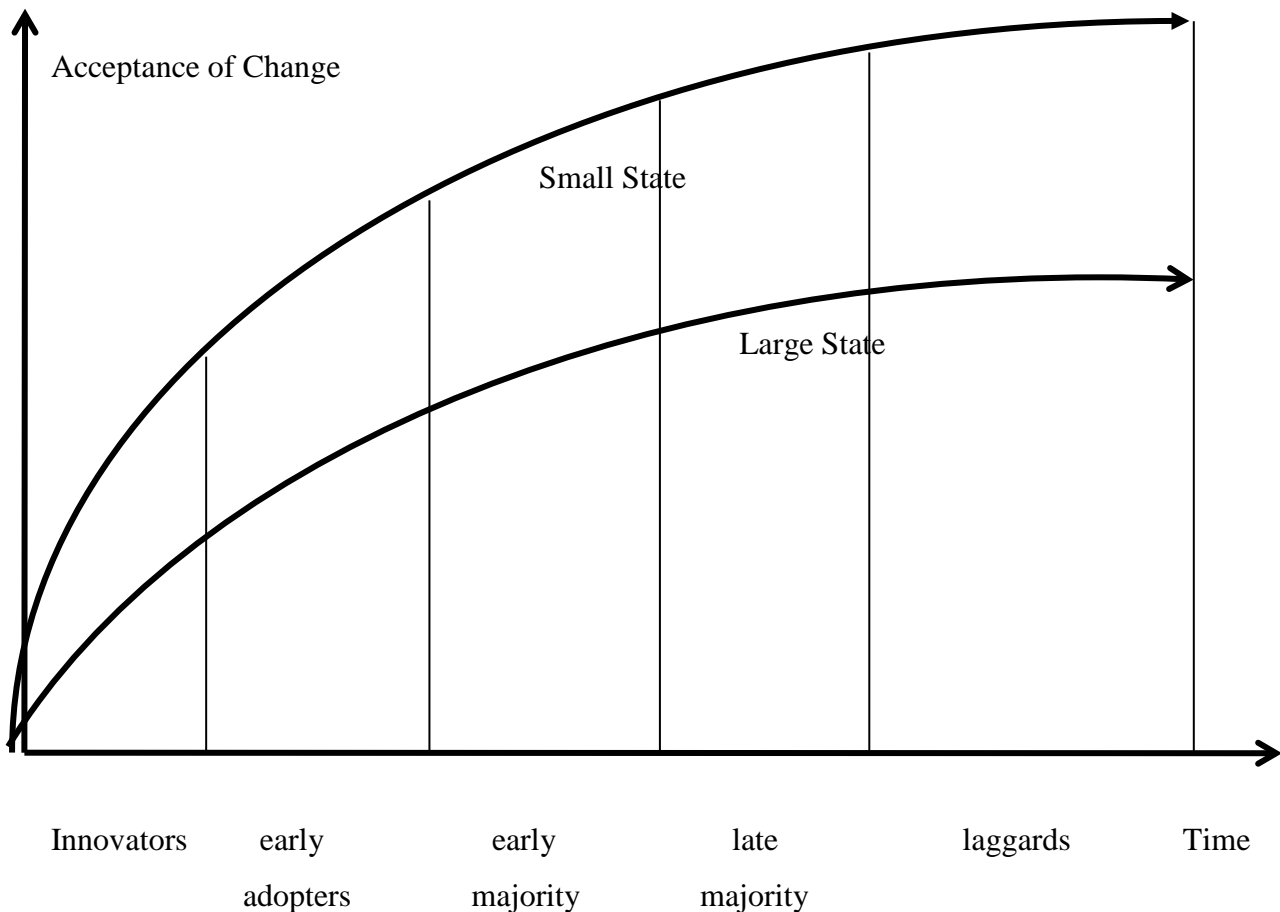
Globalisation brings new opportunities as well as changed risks, and ‘a more integrated global economy may enable smaller, more ‘nimble’ states to adapt quickly to changing conditions and more readily to identify and pursue strategic development policies’ (Bräutigam & Woolcock, 2002, p. 185). Small states are more flexible and adjust quickly to change (Bräutigam & Woolcock, 2002). Katzenstein (1985) finds that small European states adjust to economic change through a carefully calibrated balance of economic flexibility and political stability, combining international liberalisation with domestic compensation. How fast an open system anticipates, or adjusts to, exogenous change depends on its ‘propensity to change’, of which leadership and the power structure are two major determinants. Finkelstein (1992) notes that power management is a key factor that impacts and shapes strategic flexibility. Change externally triggered is likely to have a significant impact on the politico-social fabric of a small state. Stakeholders tend to have a different perception of change, and they interpret and react to it in diverse ways. Stakeholders who believe that their power and/or vested interests are threatened by change will do their utmost to resist it. This leads many political economists to emphasise the importance of involving all stakeholders in

managing the change process. Governments find it increasingly hard to find the political power to transform economies on their own and need the support of the social partners.

The politics of a large-scale system tend to be more complex as they add elements and problems not characteristic of simpler systems (Kanter, 1997). This appears to be one possible explanation as to why an open system is better able to manage the change process. Fonseca (2002, p. 8) observes that in a dynamic environment, states are constantly learning and creating knowledge as they respond to ‘gestures made by other states and other participants in complex responsive processes’. Given that an open system constantly faces exogenous change, it tends to improve its capability to deal with change through a process of ‘learning by doing’. Katzenstein (1985, p. 44) finds that ‘political leaders in the open economies of the small states are ... accustomed to accept as normal rates of economic change and dislocation that elites in large countries regard as intolerably high’. He adds that for the small (European) states, economic change is a fact of life, and that their economic openness and domestic politics do not permit them the luxury of long-term plans for sector transformation. ‘Their strategy is flexible, reactive and incremental as they continually improvise in living with change’ (Katzenstein, 1985, p. 24). On the negative side, a relatively small change on international markets can trigger strong enough forces that impact significantly on an open system. March (1991) points out that if organisations are to be successful, they need to maintain a proper balance between exploration and exploitation. Moving too slow or fast entails a risk which a small state cannot afford.

Shimizu and Hitt (2004, p. 45) remark that ‘[a]bandonment of an initiative too quickly because of initial problems may result in the loss of a large future potential benefit, while overly strong commitment to a money-losing project can only exacerbate problems’. The importance of an open system determining the strategic logic of its economic activities has already been noted and its relevance is further emphasised by the need to find this ‘right’ balance. At any point in time, too much flexibility could jeopardise the identity, RCDCs building programme and longer-term competitive advantage of an open system. Figure 27 builds on Rogers’ innovation adoption curve to graphically show how an open system differs from a large state in accepting and adapting to change.





**Figure 27: Acceptance of change by large and small states**

Finding the right balance between exploitation and exploration conditions the ability of an open system to achieve strategic flexibility. Strategic flexibility is both an arch-RCDC which permeates throughout the open system as well as a feature of its output; it is a dynamic capability in its own right as well as an outcome of other dynamic capabilities (Combe & Greenley, 2004). Staying flexible in strategic terms is not equivalent to jumping from one strategy to another, but implies a continuous transformation and incorporation of new ideas that maintains operational effectiveness while encouraging innovation. Achieving competitive advantage is a ‘war of movement’ not a ‘war of position’ (Ohmae, 1982). Movement requires that entrepreneurs identify new opportunities to consistently re-define competitive advantage. (This is consistent with R-A theory which perceives competitive dynamics to be dynamic and disequilibrium provoking).

The case study finds that the strategic thrust of the pharmaceutical industry in Malta is more ‘emergent’ than ‘deliberate’. Many of the international enterprises setting up operations in the

country find their own path on how to take advantage of existing opportunities. The Maltese pharmaceutical industry operates at the efficiency stage, and its profitability is heavily reliant on operational effectiveness rather than innovation. Efficiency in an open system assumes a different dimension than that projected by conventional competitiveness reports. In a small states, efficiency arises out of adaptability, speed, agility and responsiveness that make it possible to identify niches such as ‘managing complexity’ rather than exploiting economies of scale through mass production. Relatively higher unit labour costs in Malta (compared to most East European and Asian countries) are offset through a specialisation in short runs and fast delivery. The little market power available to local pharmaceutical enterprises arises from the ‘temporary’ opportunity window arising out of international patent laws. Only one firm, ICP, undertakes research in Malta, which can be considered as being innovative rather than a part of a quality assurance programme.

A report by the United Nations (2006, p. 31) asserts that ‘access to appropriate technologies remains crucial for the sustainable development of small island developing States’. The knowledge capacity of an open system provides the framework within which local know-how and technology develops to support economic activities and includes the capability to absorb, adapt and develop imported knowledge. Criscuolo and Narula (2008, p. 56) hold that national absorptive capacity and the accumulation of knowledge stock are simultaneously determined. This implies that different phases of technological development require different strategies, ‘During the catching-up phase, knowledge accumulation occurs predominately through the absorption of trade and/or inward FDI-related R & D spill-overs’. Imported goods embody technological know-how, ‘countries can acquire foreign knowledge through trade and increase their growth rate through trade liberalization’ (Schiff & Wang, 2008, p. 1). Openness renders a small state receptive to new products, trends and values thereby facilitating the familiarisation, absorption and possibly adaptation of technology. Familiarisation with foreign technology through international trade, however, does not automatically mean that that technology can easily be exploited for production purposes. Economic integration too may facilitate access to technology, but ultimately what matters is the ability of an open system to absorb that technology and make it part of its own pool of knowledge. For this to happen, an open system needs to have the right institutions and supporting public policies in place.

This research concludes that the knowledge capacity of an open system is an arch-RCDC as it impacts other RCDCs and conditions the ability to exploit opportunities emerging from the international market. This has been the case of the pharmaceutical industry in Malta, even though knowledge is driven by a legal competence in patents rather than conventional R&D. This study also highlights the excellent market-sensing capabilities of the Maltese. Although they generally lacked the resources and competencies associated with the pharmaceutical industry, they were quick to sense the opportunity arising out of EU membership. The Maltese have a history and reputation in trading and these market sensing capabilities were nurtured over the ages. Traders cultivate a unique sense of ‘opportunity’: under the rule of the Knights of St. John, the Maltese thrived on piracy. The opportunity of operating in a ‘patent free’ EU environment permits the pharmaceutical industry in Malta to overcome all other operational disadvantages. The EU membership facilitates access not only to the vast single European market but also to other key markets around the world. Membership also provides a certificate of legality and respectability for pharmaceutical enterprises operating from Malta. FDI originating from many parts of the world (Switzerland, India, Italy, Spain, Iceland, the United States and Palestine) provides technology, manpower and other resources, which are not readily available locally. FDI helped ‘circumvent’ local limitations and enabled enterprises to find a niche on the global market.

Actavis, the industry’s first and largest pharmaceutical venture, lobbied for Malta to obtain conditions favouring generics in the country’s pre-accession negotiations with the EU. ICP, the other pharmaceutical operator at the time, favoured an operating environment that would have facilitated the setting up of other originator companies, but it lacked the power of Actavis. Once Actavis’ desires were met, ME worked hard to induce other foreign enterprises to branch their generics operations to Malta. Ventures set up locally by FDI combined enterprise-specific ‘market sensing’ capabilities with technological and management know-how. Both the EU and FDI served as change agents, which helped ‘short-circuit’ the development process of the pharmaceutical industry in Malta. Above all, they facilitated the sourcing of specialised personnel, which was not readily available in the country. The field research also shows that innovation in a small state is not necessarily driven by business sophistication grounded in technology. In the case study, innovation arises from a unique market sensing capability; one which favours ‘exploration’ rather than ‘exploitation’. Market sensing is evidently closely associated with entrepreneurship in an open system. The local

pharmaceutical industry managed to flourish in a relatively short period through rapid changes in public policy as well as in the societal resources (including institutions). It is the merit of Maltese politicians, policymakers and social partners that the necessary changes were implemented so fast and in such an effective way. This was facilitated by the fact that the pharmaceutical industry in Malta is practically fully export-oriented, that is, there was little resistance to these changes from local vested interests and power circles.

In particular, Malta was obliged to adopt the EU's 'acquis communautaire' which stipulated the right legislative framework and called for the setting up of a Medicines Authority responsible for the upkeep of standards. The implications of this for an open system are that to tap a market opportunity, the re-configuration of existing 'resources' or the creation of new ones has to also include improvements in the supporting institutional infrastructure. Market sensing while essential in identifying emerging opportunities on international markets requires the mobilisation of the other arch-RCDCs if it is to be effective. Local pharmaceutical operators manage to build competitive advantage by focusing on operations relating to 'managing complexity', 'novelty launches' and 'batch releasing' activities. This focus enables operators not to compete just on lower costs and cheaper prices. 'Novelty launches', in particular, give operators a degree of bargaining power as there are few alternative locations within the EU which offer this possibility. This 'market power' is, however, a fleeting one as it generally disappears within a relatively short time (six months is the minimum time necessary for other suppliers to start selling a similar generic). Shortly after a 'novelty launch' is complete, that there arises the need to embark on the next one. If an enterprise is successful in achieving this, then its market power can be 'rolled-on'. Unfortunately, for local operators, there will come a time (estimated to be within the next eight years) when there will be no more medicinal patents which are not registered in Malta.

The trajectory followed by the pharmaceutical industry in Malta does not exploit externalities arising from operational linkages and networking in a significant way. Of the arch-RCDCs, 'alliance capability' appears to be the 'weakest link' of the proposed framework. While this is evidently the case at the enterprise level (within Malta itself), it can be argued that the country has made excellent use of its 'alliance capability' by forging a strategic partnership with the EU. The umbilical cord of local enterprises is not among themselves (as part of a network or cluster) but with enterprises abroad (mostly their parent company). As explained

without these alliances, the industry would not have prospered in a relatively short time. The growth of the pharmaceutical sector was an integral part of the restructuring of the Maltese economy. Its growth compensated for the relative decline of the manufacturing sector. The EU membership helped revitalise the small pharmaceutical sector that existed pre-accession and enabled it to achieve a higher than average output and value-added per employee.

One foreign pharmaceutical operator remarks that ‘Malta is the best kept secret in the EU’.

This does not mean that the pharmaceutical industry in the country has no weaknesses or faces no challenges. Reduced bureaucracy, a better qualified Patent Office, consolidation of supporting services, an enhanced physical infrastructure and the continued convergence of education and training courses to meet its needs are some of the significant challenges facing the local industry. The construction of the Life Sciences Centre is likely to be a white elephant as Malta lacks the necessary knowledge base. FDI may once again come to the rescue; but it will not be easy to transfer the high level of knowledge and expertise necessary to support such a Centre.

There is also growing awareness within the local industry that other EU member states such as Cyprus, Bulgaria and Rumania are carefully studying Malta’s experience in this field to carve a similar niche for themselves. Existing operators believe that enterprises from these countries are likely to become significant competitors in the very near future. Perhaps the biggest challenge facing the local pharmaceutical industry lies within its own basic rationale: the ability to work on patented medicines which have not been registered in Malta. This advantage will not last forever, and local policymakers need to decide upon the strategic logic of the industry. Will it be considered as just another passing opportunity, letting it ‘sunset’, or does it have the potential to be leveraged? An open system tends to be uneasy with specialisation and ‘leverage’ strategies which require ‘deep’ commitments and ‘sunken investments’. It is this that led Katzenstein (1985, p. 44) to conclude that given that economic change is a fact of life for small European states, ‘their economic openness and domestic politics do not permit them the luxury of long-term plans for sector transformation’. An open system has to be creative, building on its strengths rather than seeking to address its weaknesses. Many such open systems, like Malta, have a competence in trading rather than in manufacturing. A trader lives for the day, seizing the opportunity as it arises. Tomorrow is

another day and hopefully, it will bring a new opportunity. A trader's mindset is driven by manoeuvrability rather than sustainability. Knowledge in an open system' tends to be market, rather than technology, driven.

This explains the high propensity of Maltese entrepreneurs to build strategic partnerships with foreigners while finding it hard to co-operate among themselves. This is not so much about mistrust but a realisation that they can only offer each other more of what they already possess. The big question which follows from these reflections is whether it makes sense to talk about a 'leverage' strategic logic in small states. Should Maltese policymakers let the pharmaceutical industry try to chart its way forward in an emergent fashion or should they deliberately seek to give it strategic direction? The superior performance of Luxembourg in financial services seems to suggest that it is possible to combine an opportunistic logic with a leverage one. This is best seen as a 'snake in the tunnel' strategy, with the tunnel determining the longer-term direction but allowing the snake (local operators) to manoeuvre within the set limits to tap into opportunities as they arise.

This research journey goes through a number of paths and gathers many useful insights, which do not necessarily lead to a unique final destination. A lot more work needs to be done to determine the validity of these insights and the hypotheses suggested. Additional research is required in terms of on further case studies of successful industries in small states. In particular, there appears to be scope for comparative studies that analyse the experiences of a successful industry in a number of small states. Bullishly, Farrugia (2013) claims that it is in the genes of the Maltese people to overcome hurdles. Katzenstein (1985) concludes that small states are like frogs escaping from snakes. But the real challenge for a small state should go beyond survival: a frog may never become a snake but it may dream of becoming a prince.

In conclusion the research questions are being re-visited in the light of the knowledge gained through this thesis:

a. How do small states' economies differ from those of larger states?

This research finds that in a post-industrial world small size 'per se' does not appear to be the most distinctive criteria for giving due attention to the realities of small states. Irrespective of size, economies still have to specialise if they are to benefit from international business. Of

course, most small states remain characterised by a high degree of openness and limited economies of scale. In an age of globalisation openness is not necessarily a limitation. Indeed, if a small state manages properly its interface with the world and regional economies, openness can become a strength. Economies of scale can, and should, be replaced by economies of scope. What emerges as being of fundamental importance for small states is that they place such a high priority on risk minimisation compared to larger states. In small states specialisation becomes conditioned by the fear of over-dependence on a narrow set of economic activities.

- b. Why are these differences important for competitiveness and superior economic performance?

According to this research these differences are important for competitiveness because risk minimisation ultimately impacts on the way that a small state seeks specialisation. Specialisation is the key to achieving market power and not remaining dependent on competing on low costs. A good number of small states have shown that this is achievable. The danger is that small states which over-emphasise risk minimisation end up with a diversified but highly fragmented economy which hinders them from achieving a superior economic performance.

- c. How can insights from existing theories contribute towards developing an alternative approach?

The literature review carried out as part of this research generated a number of important insights as to the factors (such as good governance, social capital, strategic flexibility) leading to improved economic performance. Of particular relevance is R-A theory, a general theory of competition, which provides a theoretical framework for understanding the superior performance of firms as well as national economies. For R-A theory, such a superior performance is the result by the search for comparative advantage and the propensity to engage in proactive and reactive innovation. This theory also assigns a special role to the development of societal resources and structures as well as public policy. The alternative theoretical framework proposed in this research draws a lot on the logic and insights of R-A theory. It, however, goes a step further by identifying a set of higher-order competencies which give meaning to all the other competencies and resources and which have to be ever-present.

- d. How does EU membership impact on the development of the pharmaceutical industry in Malta?

The case study finds that EU membership transformed the pharmaceutical industry in Malta. EU directives had to be transposed into local legislation and this not only led to extensive changes in public policy but also in the setting up of new institutions and the restructuring of

existing ones. What proved of utmost importance for the development of the pharmaceutical industry in Malta was not operating standards or market access but the EU's patent law, including the Bolar exemption. EU membership also helped improve the reputation of the local pharmaceutical industry as foreign buyers appreciated that before exporting products stringent quality standards had to be met by Maltese pharmaceutical enterprises.

- e. Does the experience of the pharmaceutical industry in Malta confirm or otherwise the relevance of the major components of the proposed theoretical model?

Generally speaking the relevance of the arch-RCDCs was confirmed even though the importance of the 'alliance capability' did not come out strong enough. Much more research is necessary to ascertain the role that these arch-RCDCs play in determining the competitive advantage of an industry.

This thesis makes a contribution to theory in a number of ways:

International business has conventionally been concerned with global corporations and advance economies. Only relatively recently did branch out to include a study about the role of small and medium enterprises in international business. This research opens yet another branch relating to the role of small states in international business and how to strategically manage their interface with the global market to reap adequate returns. The researcher's own experience shows that the diamond of national competitiveness model proposed by Porter (1998) has been extensively applied by both analysts and policymakers in small states to understand the competitiveness of their economies or particular industries. Yet this model has limited applicability to the realities of small states and can lead to misguided policy prescriptions and decisions. The alternative approach proposed in this study emphasises the importance of understanding the resources and competencies of the small state and to seek how best to exploit them on the global market.

This research throws extensive light on the concept of superior economic performance. The comprehensive literature review on the subject confirms that although there is a general understanding of what it entails there is no one single measure by which the performance of a small state can be properly gauged. This research highlights the issues involved and suggests what such a measure could entail.



Application of R-A theory in a different context, that of a small state.

The importance of strategic management for the superior economic performance of small states and the importance of their developing the 'right' resources and competencies in line with the strategic logic of their respective industries. (Strategic logic goes beyond conventional economic parameters such as the number of jobs created, exports generated and value-added).

This thesis presents small states as an organisation, an 'open system'. It sets a precedent by drawing on insights and explanations arising from organisational theory to the study of small states. This opens new possibilities for 'organisational' theory to explore given that most states are smaller than the average global corporation.

From a practical point of view this research follows an innovative approach to the competitiveness and superior economic performance of small states which gives specific consideration to their realities. It highlights the importance of carrying out research on specific industries as at times general perceptions may be misleading. The popular perception (propagated mostly by politicians) of the pharmaceutical industry in Malta is that it is a highly successful one driven by R & D, when in reality it is driven by international patent law with R & D expenditure by the industry in 2010 falling to less than three percent of output.

It should help policymakers and the business community in small states to think differently and start focusing on competencies and resources rather than conventional economic assets. They too have to be innovative and entrepreneurial in perceiving competencies and resources in a different way. Jurisdiction, peripherality, flexibility, natural beauty are the type of competencies and resources that they should be exploiting so as to improve their competitiveness. The focus on transforming and building new competencies and resources has important implications also for education and manpower strategies. Particular industries in small states may come and go; what remains are the competencies and resources that would have been gained. This research sets the ground for future research on small states within international business as well as other business disciplines. It would be highly

interesting to study for example the performance of the pharmaceutical industry in another small state or even to study the impact of Malta's EU membership on another local industry.

This research has been a most rewarding journey which in many ways serves as a point of departure rather than arrival. If it leads to further research on small states, it would have achieved one of its primary objectives.

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## **Annex 1: Illustrative list of interview questions**

### **The Maltese Pharmaceutical Industry Semi-Structured Interviews with Management**

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**Interviewee:**

**Designation:**

**Date of Interview:**

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#### **Questions**

1. What is the impact of Malta's EU membership on the local pharmaceutical industry?
2. What is the impact of membership on the operating environment?
3. What is the impact of membership on your firm?
4. What are the primary challenges facing the industry? Have they changed since 2004?
5. Do you agree that the local industry is still competing mostly on costs?
6. What needs to be done to enable your enterprise to increase its value added?
7. What degree of control does your enterprise have over the prices it charges?
8. Do you feel that local enterprises have a say in the evolution of EU directives and policies?
9. Do pharmaceutical enterprises in Malta collaborate and network?
10. What would you say are the major assets/competencies of your enterprise?
11. How do you see the future of the pharmaceutical industry in Malta?