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# INSTITUTIONAL KNOWLEDGE: ACQUISITION, ASSIMILATION AND EXPLOITATION IN SME INTERNATIONALISATION

By

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#### **ABSTRACT**

**Purpose** – Rarely have studies on the acquisition of knowledge in internationalisation focused on institutional knowledge. The aim of this paper is, therefore, to investigate the acquisition of this knowledge, and its assimilation and exploitation processes in internationalisation.

**Design/methodology/approach** – The paper utilises ten longitudinal revelatory case studies built from multiple semi-structured interviews conducted with three different firm types of SMEs in the pharmaceutical industry and secondary documents to which the researchers obtained proprietary access.

**Findings** –The study enhances our conceptual understanding of the institutional learning process in internationalisation by, for the first time, developing a framework to characterise this process. The study explores and identifies multiple types of institutional knowledge required, the sequencing of their acquisition, sources, and learning methods utilised. It also discusses transferability of this learning across foreign markets and firms' absorptive capacity for that knowledge. Regulatory-specific product knowledge, found to be the most important type required, appeared to affect significantly both market selection and mode of entry, and when acquired insufficiently, prevented internationalisation.

**Research limitations/ implications** — While the sample size is relatively small, and sector-specific, the findings were consistent across all the SME firms and firm types. They may also be generalisable to other sectors, firm sizes such as MNEs and types, particularly those which are knowledge-based or highly regulated, given that similar institutional knowledge and processes of acquisition are necessary for firms of all sizes in internationalisation.

**Practical implications** – International marketing managers will gain valuable insights, based on a framework proven to propel firms to successful internationalisation, upon how to plan, organise, manage and match their institutional knowledge-seeking and learning activities with their firms' internal capabilities, staffing and other resources in an effective and timely manner.

**Originality/value** – This study contributes to our conceptual understanding of the institutional knowledge learning process in the internationalisation.

Keywords - Internationalisation; Knowledge management; Learning; Market entry

Paper type- Research paper

#### 1.0 INTRODUCTION

Institutional differences between countries impact economic growth and create obstacles to internationalisation (Globerman and Shapiro, 1999) and international marketing efforts. Institutional knowledge, such as knowledge of laws and regulations (Eriksson et al, 1997), and a firm's ability to learn about, understand, and address the challenges of operating in multiple institutional environments (Drori et al, 2009), have been shown to be essential for successful internationalisation yet rarely have studies focused on the acquisition of this knowledge (De Clerq, 2012).

From prior studies (e.g. Jones et al, 20011; Fletcher et al, 2013) we know that institutional knowledge about markets and regulations is typically acquired from government, export promotion agencies or through industry networks. Prior studies have focused predominantly on the acquisition of market-specific knowledge and whether those types could be transferred

across national boundaries. Unfortunately, however, those studies have told us little about how different types of institutional knowledge are acquired or what occurs where institutional voids or other barriers exist which affect the acquisition process.

In this study of the acquisition, assimilation and exploitation of institutional knowledge, we draw upon knowledge-based theory to examine these problems within ten exploratory and revelatory case studies of three different small and medium-sized enterprise (SME) firm types. Our findings demonstrate that given the extent of existent non-tariff trade barriers, and difficulties in acquiring or complying with institutional regulatory product and institutional technical methods requirements, these firms faced extensive voids in institutional knowledge which led to significant, costly and time consuming difficulties in internationalisation, and therefore, key challenges for SMEs which often lack resources. The majority of these voids were related to regulatory-specific product knowledge, shown to be the most important type of institutional knowledge required, and significantly affected both market selection and mode of entry. When acquired insufficiently, or where the firms were unable to comply with institutional regulatory requirements, it prevented internationalisation. Firms which were unable to enter markets for either of those reasons, sought alterative opportunities in other markets instead.

This paper is organised as follows. First, we review the theoretical foundation literature and develop key questions for the study to address. We then consider the sector context and the methodology, followed by a discussion of the empirical results. Finally, we develop a framework for institutional knowledge acquisition and conclude with a summary and discussion of the theoretical and managerial implications and their relevance to policy and future research.

# 2.0 INSTITUTIONAL THEORY AND LEARNING PROCESSES

Institutional theory is concerned with how firms and groups secure their positions and legitimacy, by conforming to the rules and norms of the institutional environments in which they operate (Scott, 2007). The term 'institutions' describes the formal and informal rules, shared interactions, and taken-for-granted assumptions which form structures and processes which may become institutionalised within corporate cultures, shared belief systems and political processes. Institutional theory explains how those activities are managed and perpetuated over time (Oliver 1997), based upon three pillars identified by Scott (2007). The regulatory pillar, is based upon regulations and sanctions which provide the rules of the game, monitoring and enforcement processes and which encourage conformity. The normative pillar is concerned with how institutions guide the models of organisational and individual behaviour and interaction, while the third, cognitive pillar represents the models of individual behaviour which are gradually and subjectively developed, based upon socially-constructed rules and meanings which limit actions and beliefs (Scott, 2007).

Institutional regulatory environments are dynamic forces shaping business performance but which also act to constrain agency activity and impose conformity surrounding the development of related competencies and the ways in which resource inputs are combined and deployed by firms over time (Oliver, 1997). In contrast, managerial choices about what competitive resources and capabilities firms need to accumulate help to generate firm heterogeneity and lead to the development of sustainable competitive advantage (Barney, 1991).

Given that small businesses adapt to their institutional environments in many different ways Brouthers (2002) investigated the influence of institutional and cultural context differences on entry modes in internationalisation and concluded that firms prefer to enter more socially, politically and economically stable institutional markets using wholly-owned

enterprises as a means of maximising return on investment, and joint ventures where cultural context variables such as market potential and investment risks were higher. Brouthers (2013:14) recommended that research must, in future, "develop and test models that provide prescriptive solutions to issues managers face so that research can be used to improve firm outcomes". This study will, therefore, attempt to identify key elements of the acquisition, assimilation and exploration of institutional knowledge required for market entry and develop a process model which illustrates the sequencing, timing, sources and methods of institutional learning in internationalisation.

Internationalisation process theory stresses the importance of the intensive and gradual, cumulative experiential knowledge and learning processes in internationalisation (Forsgren, 2002; Johanson and Vahlne, 1990) and in the development of competitive advantage (Jansson, et al, 1995). In contrast, international new venture research emphasises the importance of knowledge intensity and unique product knowledge to explain the rapid early internationalisation of new firms (Oviatt and McDougall, 1995). If internationalisation is to be rapid firms must learn to integrate, actively and rapidly, their existing knowledge with new knowledge (Casillas et al, 2009; Sapienza et al, 2006). The speed at which that knowledge is accumulated and learning occurs is dependent upon how effectively individuals, firms and networks are able to share their knowledge with one another (Prashantham and Young, 2011). A firm's ability to acquire and integrate domestic and foreign knowledge has been shown to be critical to its multi-country development and performance (Zahra et al, 2000).

Prior knowledge plays an important role in whether learning skills can be transferred across areas that are expressed in similar ways. Absorptive capacity describes not only how firms acquire, assimilate and transform knowledge but also how they exploit it (Cohen and Levinthal, 1990). Zahra & George (2003:186) suggest that absorptive capacity in learning also involves "a set of organisational routines and processes which produce a dynamic organisational capability". By acquiring new capabilities in how things are done and in problem solving, firms are able to exploit their absorptive capacity for new market, internationalisation and product knowledge and influence their strategic decisions, competitive advantage and performance in internationalisation (Fletcher, 2009).

Institutional knowledge, the subject of this paper, pertains to a firm's experiential knowledge of government institutional frameworks, their rules, norms and values (Eriksson et al, 1997). A lack of this knowledge may make it difficult for firms to understand what laws and norms apply in international marketing and how they are applied, in practice, by governments. For example, firms may encounter differences in the liability of foreignness or in psychic distance where new political, economic and institutional settings differ widely from their home country, thereby generating high levels of uncertainty and risk. The lack of business knowledge about how firms operate in different markets is, in contrast, related to the liability of outsidership in the firm's business environment, and how business is conducted within it (Johanson and Vahlne, 2009). Because firms lack networks in new markets it may, therefore, be more difficult at first to acquire the knowledge needed to be successful. Firms have been shown to require operational technical knowledge, defined as: the making, modification, usage and knowledge of tools, machines, techniques, and methods of organisation required to solve problems (Fowler et al, 2011). Knowledge-intensive firms use firm-specific rather than country-specific technical knowledge, to develop and adapt products for global customer needs or to add value to manufacturing output (Jones et al, 20011) in new and existing markets; to overcome disadvantages of newness and size; or to recognise and exploit opportunities (Autio et al, 2000; Zahra et al, 2000). The acquisition of knowledge related to institutionally-required technical methods has, however, yet to be explored in depth, despite forming an important part of institutional scientific product regulatory compliance requirements for many industries, including pharmaceuticals (Vogel, 1998).

Managers must also make choices not only about the types of knowledge they require, but also about who to learn from and what method of acquisition to use to acquire it. Huber (1991) linked individual knowledge and knowledge acquisition to organisational-level learning and then split organisational learning into five types of knowledge acquisition: a) experiential learning, b) vicarious learning, c) search, d) grafting and e) congenital learning. Much of what we know about these knowledge acquisition processes relates to the acquisition of market and internationalisation knowledge, and less frequently institutional knowledge. For example, Fletcher et al (2013) investigated the types of market knowledge needed for in market entry as it related to the development and selection of market entry strategies.

By far the most pervasive of Huber's (1991) knowledge acquisition types has been shown to be experiential knowledge. Experiential knowledge aids firms in learning about operating in different institutional business environments, market selection, modes of market entry and speed to launch (Casillas et al, 2009). Firms entering international markets appear to change in two ways: first, by learning from experience and current activities, and secondly, through commitment decisions, made over time, to strengthen their position within the foreign market (Johanson and Vahlne, 2009). Networks play critical yet indirect and informal roles in experiential and vicarious learning by helping to co-create privileged new knowledge from both the firm's own experiences and activities and those of its partners during the interaction process. A lack of network partners or homogeneity in networks may, therefore, limit the knowledge acquired or prolong the time needed to access it. Networking leads to the generation of trust-building, commitment and, potentially, additional learning between the network partners over time. Learning by experience also results in a gradually more differentiated view of the firm's own capabilities and its view of foreign markets (Johanson and Vahlne, 2009). General knowledge about how to operate in foreign markets using its own resources and capabilities, how to coordinate relationships, foreign market entry, and specific modes of entry may be transferred between organisational units in larger firms but not in smaller firms (Eriksson et al, 1997).

Experiential and vicarious forms of knowledge acquisition result in the generation of deeper knowledge about the process of internationalising, by helping firms develop new internal routines, increasing their understanding of how to negotiate the challenges of foreign operations, and developing foreign partnerships (De Clercq et al, 2012). We would expect, therefore, given the international diversity of institutional pharmaceutical regulations that experience in dealing with related or similar problems in other institutional markets may be of benefit to managers.

Vicarious learning, or learning through the experiences of others, plays a central role in the speed, breadth and depth of early internationalisation and occurs most often when firms lack relevant experiential knowledge (Bruneel et al, 2010). While firms may mimic the activities of others who have already entered foreign markets successfully (Forsgren, 2002), vicarious learning occurs most often in networks (e.g. between firms or in trade and professional associations), or where firms piggy-back other firms already operating in foreign markets (Schewns and Kabst, 2009). Information sharing requires only weak network tie relationships (Granovetter, 1973) because the information provided is less likely to be redundant (Loane and Bell, 2006) and enhances the firm's capacity to build rapidly operational scope (Oviatt and McDougall, 2005). SMEs which lack relevant experience and useful networks have been shown to rely on weak ties with government advisors, consultants (Fletcher and Harris, 2012; Fletcher et al, 2013), specialist groups, export intermediaries (Peng and Ilinitch, 1998) and other commercial or government sources (Leonidou and Adams-Florou, 1999) to acquire experience indirectly. We do not know, what role weak or, indeed, strong tie relationships play in the acquisition of institutional knowledge in networks.

Congenital knowledge arising from geographic diversity in managers' (Yeoh, 2004) and network partners' prior international experience has a strong positive effect on the foreign market learning of firms by deepening understanding of the information exchanged. Grafting, i.e. hiring outside managers or through the use of inter-organisational resources such as strategic alliances, is not a precursor to internationalisation but does hasten the pace of early internationalisation when those managers bring new technical knowledge, knowledge of foreign markets, or introductions to foreign networks (Loane and Bell, 2006).

Active search helps firms gain organisational information on markets, potential customers and competitors (Zhou, 2007) and connects them more closely to the market, through intangible commitments, rather than by simply collecting and analysing information (Forsgren, 2002). Firms may search externally for knowledge from network ties (Prashantham and Dhanaraj, 2010) or by gaining access to, sharing, integrating and validating new knowledge between ties (Tolstoy, 2010). Firms may search in publications or other objective sources, scan their external environments (Huber, 1991) in an effort to problem-solve or enhance their strategic effectiveness (Chandler and Lyon, 2009), and conduct their own market research, education or training to secure internationalisation information from others (Fletcher and Harris, 2012).

Congenital or prior knowledge is the key difference between the international process model (Johanson and Vahlne, 1990) and Oviatt and McDougall's (1995) international new venture process. Theoretically, the importance of prior international experience in the early internationalisation of new international ventures is based upon the assumption that with experience comes greater awareness of international opportunities, a greater ability to assess their value, and a predisposition to pursue them (Casillas et al, 2009; Oviatt and McDougall, 2005). While vicarious and congenital forms of learning appear to play a central role in both the initial decision and processes to internationalise and the depth of learning, experiential, active search and grafting appear to be more important in rapid learning and post-entry processes, with search the most important predictor of post-entry performance in learning and marketing orientation (De Clercq et al, 2012).

Despite the importance of institutional knowledge in marketing, an analysis of academic literature on the acquisition of knowledge in internationalisation reveals that research has focused overwhelmingly on the acquisition of market knowledge; to a lesser extent on internationalisation knowledge, but very rarely on the acquisition of institutional knowledge (De Clercq et al, 2012). A recent review by the authors confirmed this and, in particular, the lack of research on the acquisition of both institutional regulatory product and technical methods knowledge, which are investigated in this study. We also unfortunately do not appear to know whether institutional learning, like other types of learning in internationalisation, can be transferred between markets, especially given that institutional pharmaceutical regulation appears to vary so extensively between countries and may act as a trade barrier (Vogel, 1998). Can firms develop absorptive capacity i.e. dynamic capabilities for learning institutional knowledge? This study, investigates institutional knowledge further, extending our understanding regarding the types required, sequencing, sources, and learning processes utilised in its acquisition, assimilation and exploitation.

#### 3.0 RESEARCH METHODS

The objective of this research was to gain a deeper understanding of the acquisition, assimilation and exploitation of institutional knowledge and learning activities of firms during their internationalisation processes.

#### **Industrial Context**

Boter and Holmqvist (1996) identified the importance of industry context in understanding internationalisation patterns of firms and their behaviour. Despite this, over 70% of the research on internationalisation, particularly single studies, and much of the research on learning, has focused on high technology sector firms which internationalise early and less on the internationalisation practices of SMEs in other sectors (Zahra, 2004). These other sectors, have only recently begun to attract academic attention but they may offer additional valuable learning about internationalisation (Jones et al, 2011) and marketing efforts as we propose to illustrate by using, for the first time, the dietary supplement sector of the pharmaceutical industry. The institutional structures of national healthcare markets have been shown to significantly impact both market selection and the entry mode used by firms (e.g. Laurell et al, 2013). Pharmaceutical firms, like knowledge-based firms in other sectors, must overcome institutional barriers such as psychic distance, comply with significant country-specific regulatory product trade barriers, and secure a wide range of other institutional knowledge necessary for internationalisation.

Life sciences-based firms provide specialised and innovative products and operate in globally dynamic, highly institutionally-regulated and science-based industrial contexts embedded in different socio-political systems (Laurel et al, 2013). The life sciences industry also has unique characteristics and requires industry-specific knowledge (Stremersch and Van Dyck, 2009) because institutional regulatory environments within countries influence firms' international behaviour (Vogel, 1998). Structural factors, such as high development costs and niche products, influence these firms' international behaviour (Laurell et al, 2013). The sector is not homogenous, however, for example, the Natural Health Products (NHP) or dietary supplement industry's structural factors appear to differ from other life sciences firms (Bell, 2015). NHP firms had lower development costs than therapeutic drugs and were not niche products given growing international interest in self-care and increased demand for higher quality and efficacy dietary supplement products from developed markets in emerging markets where similar domestic products already enjoyed strong demand. While entrepreneurs and their teams aid firm internationalisation, institutional and science-specific factors have instead, constrained internationalisation in the life sciences industry (Laurell et al, 2013).

Despite the efforts of governments and the World Trade Organization (WTO) to reduce trade barriers, institutional differences remain a significant barrier to international trade and marketing efforts, (Eliason, 2006). For pharmaceuticals, the WTO specifically allows non-tariff trade barriers which are deemed necessary to protect health, safety, sanitation or depletable natural resources (Eliason, 2006). Drug regulation, consequently, has become "virtually synonymous with national sovereignty because individual governments now (create regulations with regards to, and then exercise and) supervise all aspects of the development, testing, production, marketing, pricing and distribution of pharmaceutical products; and force firms to comply with distinctive regulatory criteria for each national market" (Vogel, 1998:1). While the pharmaceutical industry has made great strides in its attempts to bring international clarity and consistency to regulations pertaining to therapeutic drugs (Vogel, 1998), it has done little in that regard in many other subsectors of the industry, including dietary supplements, the subject of this study.

Between 2004 and 2010, Canada introduced a unique, new regulatory system that defined dietary supplements as NHPs which could be sold as over-the-counter non-prescription drugs (Nestmann et al, 2006). In other jurisdictions these products are called food or dietary supplements and controlled under highly-differentiated regulatory systems for foods, drugs, traditional medicines, herbal medicines, novel medicines or ingredients, or a combination of those regulations, depending on the country and specific product content. As a result of the many international trade obstacles these firms face, and the resources required, few actually

internationalise. Thus, the Canadian NHP industry was selected for study, given both a lack of prior research on this pharmaceutical industry sector and anecdotal evidence suggesting that these NHP firms were not heavily engaged in international markets.

#### Case Selection

A qualitative methodology was selected given the study's inductive and exploratory nature (Denzin and Lincoln, 2000). A multiple case study approach allowed local context and situational constraints to be considered, and greater attention to detail and interdependencies while simultaneously providing a holistic picture of the phenomenon without chance associations (Yin, 2011). The findings reported here were derived from ten case studies of Canadian pharmaceutical NHP SMEs which had previously overcome trade barriers to internationalise (Table 1). This number falls within Eisenhardt and Graebner's (2007) suggestion of four to ten cases to allow for sufficient generalisation whilst avoiding overwhelming data.

Revelatory cases are appropriate where the researcher has a unique opportunity to observe and analyse a phenomenon which was previously inaccessible and has not been studied (Yin, 2011). Here, neither the dietary supplement industry nor institutional knowledge acquisition in this context had been explored previously. Given that learning and knowledge acquisition occur over time, the use of ten longitudinal revelatory cases allowed the authors to draw theoretical generalisations and increased the research credibility (Eisenhardt and Graebner, 2007; Yin, 2011).

The authors secured proprietary access to the supplier membership directory of the Canadian Health Food Association (CHFA), the largest trade group representing the dietary supplement sector in Canada. That directory was then used to select firms. Consistent with anecdotal evidence, very few firms, overall, were found to have internationalised. Internationalisation, for the purposes of this study, was considered as the process of increasing involvement in international markets. From the list of available firms, only ten firms met the following selection criteria.

They were either small or medium sized enterprises, were located in one of two industry clusters in either the greater Toronto or Vancouver areas (although the effects of the cluster on their activities was neither discussed nor analysed in this study) and were independent, and not subsidiaries of larger domestic or international companies, thus avoiding the effects of potential resource or cultural influences on their decision-making processes.

As different firm types may experience contrasting challenges, this research also took the opportunity to examine different firm types, existent in this sample. Participating firms were, divided into three representative firm sub-types, and assigned letters in an effort to maintain confidentiality. Respondents included two regulatory service consultancies (RSCs), Firms A and B, which worked exclusively within the NHP industry to provide regulatory services support in the form of pre-market product clearance and compliance documentation for firms in both domestic and international markets; three combination firms (Firms C, D and E) which were simultaneously both ingredient suppliers and contract manufacturing service suppliers (ISCMs) for other firms in the industry; and five manufacturing firms with their own consumer brands (MFB), Firms F, G, H, I and J.

Two rounds of semi-structured interviews, conducted between 2011-2014 with a CEO/owner or member of the senior management staff responsible for internationalisation decisions, were used to develop each of the cases. Given that this was a retrospective study, one of the authors confirmed the interviewees' memories of each of the firms' internationalisations by reviewing historical membership data that the firms provided over time to the CHFA. The focus of the interviews was on the development of case histories illustrating the firms' internationalisation patterns.

Table 1: Owner and Firm Backgrounds

Firm	Owner's Backgrounds	Immigrant / Non-immigrant	Year Founded	Year Internationalised	Number of Countries	Number of Employees
Regulatory	Service Consultancies					
A	Strong academic science background; instrumental in development of NHP Regulations	Polish	2003	2003	20>30	15
В	Involved in herbal industry from childhood; instrumental in development of NHPR and industry association	Canadian (Austrian parents)	2003	2003	20>30	10
Combination	on Firms (Ingredient Suppliers and Co	ntract Manufactur	ers)			
С	Previous owner of two NHP-related firms	Canadian	1998	1998	>50	50
D	Previously worked in NHP industry	Canadian	1990	1990	>50	140
E	Physician specialising in Diabetes	Chinese	1996	1996	10>20	65
Manufactur	ers with their Own brands		1			1
F	Pharmacist; now operated by son who has an unrelated profession	Canadian (US parents)	1965	1966	>50	350
G	Accountant in the NHP industry	Canadian (UK parents)	1982	1982	20>30	160
Н	Retail baker using natural ingredients	Canadian	1967	2000	20>30	125
I	Bodybuilder interested in nutrition and health	Canadian	1985	1987	10>20	60
J	Son has an MBA and father unrelated export experience and health condition mitigated by NHP	Canadian	2003	2003	2	8

Source: Authors

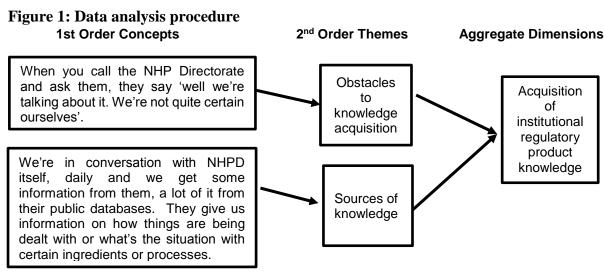
To increase the construct validity of the study, we used semi-structured in-depth interviews and standardised the order of the questions which allowed the subjects to generate their own ideas (Yin, 2011). The first set of interviews (2011) focused on the firm's internationalisation activities since inception, and the second round (2013/14) on knowledge acquisition, and it also updated internationalisation activities which had occurred in the interim.

Each interview lasted, on average, 90 minutes and was conducted either in person in Toronto, or using Skype internet telephone service when firms were located in Vancouver. The interviews were recorded and verbatim transcripts returned to each participant to review and agree as an accurate representation of their conversations in an effort to enhance further credibility and avoid bias. A comparison of the Skype and in-person interviews showed no difference in the richness of the data. Proprietary access to secondary membership documents from CHFA aided in the construction of the cases and also served to confirm the historical patterns of internationalisation identified in the interviews.

# Data Analysis

The text from both sets of interviews was coded using NVivo software to identify key themes and patterns and the Gioia method of analysis (e.g. Gioia et al, 2010; Gioia et al, 2013) was employed (Figure 1). This method provides both rich and deep theoretical descriptions of the "contexts in which organisational processes occur" (Gioia et al, 2013:17), making use of scripts arising from the interviews. Since organisations consist of rituals, procedures and other institutional interactions or socialisation processes, scripts not only guide staff but also help to guide their understanding and performance of activities in culturally appropriate ways.

In this study, use of the Gioia method involved the presentation of first order scripts using informant terms and second order analysis using researcher-based concepts, themes, and other dimensions which then allowed for a rigorous validation of the links between the data in the informant's voice and the induction of new concepts and theories through sense-giving in the researcher's voice (Gioia et al, 2013). Second order analysis focused on describing or explaining things which either did not appear to occur in the literature, or which had few referents and, therefore, jumped out to the researchers because of their relevance to a new domain. Once saturation occurred, second order themes were condensed further into aggregate dimensions. This set of first order terms, second order concepts and aggregate dimensions formed the basis of the data structure, and reflected the progression of the analysis and the rigour of the research.



Source: Authors

Analysis of the data occurred between individual interviews, between and within firm types, and later, between the conclusions looking for patterns and meanings. Care was taken to explain emergent concepts or themes, expose them to examination, and use them to illustrate the core ideas that were most interesting, and in a manner which made their sense-giving apparent (Gioia et al, 2010). In this process, the data structure led to the formation of new theories or modifications to existing ones.

# 4.0 FINDINGS AND DISCUSSION

#### International Activity by Firm Type

The firms ranged in age from eight to 45 years of age. All ten firms internationalised rapidly with each firm, interestingly, following a process of internationalisation which was similar to all the other firms within its type. Only one firm (H) required more than two years to internationalise, evolving first from retail bakery operations to manufacturing 20 years later when, in response to unexpected events, it rapidly began to export (Table 1).

# Regulatory service consultancies (RSCs) SMEs

Both RSCs internationalised through an unplanned process within their first year of operation (Table 1), first to the United States (US), and later to over 20 markets. Rather than piggy-backing their clients' entry into foreign markets, like many other service firms, they entered each market prior to their MFB clients in an effort to secure regulatory product knowledge needed to prepare institutional regulatory compliance documents necessary to secure pre-market authorisation for products their MFB clients wished to export. Separately, MFBs from around the world also sought out the RSCs' expertise to support their own Canadian market entries or to bring products already in Canada into compliance with the new Canadian institutional NHP Regulations. Later, a desire for new business growth motivated the RSCs to investigate entering additional markets to secure new clients while taking part in tradeshows and trade missions. Firm A investigated European markets because the owner was a European immigrant to Canada and spoke several European languages. Firm B investigated the US and Mexico because its owner spoke Spanish and frequently vacationed in Mexico. Both RSCs discovered their ability to make foreign direct investments (FDIs) in international markets was virtually blocked by their inability to acquire a sufficiently extensive range of either codified and tacit institutional regulatory product knowledge across a huge range of products and product categories. This finding concurred with Vogel's (1998) observation regarding the diversity of regulatory models encountered internationally. Their lack of competitive advantage in new markets compelled both RSCs to build extensive international regulatory knowledge network ties and strategic alliances and to develop mutual referral systems with competitor RSCs in markets they wished to enter.

# Ingredient supplier and contract manufacturer (ISCM) SMEs

ISCM firms C, D and E internationalised from inception and eventually exported to 40 to 50 different markets (Table 1). Given their dual roles as ingredient suppliers and contract manufacturers, they first used trade networks to search actively for and locate globally ingredient products and resources to meet their MFB customers' demands. As the ISCMs' absorptive capacity for ingredients, standards, manufacturing processes and institutional regulatory requirements increased so did demand for their ingredient sourcing services. Simultaneously, they also sought out higher quality, lower-priced and unique products which further increased their competitive advantage.

Using networks on the contract manufacturing side of their businesses, the ISCMs first provided services to US-based and later international MFB and retailer firms. Given that many of their customers had already internationalised, ISCMs were contracted to manufacture supplement products for those additional markets. Motivated by growing reputations for quality products and services, the ISCMs marketed their services at domestic and international trade shows, locating new customers and enlarging their trade networks. ISCM firms increased their commitment and became more embedded in international markets by developing business networks, strategic alliances and contractual relationships with competitor ISCM firms and later making FDIs into them.

# Manufacturing firms with their own brands (MFB)

All the MFBs first developed the domestic Canadian market for their products which had higher and more complex pharmaceutical standards. MFB Firms G and J also simultaneously entered the US market, where their products were regulated at the lower level of foods. Their prior assumptions about similarity in psychic distance between the Canadian and American markets prevented them from learning about critical differences that were import to their success and they also ran into both financial and market knowledge obstacles before withdrawing. Only Firm G re-entered the US, years later, on a regional basis. Firm F began exporting to Canada soon after its establishment under American ownership and was, therefore, already internationalised when it was purchased by Canadian owners in 1965. All MFBs initially used distributors, brokers or agents to enter export markets. Later, each developed strategic alliances, made FDIs and used international trade consultants and participation in trade shows and trade missions to increase penetration of export markets and locate new markets. Four MFB firms (F, G, H and I) internationalised extensively with the three largest firms (F, G, and H) exporting to more than 20 countries and most continents. Firm J encountered two domestic non-tariff institutional regulatory obstacles that partially, albeit only temporarily, restricted its export markets to two countries.

# **Types of Institutional Knowledge Acquired**

All three firm types first identified various types of institutional knowledge they thought they required, and then began identifying various sources of that knowledge. The sources, as will be discussed later, often drove the method by which that type of knowledge could potentially be acquired, and also led to the identification of additional types of knowledge and sources which the firms were unaware, at first, that they needed. The elements of this process are described later in Figure 2.

All the firm types, over time, acquired different types of institutional regulatory knowledge, including import/export, regulatory product (including, for the first time, institutionally-required technical methods and ingredient and quality standards), financial reporting and taxation, intellectual property protection, and health, safety and human resources knowledge related to manufacturing production compliance. These findings highlight the diverse range of operational areas within the firm which are directly impacted by the need for institutional knowledge for compliance in foreign market entry.

# Import and export regulations

The first knowledge goal for all NHP SME firm types was to determine whether or not MFBs' products (some of which were produced by ISCMs) could enter desired foreign markets in their existing forms, or, if not, how extensive were the changes needed to achieve regulatory compliance for market entry.

Table 2: Illustrative quotes related to product regulatory knowledge acquisition

Firm Types and Firms	Comments
RSC Firms	
Firm A	"We realised early on that we couldn't possibly know all the regulations or how they are actually implemented in every country".
Firm B	"You think you've got all your compliance papers covered and then you realise, oh no, we're missing this or that, and this is something new that we've never done before. It can be very, very challenging to collect information you need".
ISCM Firms	
Firm C	"We prepare a large dossier of material that our customers need in order for them to get products registered. We have to complete their compliance applications, provide certificates of free sales, certifications of Good Manufacturing Practices, flow diagrams for our manufacturing methods and processes, shelf life stability testing, clinical trials etc. but the exact details change with every individual product and market".
Firm D	"You start dealing with a distributor and discover that they aren't doing things as per regulations. They have different interpretations. A 500 mg Vitamin C is considered a drug but if contains 30 mg or less it's regulated as a food. To file there as a drug, requires a tremendous amount of applications and justifications. Registering as a food is a different story. One distributor came to us and said they wanted us to label the 500 mg as 30 mg. They said it was perfectly legal to do that because foods don't have an upper limit, just a minimum limit but obviously doing things domestically is different than trying to import it into a country".
MFB Firms	
Firm E	"In Canada, cupric oxide is considered a source of copper because copper is very difficult to assimilate within the body. In other countries because cupric oxide is not readily available as a source, they don't allow it. We make a children's multivitamin where cupric oxide is used in Canada, but the other market wants a different source because it's not allowed in their country. We therefore have to develop a different product for them. This is where we go back and forth with our distributors and the local Ministries of Health. It has to be a very transparent relationship but we also have to worry about things getting lost in translation too".
Firm F	"We may be two, three years out of getting our products registered, so before commencing the compliance process, we're already putting processes in place to accumulate and generate the data that's necessary for international registration".
Firm G	"But first we have to find out who has access to the regulatory requirements, then look at our formula, look at the local rules and regulations and tell us which dosages are allowable in the category you want to sell into. Are there substances which are allowed in Canada, but not allowed in your country?"

Sources: Authors' analysis of interview transcripts

Canadian export regulations, available on Health Canada's website, specified what manufacturing licenses and international trade certificates were required to allow NHP firms to export. The MFBs and ISCMs were also subject to the import regulations of foreign markets and could only use specific importers (e.g. licensed drug or an unlicensed food or other distributors). National regulations in each country often stipulated how products could be marketed and sold locally, as well as import duties and other customs' requirements needed for comply with upon entry. This meant that firms were in many instances not free to make their

own choices but rather were forced to comply with local regulatory product requirements if they wished to enter a particular market.

Regulatory product knowledge and technical methods

Institutional regulatory product knowledge in the pharmaceutical industry was found to refer to controlling or directing the development, manufacture and sale of products according to the laws and regulations which existed in any country. (Table 2 contains illustrative quotes.) In most countries pharmaceutical firms, unlike those in many other sectors, were required to submit applications for pre-market authorisation prior to importation. Each product application had to be supported with extensive scientific data, clinical trials, quality assurance tests, labels, translations, manufacturing information, and a wide range of other documentation specific to each country and, sometimes, to the state or city level. Given the extent of the information required, and the time needed to procure it, this process commenced years in advance of either the firm's actual operational foreign market entry or the establishment of any physical presence there. A delay in acquiring this knowledge forced firms to re-submit applications later or created other extensive delays in securing pre-market authorisations.

All the firm types actively searched for access to codified government regulations and norms using a two-part process immediately after viewing each market's import/export regulations. First, because SMEs typically had limited knowledge of these requirements, they searched on foreign governments' websites which, unfortunately, frequently failed to include guidelines or interpretations of regulations which could answer all the questions SMEs had about the application process, or how non-conforming products might achieve compliance.

Details of who to contact in government departments or how to contact them were rarely noted on websites. The RSC, ISCM and MFB firms sought out locally-situated Canadian embassy or consular staff to secure referrals or assistance in arranging introductory meetings with foreign government staff who could locate this knowledge.

In the second part of the process, during in-person meetings, telephone conversations or via email correspondence, these new government contacts tacitly clarified the norms and guidelines of how regulations were implemented. This helped to elucidate a wide range of issues related to product categories, ingredients, claims, quality assurance, or other evidence required to complete these applications. Given that meetings with government staff were conducted in the local languages, highly-skilled translators were required. Where less experienced translators were used, important knowledge was often lost in the process. All but two MFB firms (H and I) later took part in trade missions where they also secured introductions to key foreign government regulatory contacts.

Some of the knowledge acquired created problems which delayed filing of pre-market authorisation applications. For example, it appeared common for multiple government departments to control, simultaneously, different aspects of the manufacturing, sale or marketing of dietary supplement products, with conflicting and overlapping guidelines. Local business practices and ethics also played a role in the accuracy of the information obtained. Such situations required additional meetings and negotiations with some issues never being resolved successfully. Where specific ingredients were not permitted, or where MFB clients wanted to challenge allowable dosage levels of ingredients based on scientific evidence, the RSC firms lobbied on their clients' behalf for temporary market authorisations or changes to regulations which would allow products' future entry.

Sometimes, even when knowledge was acquired successfully, the compliance process was extended because products had to be reformulated rather than simply repackaged, or locally-appealing ingredients added. Some countries only allowed evidence to be used if supporting clinical trials had been conducted in that specific market (e.g. China), forcing firms to reproduce those trials prior to submission of pre-market authorisations. Institutional product

regulations were also subject to change, sometimes without notice. All of these situations complicated, delayed or forced firms to recommence the entire process.

Technical knowledge was found to include technical methods of analysis, such as for quality and the determination of nutrient content. While Autio et al (2000) identified that knowledge-intensive firms may use new firm-specific technological knowledge to develop and adapt products for new and existing markets, in this study these methods were actually specified as part of regulatory product compliance processes specific to each country. One of the most common delays in achieving compliance resulted from the need for new shelf-life studies of products conducted over different time periods or conditions.

The result of this two-part institutional, regulatory product knowledge acquisition process was that the time required for preparation of pre-market authorisation applications could take from as little as three months to several years. Similarly, lengthy periods were also required to secure local government approvals, post submission, with time varying according to the complexity of the products, state of development of the country, and level of experience of both the firm and government staff involved and frequently several years. Where applications were rejected, firms clarified the issues involved, provided additional documentation or reformulated products, thereby further delaying both MFBs' product and organisational entries into those markets. Given their degree of involvement in MFB firms' decisions of whether or not to enter the foreign markets, and which entry mode to utilise, RSC firms played a key role in recommending market entry or avoidance and entry strategies. Often, they made these recommendations based on the known difficulty of the institutional process involved and prior to the actual submission compliance documentation. Given that institutional regulations were also subject to change without notice, knowledge could, unfortunately, also be acquired after the process was completed, necessitating modifications to existing or the production of entirely new submissions.

All of these issues, combined, made institutional regulatory compliance for internationalisation not only extremely expensive but also a highly complex and protracted, multi-stage process which required years of advanced planning. Many SMEs, lacking the necessary resources to undertake this process, failed to internationalise. The acquisition of regulatory product knowledge also forced all three firm types to innovate new market entry strategies and thousands of new products, formulas, processes, health claims and to take advantage of institutional regulatory loop-holes which did not exist in their home markets and which they were not likely to have otherwise undertaken. Many of these innovations, they later discovered were also useful in entering other markets with similar cultural or institutional characteristics.

#### Financial and taxation regulations

Information regarding finance, taxation and accounting methods was another form of institutional knowledge acquired by all three firm types from government websites. Again, a great deal of tacit experiential information, obtained through meetings with local accounting firms or from local government officials, was also needed to comply with these regulatory standards and to learn how to maximise the firm's tax savings. These procedures were, however, often standardised internationally or regionally, and typically enjoyed significantly less variation than product compliance regulations.

Import and customs duties varied from single digit percentages to more than half the retail value of the products, depending on the form of the product imported (e.g. ingredients, bulk tablets/capsules or finished products) and the impact of regional trade agreements.

Regulations clearly favoured locally-manufactured goods over imported ones. Where it was cheaper to import ingredients or bulk tablets and capsules, or where local labour costs were

low, MFB firms used that knowledge to import those products for repackaging and local distribution.

Business entity and intellectual property regulations

While the first priority for many SMEs entering new markets is to establish a new business entity and protect their trademarks in the local market, this study found that these forms of institutional knowledge acquisition had a much lower priority for all three firm types and, typically, were not acquired until the after the regulatory product compliance documentation was ready for submission. Websites or printed materials from government departments were the primary sources, but several firms also sought out information on local research and development support by meeting with local government officials in an effort to determine if that support made any difference to how the firm was established within that market.

Where patented technologies were involved, those firms' external legal teams, with input from RSCs, evaluated the security of local intellectual property protection in markets and acquired the necessary information either from websites or communications with local legal strategic alliance partners and made recommendations accordingly. These filings occurred at the same time as the business entity documentation.

Manufacturing regulations including health, safety, and human resources

Some countries required products to be manufactured locally, or encouraged this by charging high import duties on finished goods. This meant that the RSC firms, in conjunction with their MFB or ISCM clients' quality and manufacturing departments, had to locate and learn how to secure, qualify and approve local manufacturers. This work was typically accomplished using direct international trade network connections.

Because these firms were already familiar with production processes, they only needed to secure country-specific institutional knowledge related to health, safety and human resources issues. While their locally-contracted manufacturing partners were legally responsible for these processes, the Canadian firms searched websites and utilised local consultants to advise them to ensure the accuracy of that information. In doing so, they complied with their own internal corporate policies for corporate social responsibility, and avoided potentially negative media coverage.

# **Sources of Institutional Knowledge**

Whereas Fletcher (2009) and Fletcher et al (2013) suggest that internal experts, direct experience, external advisors and consultants including government staff, and recruitment, in this study firms used a broader range of sources to access the different types of institutional knowledge they required. These included foreign and domestic trade, trade associations and networks, commercial and government intermediaries, websites and publications, and competitors (Table 3). In many instances, the knowledge was acquired from one original source and then validated using additional sources.

All the NHP firms and firm types made extensive use of these sources to: a) reduce time required to accumulate regulatory product knowledge and experiences b) affect foreign market selection, c) determine specific entry modes and d) locate resources. It was often difficult, however, to access specific government staff who were able to respond to questions not covered by information on department websites. This lack of access negatively affected firms' market entry by significantly slowing the overall compliance process, contributing to the need for revised applications to be developed (as a result of the presence of mistakes or incomplete information) and, thus, delayed or prevented potential local economic contributions.

Institutional knowledge was also subject to change, so firms (as noted in Figure 2) also had to identify how they would be able to become aware of and access information regarding those changes, and this often involved being alerted to the changes by multiple, different sources, which validated either the new regulations or their interpretation related to their implementation.

**Table 3: External Sources of Institutional Knowledge** 

	Knowledge Network Sources						
Institutional Knowledge Acquired	Canadian Trade <sup>a</sup>	Canadian Trade Associations	Canadian Government <sup>b</sup>	Foreign Trade <sup>a</sup>	Foreign Trade Associations	Foreign Government	Foreign RSC Competitors
Import regulations		1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1
Export regulations	1,2,3	1,2,3	1,2,3				
Dietary supplement/NHP regulations	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1
Technical methods	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3
Guidelines and interpretations of regulations	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1,2,3	1
Financial and taxation regulations		1,2,3	1,2,3			1,2,3	1
Business establishment regulations			1,2,3			1,2,3	1
Intellectual property regulations			1,2,3			1,2,3	1
Manufacturing regulations including health, safety and human resources				1,2,3	1,2,3	1,2,3	1

<sup>1 =</sup> RSCs

Source: Authors

# **Timing of Knowledge Acquisition**

Each type of knowledge was found to be acquired at a specific time, as needed, in the internationalisation process (Table 4), either prior to the start or early in the institutional product regulatory compliance process. In contrast with many other sectors where SMEs begin their internationalisation process by acquiring business entity and intellectual property registration knowledge, the pharmaceutical SMEs in this study considered institutional regulatory product knowledge to be more important, both initially, and overall. The timing of the acquisition of specific types of information appeared to be proscribed by the nature of the industry in this study, but this needs to be confirmed by research in other industries.

<sup>2 =</sup> ISMCs

<sup>3 =</sup> MFBs

<sup>&</sup>lt;sup>a</sup> Includes clients

<sup>&</sup>lt;sup>b</sup> Includes domestic departments as well as embassies, consulates and trade missions

Table 4: Timing of Knowledge Requirements and Acquisition

	Timing of Knowledge Acquisition in Product Compliance Process				
Type of Institutional Knowledge Acquired	Prior to start	Early in process	Later in process	Post process	Regulatory changes beyond process
Import regulations	1,2,3				1,2,3
Export regulations	1,2,3				1,2,3
Dietary supplement/ NHP regulations	1,2,3	1,2,3			1,2,3
Technical methods and standards	1,2,3	1,2,3			1,2,3
Guidelines and interpretations of regulations	1,2,3	1,2,3			1,2,3
Financial and taxation regulations		1,2,3	1,2,3	1,2,3	1,2,3
Business establishment regulations			1,2,3		1,2,3
Intellectual property regulations	1,2,3	1,2,3			1,2,3
Manufacturing regulations including health, safety and human resources		1,2,3	1,2,3		1,2,3

3 = MFBs

1 = RSCs 2 = ISMCs

Source: Authors

# **Knowledge Acquisition Methods**

As a result of the many and varied experiences involved in the process of institutional knowledge acquisition, all three firm types and all the NHP SMEs studied, secured experiential, vicarious and grafted knowledge (Table 5) that steadily built on any pre-existing institutional knowledge and learning, and helped the firms to mitigate the risk of entering new markets. Prior research, e.g. Eriksson et al (1997), based upon experiential international process models such as that of Johanson & Vahlne (1990; 2009), have typically investigated how firm's acquire experiential knowledge of government institutional frameworks, their rules, norms and values. Those studies found that a lack of this knowledge made it difficult for firms to understand what laws and norms applied in international marketing or how they were applied, in practice, by governments. In this study, because we investigated a broader range of knowledge acquisition options, the firms were found to have not only gained institutional knowledge experientially, but they also secured institutional knowledge which was not codified and could not be obtained experientially, through congenital, vicarious and grafting processes as well.

In the past, firms have also been shown to have mimicked successfully the activities of others already operating in foreign markets in an effort to obtain institutional knowledge (Forsgren, 2002). In this instance, because institutional knowledge was both product-specific and country-specific, and few other MFB firms were internationalising or had similar products, MFB firms had few role models to mimic, so information could not be obtained in this manner.

The methods of acquisition (Figure 2) also appeared to have been driven by the type of knowledge needed and often led to the generation of additional new and valuable learning about topics which could prove valuable in future markets or in the introduction of other new products and the creation of new innovations.

**Table 5: Knowledge acquisition types and methods** 

	Foreign Institutional Knowledge Acquisition  Methods					
Turner of brotitutional Knowledge Assuined	Congenital	Experiential	Vicarious	Active Search	Grafting	
Types of Institutional Knowledge Acquired Import regulations		1,2,3	1,2,3	1,2,3	1,2,3	
Export regulations		1,2,3	1,2,3	1,2,3	1,2,3	
Dietary supplement/NHP regulations	a	1,2,3	1,2,3	1,2,3	1,2,3	
Technical methods and standards	1,2,3	1,2,3		1,2,3	1,2,3	
Guidelines and interpretations of regulations		1,2,3	1,2,3	1,2,3	1,2,3	
Financial and taxation regulations	a	1,2,3		1,2,3	1,2,3	
Business establishment regulations	a	1,2,3		1,2,3	1,2,3	
Intellectual property regulations	a	1,2,3		1,2,3	1,2,3	
Manufacturing regulations including health, safety and human resources	а	1,2,3	1,2,3	1,2,3	1,2,3	

<sup>1 =</sup> RSCs

Source: Authors

#### Knowledge Assimilation and Exploitation

Institutional knowledge such as financial reporting, taxation, intellectual property protection, and health, safety and human resources knowledge related to production compliance, included some country-specific aspects but, typically, conformed closely to international best practices and standards and were more easily transferred between countries.

Regulatory product knowledge, was however, shown to be country and productspecific, and therefore more difficult and time-consuming to acquire given that it required much more extensive tacit and experiential learning. Rules, regulations and norms of regulatory product knowledge also appeared to be much more difficult to transfer given the presence of high non-tariff trade barriers, including those of the WTO which have made drug regulation "virtually synonymous with national sovereignty" (Vogel, 1998:1) and an extremely arduous institutional process of navigating through pre-market regulatory product approvals, prior to internationalisation. In some instances learning within one market within a region was, applicable to some other markets in the same region, or to different markets in different regions. For example, technical quality methods, such as shelf-life testing protocols, might be similar within specific regions (e.g. Southeast Asia) given similarities in temperatures in warehousing, transportation and retail environments. Similarly, experiential knowledge of international regulatory systems and structures, Good Manufacturing Practices (GMPs), some drug and food standards or quality systems, general principles of claim substantiation, and knowledge of ingredients could also be transferred. Similarities between markets that used the same regulatory systems aided firms to understand if they were dealing with a higher (e.g. drug) or lower regulatory standards (e.g. food) and, hence, the amount of work required for compliance.

Similar to prior research, all of the firms appeared to learn to integrate, actively and rapidly, existing knowledge with new knowledge because individuals, firms and networks were

<sup>2 =</sup> ISMCs

<sup>3 =</sup> MFBs

<sup>&</sup>lt;sup>a</sup> Limited aspects of domestic regulations or standards learned congenitally by all three firm types was consistent with those in foreign markets

so willing to share institutional knowledge extensively. Each of the firms increased their absorptive capacity for this knowledge and developed new dynamic capabilities in institutional knowledge acquisition and learning processes even where institutional voids existed, and in problem solving, the later similar to Fletcher (2009) in the acquisition of market knowledge in internationalisation. These changes influenced the firms' strategic decisions and increased their competitive advantages and multi-country performance.

# **Institutional Learning Framework**

Based on the data collected in this study, we developed a conceptual framework (Figure 2) for institutional learning which incorporates the knowledge requirements, the sequencing of their acquisition, the range of sources utilised, the methods through which learning is acquired and triggers for future adaptation. Institutional knowledge requirements, depending on the market and the firm, may be either individual or of several parallel types and include a range of both domestic and foreign knowledge. The breadth of the range of types needed may be unexpected for firms new to the internationalisation process or serve as a checklist for those who are. It is also important that firms understand the sequencing of knowledge needs. Knowledge may logically be needed early, midway, later or even post process, and types which require lengthy acquisition periods must also be planned for well in advance. There are key differences, too, in how information is acquired, assimilated within the firm and exploited. If any one of these processes is carried out inadequately, internationalisation may be prevented. Firms must, therefore, think about how the learning process is managed, shared internally within the firm and its functions, and exploited externally if firms are to succeed in internationalisation and develop dynamic and substantive capabilities, absorptive capacity and sustainable competitive advantage as the firms did in this study.

One of the key challenges for the pharmaceutical SMEs studied here, was in determining actually where to find foreign or domestic sources of institutional knowledge, in particularly when institutional voids existed, or where the information needed was not codified. The information might be needed for the first time, and in other instances, conformational. Networking, individuals, the use of documents, websites and research may all play important roles in sourcing the information directly, or in identifying potential new sources of 'missing' knowledge. This model, therefore, identifies a range of domestic and foreign sources which may be leveraged in that regard.

Huber (1991) identified a range of methods of knowledge acquisition which were consistent with the findings of this study on institutional knowledge, whether in obtaining knowledge for the first time (i.e. original) or as conformational findings. Given the dynamic nature of institutional knowledge, for changes to be incorporated either during the process itself, or subsequent to it, it appeared in this sectoral study, that the types of knowledge required drove which sources were utilised to access that knowledge, and the types of methods employed.

Institutional knowledge is, however, not static, but rather subject to change. Political and legal triggers can affect not only the acquisition process, but also its assimilation, change requirements and impact how that knowledge can be exploited in the future. Those adaptations may, as a result, make the process a series of iterative loops driving further knowledge acquisition, assimilation and exploitation processes in future. Given that some institutional knowledge or its principles may be transferred across markets, the framework may also be applied between and across markets in the internationalisation process.

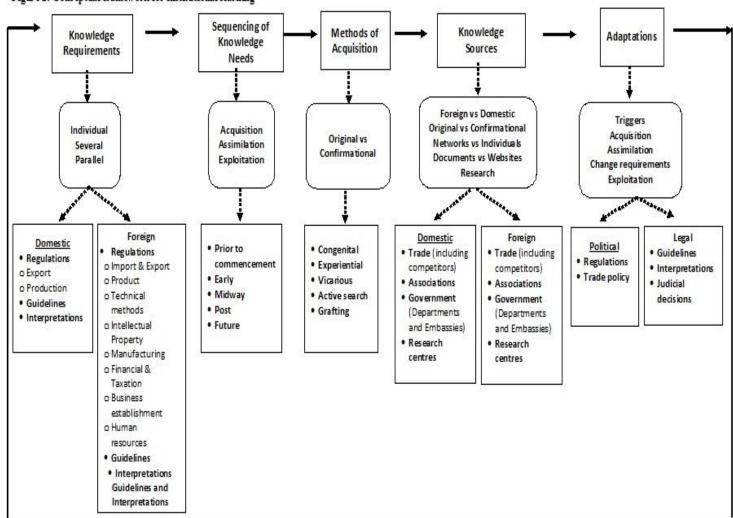


Figure 2: Conceptual framework for institutional learning

Source: Authors

#### 5.0 CONCLUSIONS

This study contributes to our understanding of the institutional knowledge learning process in internationalisation in a number of different ways. First, it presents a new conceptual framework for institutional learning which seeks to move from the empirical data to a higher level of abstraction and conceptualisation of various aspects of the process. It also reflects the dynamic nature of institutional knowledge, including the iterative loops required as firms determine, source, access and incorporate new knowledge required to address new regulatory regimens. Even though some parts of the framework are not unexpected or may be taken for granted, the model points to the magnitude of the institutional knowledge acquisition, assimilation and exploitation process needed for successful internationalisation. The elements of each step in this process are obviously complex and each must be successfully completed before new knowledge can be assimilated with other elements, firms' absorptive capacity increased, and learning exploited successfully. This framework has, however, been shown clearly to propel a range of different service, manufacturing and combination firms within the pharmaceutical sector to internationalise successfully in more than 50 different markets. While the focus on a single sector in this study could be considered a limitation, the findings may, nevertheless, be generalisable to other knowledge-intensive or highly regulated industrial sectors, born-global SMEs and MNEs.

The framework may prove useful for governments in understanding the knowledge acquisition processes of firms entering their own and other foreign markets. How a manager will find value in the model is based on how it helps them navigate through the process. The model seeks to characterise a much more holistic view of the process, both conceptually and practically, and aids in decision making. For example, international marketing managers may gain valuable insights into how to plan, organise, manage and match their institutional knowledge-seeking, learning and exploitation activities with their firms' internal capabilities, staffing and other resources in a more effective and timely manner. The framework should now be tested within other sectors and MNEs to confirm its validity. Future research might also investigate how sustainable competitive advantage arises from the heterogeneity of firm types, sizes, sectors and utilising this process.

The study also clearly identified what types of institutional knowledge could be transferred successfully between markets as this has not been discussed in the literature. Institutional regulatory-specific product knowledge, the most important type required, significantly affected both market selection and mode of entry, and when acquired insufficiently, or where firms were unable to comply with those requirements, prevented internationalisation. Technical knowledge and methods related to institutional regulatory compliance were also identified to be important components of the institutional scientific product regulatory compliance requirements, as previously suggested by Vogel (1998), and but this study established that if they were not acquired sufficiently, they could also prevent internationalisation.

The internationalisation process of SMEs in this sector study was found to be particularly challenging, time-consuming and expensive for several reasons. First, the normal regulatory compliance processes required anywhere from several months to years to be developed and approved successfully, depending on the market involved. Secondly, where firms encountered voids in codified institutional knowledge, they faced the challenge of having to obtain access to the missing knowledge via new experiential, tacit and often simultaneous learning processes as well as via other acquisition methods, and using a broader range of sources than had been identified previously (e.g. Fletcher, 2009; Harris et al, 2013). An inability to fill these institutional knowledge voids prevented firms from entering specific markets where those voids were encountered and could not be overcome. Thirdly, where firms were, unable to achieve compliance with their existing products, or where they wished to take advantage of

loop-holes in regulations which did not exist in their home markets, they utilised and combined both existing and new learning, and increased their absorptive capacity for institutional knowledge, to extensively and intensively problem-solve, innovate new products, formulae, processes, health claims, and marketing and market entry strategies, innovations which they may not have undertaken otherwise. Many of these new innovations allowed the firms to create sustainable competitive advantages both in these local markets, and for the firm globally. The firms later discovered that many of these innovations and competitive advantages were also useful in entering other markets with similar cultural or institutional characteristics, or even in their own home markets. SMEs which lacked the necessary funds to pursue these changes were often discouraged from market entry and perhaps the internationalisation process overall. While these findings reaffirm that internationalisation (Johanson & Vahlne 1990, 2009) is an experiential learning process, this study suggests that this process may also be much more innovative across a wider range of products, services and processes than has been suggested previously.

Once acquired, institutional knowledge was shown, in this study, to be quickly assimilated and exploited because it allowed firms to then determine successfully: a) if products could enter markets in their existing forms, b) what changes or innovations were required to comply with pre-market authorisations, c) if markets were, therefore, attractive to enter, d) to generate more successful regulatory compliance applications, e) determined what resources were required for market entry, and f) identified the specific mode of entry needed.

During this learning process, the firms were observed to have developed new and complementary dynamic and substantive capabilities related to knowledge acquisition, assimilation, exploitation and problem solving which, firms which did not have to face those obstacles might not, otherwise, have developed. Similar to Fletcher's (2009) findings, these new dynamic capabilities allowed SMEs to transform and exploit a large range of new knowledge about how things were done and in problem solving, to similar experiences in other markets. These new capabilities also influenced the firms' strategic decisions, and aided them in the development of new competitive advantages which improved their international performance.

This study is valuable for firms seeking to internationalise as it highlights the importance of on-going operations and innovation in the learning process and in the development of absorptive capacity for institutional knowledge in internationalisation. By increasing the diversity of the knowledge acquired across multiple markets, these activities improve not only the success rate of internationalisation, but also contribute significantly to the development of a wider range of innovations than would likely have occurred had the firms remained in their home markets. The study also demonstrates the challenges of operating in markets with institutional voids and provides a new framework for planning, organising and managing knowledge acquisition activities related to new markets which may be generalisable to MNEs in this sector as well as other knowledge-based or highly-regulated sectors in internationalisation.

From this research, policy makers gain insights into the costly effects of institutional voids on the ability of SMEs to internationalise, and how those voids stretch the capabilities, and resources of the firms involved. In the development of future trade agreements governments should, therefore, place more importance on achieving greater harmonisation of international trade policies if these firms are to contribute more effectively to economic development. Our findings highlight an interesting dilemma: should firms proceed in the shorter term to internationalise, given the extent of non-tariff trade barriers (or can they afford not to, given the competitive nature of business) or should they await governments' notoriously slow harmonisation processes before seeking internationalisation? Given that this was the first major study on this particular industry, outside practice-based research, future research might

usefully be extended to examine other sectors to provide a multidimensional and complementary perspective on this rapidly growing industry, and its international trade policy needs.

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