

Panos Kanavos, Willemien Schurer and Sabine Vogler
**The pharmaceutical distribution chain in
the European Union: structure and impact
on pharmaceutical prices**

Report

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The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices

Panos Kanavos¹, Willemien Schurer¹ and Sabine Vogler²

¹ London School of Economics, London, UK

² Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG, Vienna, Austria

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List of Abbreviations

AESGP:	Association of the European Self-Medication Industry
AM:	Agency Model
DF:	Dispensing Fee
DH:	Department of Health
DKK:	Danish Kronor
DoH:	Department of Health
DTP:	Direct to Pharmacy
EKO:	Erstattungskodex (reimbursement code) (Austria)
EFP:	Ex-Factory Price
EU:	European Union
GIRP:	European Association of Pharmaceutical Full-Line Wholesalers
HBV:	(Austrian) Federation of Social Insurance Institutions (Austria)
HC:	Health Counselling services
INN:	International Non-Proprietary Name
MS:	Member State
NAO:	National Audit Office (UK)
NHS:	National Health Service
OTC:	Over the Counter
OFT:	Office of Fair Trading (UK)
OP:	Off Patent
PCT:	Primary Care Trust (UK)
PGEU:	Pharmaceutical Group of the European Union
PoM:	Prescription only Medicine
PPP:	Pharmacy Purchasing Price
PPRI:	Pharmaceutical Pricing and Reimbursement Information
PPRS:	Pharmaceutical Price Regulation Scheme (UK)
PR:	Private Market Medicine
PRP:	Pharmacy Retail Price
PSNC:	Pharmaceutical Service Negotiating Committee (UK)

RWA:	Reduced Wholesaler Agreement
RWM:	Reduced Wholesaler Model
SF:	Sickness Fund
SHI:	Social Health Insurance
UK:	United Kingdom
VAT:	Value Added Tax
WS:	Wholesale
ZD:	Zero Discount

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Executive Summary

Objectives

In an environment characterised by fragmentation in the market structure of wholesale and retail entities, significant diversity in terms of remuneration schemes as well as regulations pertaining to operational features of wholesale and retail entities, but also significant developments in policy and practice concerning distribution, the objective of this report, is twofold: First, to map the distribution chain in EU Member States, including the main actors in wholesaling and retailing, discuss the requirements to provide certain services and outline their sources of remuneration, both direct and indirect. Second, to collect and analyse data on distribution margins, fees and service requirements in the originator and generic markets in EU Member States with a view to understanding the impact the distribution chain is having on the prices of reimbursable prescription only medicines (POMs). The report does not address issues relating to over-the-counter (OTC) medications.

Methods

The report relies on both primary and secondary data and information. Secondary data and information come from available peer review literature and reports, whereas primary sources relate to information collected via semi-structured interviews with key stakeholders (both individuals, corporate entities and associations), notably wholesalers, pharmacists, representatives of pharmaceutical industry (both branded and generic), patient representatives and payers/health insurers.

Market structure of pharmaceutical wholesaling and retailing in the EU

There is a diversity and fragmentation of wholesaling and retailing entities at EU level, as reflected by the market structure of both wholesaling, but, more importantly, retailing entities. Significant variation continues to exist in the density of wholesale and retail outlets in the EU, propagated by national regulation and historical patterns.

There exist different densities in terms of number of wholesalers and number of pharmacies in the population in the member states, as well as different regulatory policies setting the operating framework for distribution (both wholesale and retail) outlets.

Some consolidation in activities has been observed over time, particularly in pharmacies, as experienced by horizontal integration through pharmacy chains, but also differential regulation regarding the extent to which such consolidation can take place.

Vertical integration has been on the ascendancy particularly with wholesaler groups taking over pharmacies or pharmacy chains, although the opposite is also possible.

The frequency and influence of schemes such as DTP and RWM has risen substantially in the past 5 years; this trend can alter the rules of the game, particularly where the public service obligation is not present. Through a variety of schemes manufacturers are in a position to bypass wholesalers and sell directly to pharmacies.

Elements of diversification (expansion of services) by both wholesalers and pharmacies, particularly where there is a squeeze on margins have been shown to exist as a response to some of the pressures on margins and the emergence of new distribution models.

Distribution Margins

The majority of Member States have regulated markup/margin schemes to both or either wholesalers and pharmacies, at least for reimbursable medicines.

There are different markup/margin schemes for reimbursable and non-reimbursable medicines in a few countries; there exist specific schemes for other retailers of prescription medicines in the very few countries with such other retailers; and there is a specific incentive for dispensing generics in one country (France).

Regressive markup/margins are very common, but some countries also apply linear markups/margins. For pharmacies, dispensing fees are used in a few countries, and in one country (Slovenia) pharmacies are funded on a fee-for-service remuneration. Average wholesale margins range from 2-24% of PRP (low in Sweden, high in the Netherlands, both unregulated private negotiations), with the majority ranging between 4-8% of PRP.

Considerably less information is available regarding the average pharmacy margin in individual countries, however, for the 15 countries for which average pharmacy margins could be surveyed, the range is 12-50% of PRP (low in Romania, high in Luxembourg).

Discounts and rebates play an important role in defining the exact amount of the wholesale and pharmacy remuneration. On the one hand, in several countries commercial discounts (offered by manufacturers to wholesalers, by wholesalers to pharmacies, by manufacturers to pharmacies, and in some cases by pharmacies to patients) are granted, in a few cases limited by regulation. The exact amount of these discounts and rebates is confidential. On the other hand, wholesalers and, in particular, pharmacies, are obliged to grant discounts and rebates to public payers in nine countries (known as “claw back” or “solidarity contribution”).

Impact of Wholesale and Retail Margins on the Prices of Prescription Medicines

It looks as though that there is a tremendous range in prices at each stage of the exercise from EFP to gross PRP between EU27 Member States. This price spread is significantly more apparent in generic medicines than it is in branded, and far more apparent in less expensive medicines than more expensive medicines.

Although EFP appears to some extent to predict approximately the final gross PRP to the payer, this is not always the case. Countries such as Greece, Italy and Luxembourg for branded medicines, and the Netherlands for generic medicines saw dramatic changes in their ranking with the addition of wholesale and pharmacy margins. This highlights the fact that the impact of distribution is different in different Member States.

It appears that the application of distribution margins may be different between branded and generic medicines, in some countries in particular. Countries with consistently low EFP, in some cases less than 5 percent of the final gross PRP, were Belgium, Denmark, Germany, Netherlands, Sweden – of interest these countries also had low relative EFP for their branded counterparts.

The impact of distribution costs and taxation on health systems and payers also seems to vary significantly by type of drug (brand vs generic).

The impact of distribution costs and taxation on health systems and payers also seems to vary significantly in the generics case as it does in the branded medicines case, although the variation in this case is far greater than in branded medicines (as shown on Figure 5.3).

The structure of wholesale and retail margins does mean that in certain, but *extreme*, cases the impact of distribution costs and taxation exceeds 90% of the total cost to payer and the average seems to be higher than in the case of branded medicines.

The changing market structure – impact on stakeholders

Manufacturers would in principle be interested in a supply chain that guarantees the efficient distribution of their products for the intended markets and at reasonable cost. Access to patient information at the micro level (i.e. in individual communities) would be key and an area worth investing in. In an era of logistics and stock management being driven remotely by advances in information and communication technology (ICT), the value-added of certain components of the distribution chain have often been questioned in relation to the services provided and the overall cost of these services. As a result, it is not surprising that manufacturers explore alternative (wholesale) distribution arrangements.

Wholesalers feel squeezed by current practices as well as some recent developments. Current practices in wholesaling suggest that wholesalers typically offer a proportion (in some cases significant) of their allowable margin as a discount to pharmacy. Interviews with wholesaler stakeholders alluded to actual margins ranging between 1.5 – 3.5%. Pharmacy chains may have greater negotiating power and can, as a result, benefit from a higher discount from wholesaling, although the extent to which this is true at aggregate level is unclear and can be the subject of further scrutiny.

Competition among wholesalers for the retail business has intensified in recent years by developments in IT and logistics, as well as the entry of manufacturers who are increasingly interested in establishing direct vertical links with the retail business. In some cases, this is resulting in the map of players on the market being re-drawn with consolidation of existing entities and entry of others or a re-definition of activities by existing players.

These dynamic developments can have a significant impact on wholesaling and the competitive advantages it has in the distribution of medicines. Interviews with wholesalers and other stakeholders indicate that the traditional full-line wholesaling model (stocking the widest possible gamut of pharmaceutical products, easy access to stock by and timely & frequent delivery to retailers) is under dispute – indirectly - in a number of Member States, particularly those where the environment is more flexible regarding ownership and

integration. As a result, if wholesaling is to survive it will probably need to develop further competences and links downstream strengthening existing advantages.

Retail market structure remains diverse across EU Member States, as does the regulatory environment relating to ownership, procurement and ability to integrate both horizontally and vertically.

Greater efficiencies can be achieved by joint procurement and this can materialize through a horizontally or a vertically integrated structure or a cooperative. Countries where horizontal or vertical integration are limited by current legislation are taking advantage of the “cooperative solution”, e.g. Spain, France and Greece.

Redefining the role of pharmacy is a great pursuit, particularly in what concerns health promotion, prevention, aspects of disease management and monitoring. There may be considerable benefits to society and the health care system from this development in terms of quality, access and cost. Pharmacy chains are likely to benefit more from this development in terms of volume, facilities within pharmacy and network or population coverage. Yet, the willingness of health authorities to pursue this remains sluggish.

An important competitive advantage of pharmacy, making it an attractive target to pursue further consolidation in the field is its direct relationship with the patient population and the use by the latter as a source of information and advice. This is already driving developments in some Member States and further developments are still to come. Where access to pharmacy problems exist, particularly in rural or/and remote areas, alternative solutions may exist, e.g. via dispensaries or dispensing physicians.

Patients are in principle neutral to consolidation in the distribution sector, so long as access and availability of medicines are not compromised and the range of available services increases at no additional cost to them. Increasing services at pharmacy level could prove beneficial particularly if they are offered in a timely fashion and avoiding waiting times. In some instances, patients have raised questions about access to services and the length of time it takes for them to access a pharmacy. This is particularly important for elderly and vulnerable patients in rural areas. Where these phenomena exist action could be taken by the competent authorities to ensure that access remains at acceptable levels. Where pharmacy chains occupy a significant proportion of retail distribution access problems in rural areas could be addressed by operating chain outlets in problem areas.

From a payer perspective, greater consolidation could mean lower distribution costs because of economies of scale in procurement and distribution, taking advantage of common networks and more efficient operations. In theory, consolidation would imply lower fixed costs, but it is questionable whether compressing these can be achieved *ad infinitum*. It may even be doubtful whether cost reductions can be achieved in the first place given the changing patterns in the distribution of medicines and the increasing proliferation of agency and reduced wholesaler models.

But even if these models are not taken into account for a moment, it is likely that the environment in the distribution chain is becoming more competitive with payers demanding greater generic dispensing (and, therefore, at a lower overall margin) and driving the market for generic products, as it has recently been seen with outpatient tendering in some countries (the Netherlands, Germany, and Hungary, among others).

Such developments are unlikely to enable further sustainable reductions in margins without having an impact on market structure of distribution.

Additional services that can be provided by retail pharmacies could go some way to maintain existing structures, yet, it is not always clear what additional value these services create and what an adequate remuneration is as a result. For instance, health promotion campaigns, monitoring, audit, or clinical governance could be undertaken by pharmacies, yet, a number of stakeholders at national and regional level have suggested that they cannot support financially these services.

In an environment characterized by consolidation, payers need to be mindful that access to pharmacies is maintained overall, particularly in rural areas, which are, in principle, under-provided. In areas where there seems to be a problem, rural pharmacies can be offered financial incentives to continue operating for the benefit of the wider community they serve.

Changes to the prevailing distribution model

The changing nature of distribution and the advent of the agency and the reduced wholesaler models, is beginning to have a significant impact in some countries. In principle, changes in the distribution model should make the process of delivering medicines from factory gates to the patient bed-side more efficient and cost-effective. Yet, there seem to be some concerns about the availability of medicines; it could be the case that manufacturers' activities in streamlining supplies and managing stock coupled with the ever fragmented nature of distribution, can lead to shortages in some markets.

Clearly, there all kinds of incentives and disincentives from different stakeholders' perspective (manufacturers, wholesalers, retailers) in this process, but these do not seem to be aligned at all times. Payers, on the other hand, find little reason to intervene unless patient access to medicines is significantly affected or shortages are shown to be having an impact on care and outcomes. At the same time, it looks as though breaches from the public service obligation do not necessarily occur in situations where a reduced wholesaler model operates. This may be the subject of a wider further discussion on the subject. Competent authorities, where appropriate have intervened to provide some clarity on some of the newly emerging rules of the game.

Policies on distribution margins and their implications

The stakeholder perspectives in this part of the analysis revealed significant rifts in the perceptions of stakeholders about their respective contributions.

Manufacturers recognize the importance and contribution of the distribution sector to ensuring access and availability of medicines to patients. Yet, it is often argued that the cost of distribution is in many cases disproportionate to the value it offers to the general public and, as such, should be reconsidered and become more in-line with the contribution that the pharmaceutical sector makes in terms of bringing new therapeutic alternatives to market. Equally, it has been argued that where brands and generics co-exist, the structure of margins and markups in many cases favour generic medicines, thus creating an unequal playing field among equivalent therapeutic options. This is exacerbated in situations where

therapeutic reference pricing exists and where branded, in-patent products are included in therapeutic clusters.

Partly as a result of the above, it is not uncommon for manufacturers to consider more direct options to distribute their products and reach pharmacies. Although this implies considerable initial investment, it is often considered worthwhile. Other stakeholders in the distribution chain contend that these movements by manufacturers automatically result in wholesale (and, potentially, retail) margins and other income being curtailed as manufacturers can re-define the terms of wholesaler engagement.

Wholesalers operate on the basis of large volume and small margin. They feel squeezed by the nature of competition and the requirements of public service obligation and frequent distribution to retail outlets, the net result being a very low net margin on wholesale distribution of medicines. They also perceive recent changes in the distribution model in a number of Member States, particularly relating to higher cost medicines, as partial and creaming off a significant source of revenue for their operations. Where already experienced, the direct involvement of manufacturers in distribution has changed the way the sector operates and the ability of wholesalers to compete and offer value deals to their customers.

It is likely that if these trends become more generalised in the years to come, the wholesale sector will experience further consolidation. Already, as pointed out at interview, a number of wholesalers have gone out of business or have merged with others, as a direct impact of the above trends.

Pharmacists often feel they are asked to do more for less, that there is reluctance by payers to remunerate them for additional services rendered and that, as a result, other segments within pharmacy is cross-subsidising the POM segment. Importantly, the changing role of pharmacy in the community does not necessarily seem to be reflected by actions at policy level. In addition, their ability to negotiate terms with wholesalers is beginning to change in environments where products are delivered directly by manufacturers and where pharmacy is incurring a significantly higher cost in search of product.

Patients are largely unaware of the costs of distribution and their primary consideration is the availability and affordability of medicines. Distribution remuneration, particularly at retail level, should capture some of the gaps in availability, particularly in remote or rural areas where such problems seem to be more acute. Patients in some cases argue that the pursuit of profit across pharmacy chains is responsible for problems in the geographical allocation of pharmacies and that this ought to be addressed.

Insurers face a significant cost of distribution and taxation. Significant changes have taken place over the past decade in the majority of Member States in an attempt to reduce the impact of distribution (but not taxation) and calibrate remuneration structures, often resulting in a reduction of wholesaler and – in some cases – retail margins.

In some cases, health insurers have experimented with “novel” initiatives for the retail market, such as tendering and rebate policies. Apart from the unintended consequences that such schemes may have, these initiatives have revealed, among other things, the reservation price of mature (off-patent) medicines and the cost payers should be paying without it being inflated by discounts.

In some Member States the cost of taxation is set at disproportionate levels. While a majority of Member States have set reduced (or zero) VAT rates for prescription medicines, in some (e.g. Austria, Denmark and Germany) normal rate VAT levels reflect the perception of prescription medicines as normal consumption goods. While there is little in terms of a theoretical or empirical justification for imposing VAT on prescription medicines, its use reflects a reverse tax by national Treasuries on health care resources. Yet, it appears that there is little Ministries of Health or sickness funds can do to mitigate this, as it relates to national (taxation) policy priorities, where decisions are taken by Finance Ministries.

1. Background and Objectives

In recent years there has been considerable focus on the impact the distribution chain is having on the total cost of prescription pharmaceuticals. Policy-makers have been cutting the remuneration for distribution, while in a few countries they have also been trying to provide incentives to certain parts of the distribution chain to enable the use of cost effective alternatives. At the same time, the distribution chain has witnessed considerable consolidation in the past decade, which has manifested itself in horizontal but also vertical integration with varying degrees of intensity and depending on national regulations. New paradigms in prescription medicines' distribution, such as Direct to Pharmacy Distribution (DTP), have begun to manifest themselves in some European markets with varying degrees of intensity.

There is limited literature relating to distribution margins and their impact on prices of medicines. One cross-country European study comparing prices and margins for a basket of 20 medicines found significant variations in ex-factory prices (Italy lowest), distribution margins (Netherlands and UK lowest) and third party payer prices (Germany highest) (Garattini et al, 2008). Earlier studies found similar results (Martikainen et al, 2005; ÖBIG 2004), and both studies concluded that prices were lower in countries with strict pricing control policies, such as Italy, France and Spain.

Evidence from available sources suggests that wholesale margins, particularly in some Scandinavian countries, are the subject of negotiation between manufacturers and wholesalers; there are often different margins for non-reimbursable OTC drugs versus reimbursable drugs; that in most countries margins appear regressive and linear, and that in most maximum-set margins exist; most countries have lower value added taxation for pharmaceuticals than other goods, and may have different rates for reimbursable versus non-reimbursable medicines.

In an environment characterised by fragmentation in the market structure of wholesale and retail entities, significant diversity in terms of remuneration schemes as well as regulations pertaining to operational features of wholesale and retail entities, but also significant developments in policy and practice concerning distribution, the objective of this report, is twofold:

- First, to map the distribution chain in EU Member States, including the main actors in wholesaling and retailing, discuss the requirements to provide certain services and outline their sources of remuneration, both direct and indirect.
- Second, to collect and analyse data on distribution remuneration (margins, fees) in the originator and generic markets in EU Member States with a view to understanding the impact the distribution chain is having on the prices of

reimbursable prescription-only medicines (POM). The report does not examine the requirements for or regulations and arrangements pertaining to counter medicines (OTC) medicines.

Section 2 outlines the methodology employed in the report outlining primary and secondary data collection sources. Section 3 presents the key trends in market structure of wholesaling and retailing in EU27. Section 4 presents updated remuneration policies and practices in wholesaling and retailing, while section 5 builds on the previous sections by presenting the impact distribution is having on the final prices of prescription medicines (both branded and generic) reimbursed by payers in EU-27. Section 6 teases out some of the emerging issues in distribution in a small number of EU countries, whereas section 7 provides an overall discussion of developments in the EU pharmaceutical distribution also by drawing on views and perspectives of individual stakeholders. Finally, section 8 summarises the main conclusions of the study.

2. Methodology

The study relies on both primary and secondary data sources. Primary data collection consisted of structured interviews conducted between May and September 2010 with a number of stakeholders, including:

- the European Association of Pharmaceutical Full Line Wholesalers (GIRP – www.girp.eu), representing the national associations of full line wholesalers,
- the Pharmaceutical Group of the EU (PGEU – www.pgeu.eu), representing the national associations of pharmacists, in EU countries.

These structured interviews primarily explored the degree of regulation of their country member activities, the degree of integration occurring both vertically and horizontally, as well as confirming the information contained in the distribution database. A list of the questions posed to these associations is contained in Appendix 1. Additional material and information was collected during the workshop on distribution organized by the European Commission in Brussels on July 1 and 2, 2010.

Supplementary structured interviews took place with key stakeholders in Austria, Belgium, Greece, France, the Netherlands, Spain, Sweden, Switzerland, the Baltics and the UK in order to tease out issues related to wholesale and pharmacy retail distribution developments, regulation and market structure. Stakeholders included wholesalers, pharmacists and their representative bodies, decision makers (health insurance and payers), patients and manufacturers. Interviews took place between May and mid-September 2010. This information was subsequently used to inform some of the issues facing individual countries (section 6) and the stakeholder analysis (section 7).

The secondary data collection comprised a comprehensive literature search, review and analysis of both peer reviewed studies and grey literature. The search phrase [wholesale AND (“margins” OR “mark up”) OR (“pharmacy” OR “retail” AND (“margins” OR “mark up”))] with limits of English language was entered into PubMed and returned 46 published studies from January 1998 to July 2010. Of these 46 studies, 23 were not related to pharmaceutical distribution systems, 6 were related to medical devices or illicit drugs and 2 were related to distribution in developing countries. The abstracts of the remaining 15 articles were read for relevance, with 2 rejected due to non-relevance and 7 addressing distribution outside the EU27. The remaining 6 studies were read, of which 3 studies were relevant to this paper and the rejected 3 did not include sufficient details on margins to warrant adding to this document. Exploration of similar terms in Google Scholar generated 5 additional non-peer reviewed studies. Additional sources of information were gathered from studies on the subject conducted by ECORYS, ÖBIG as well as the Pharmaceutical Pricing and Reimbursement Information (PPRI) Country Reports.

Second, a distribution database was created containing the most recent details (2008 onwards) of wholesale and retail distribution for reimbursable pharmaceuticals in EU27. Details included: margin/mark up types (regressive, linear, fee for service), variations in margin application (client differentials, medicine class differentials – eg for different types of medicines), VAT, average margins/markups, discounts/clawbacks/rebates (mandatory, commercial), regulation details, degree of integration allowed (horizontal, vertical), wholesale distributors (how many, top companies), pharmacies (how many). Data was collected from the most recent Pharmaceutical Pricing and Reimbursement Information (PPRI) country reports plus updates by the PPRI secretariat in consultation with the authorities as well as national and EU-operating associations. The country information per margin/markup types were classified and graphed.

3. Market structure of pharmaceutical wholesaling and retailing in the EU

3.1 Market Structure in Wholesaling

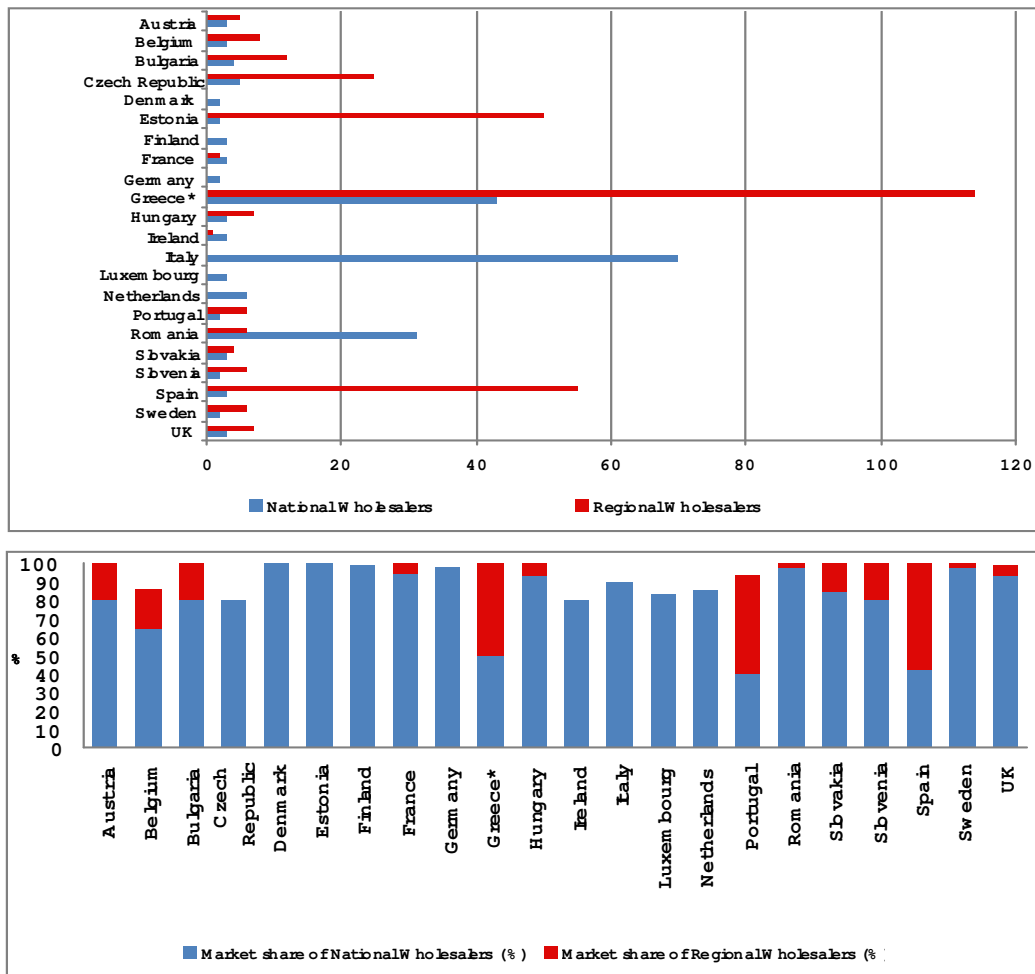
The majority of countries have a mixture of national and regional wholesalers supplying medicines to pharmacies, with national wholesalers in principle providing the full range of medicines (“Full Line Wholesalers”) and regional wholesalers providing either full or partial range of medicines (“Short Line” refers to stocking of limited list of medicines, Figure 3.1). Although regionally-operating wholesalers may be more plentiful than wholesalers operating at national level, except for France, Ireland and Romania, national wholesalers command the largest share of the market, except for Portugal and Spain where regional wholesalers have greater than 50 percent market share. In Greece there is spatial segmentation, whereby wholesalers operate at regional level as legislation only allows them to have one warehouse in the part of the country where they operate, plus a commercial interest in another warehouse in another part of the country. Minimum frequencies of delivery by wholesalers range from once to three times daily (Figure 3.2) and in the majority of cases are the outcome of public service obligation (with the exception of the UK, where such requirement does not exist).

A minority of countries (Sweden, Finland) have single channel systems where a wholesaler has the exclusive right to distribute medicines for a manufacturer. This has an impact on the relationship between manufacturer and wholesaler. In single-channel countries, there is usually a very low number of wholesaler companies, which have a stronger market power than wholesalers in multi-channel systems (ÖBIG 2003). The remaining 25 EU Member States apply multi-channel systems in wholesaling, in which medicines of a manufacturer are distributed and supplied in parallel via different wholesalers.

In the last decade, nearly all countries have seen mergers in the wholesale sector and a decline in the number of operating wholesaler companies (PPRI Country Reports).

The above patterns and trends in market structure must be examined critically in view of recent changes in wholesale and retail distribution of pharmaceuticals. The advent of agency models and reduced wholesaler models (discussed in greater detail in section 3.4) in wholesale distribution of medicines now means that pharmaceutical manufacturers can supply pharmacies directly (Direct-To-Pharmacy or DTP) by using a single (or multiple) wholesaler (s) as logistics provider (Agency Model, AM) for part or all of their product portfolio. Equally, manufacturers can contract with a small number of wholesalers for part or all of their product portfolio. This unavoidably has implications for the market structure in the wholesaling business and implies that wholesaling becomes more segmented as a result.

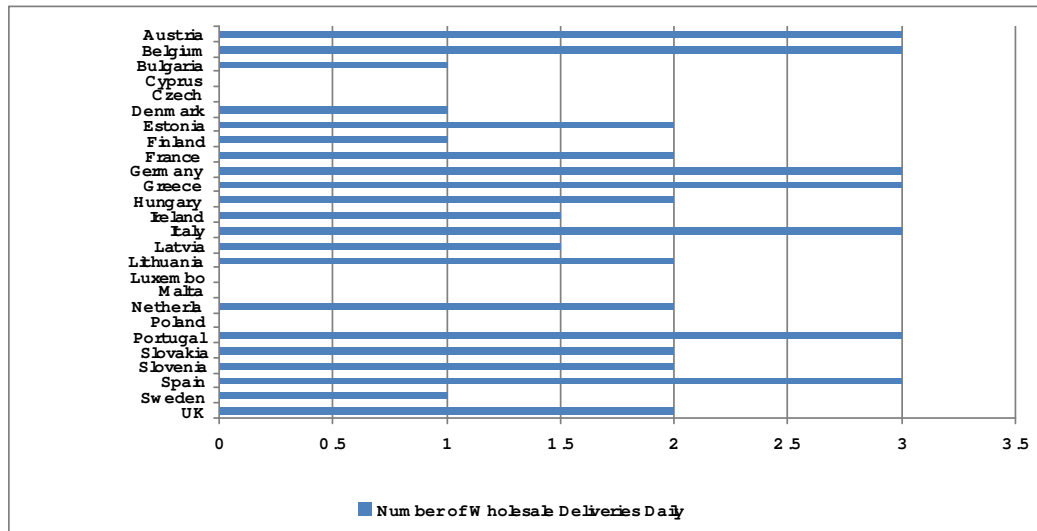
Figure 3.1: Description of national and regional wholesaler presence per EU27 member state countries (2010).



Source: Authors' compilations from GIRP Member Database, 2010.

Note: Greece is starred (*) as its comparison is between cooperative wholesalers (each working regionally however have strong bonds nationally) and private regional wholesalers. Greece has no national wholesalers.

Figure 3.2: Number of minimum daily Wholesaler deliveries to Pharmacies across the EU27 member states (2010).



Note: No data available for Cyprus, the Czech Republic, Malta, Luxembourg, and Poland.

Source: Authors' compilations from GIRP Member Database, 2010; PPRI Country Reports (2006-2008).

3.2 Market Structure in Retail Pharmacies

All countries display a stable number of community pharmacies since 2000, with community pharmacies being the primary pharmaceutical retailers although in Austria self-dispensing physicians still play a strong role (Figure 3.3, upper panel). Greece, Bulgaria and Cyprus have the highest number of pharmacies per capita, while Denmark, Sweden and Slovenia have the lowest (Figure 3.3, lower panel). In more than half of the EU27, there are regulations on pharmacy ownership (13 countries) and/or criteria regulating the establishment of new pharmacies (16 countries) (Table 3.1). In Finland, there is no legislation regarding the establishment of new pharmacies, but according to the Medicines Act, there must be a sufficient number of pharmacies country-wide to allow the general public, wherever possible, to obtain medicines without difficulty. There is some trend towards deregulation of establishing new pharmacies. For instance, criteria for the opening of new pharmacies were removed.

Usually, geographic or demographic criteria, or a mixture of both, apply for the opening of new pharmacies. For example in Austria, pharmacies must be more than 500 meters apart and the number of people who continue to be supplied by adjoining pharmacies must not drop below 5,500 customers for a new pharmacy to be opened. In France, Greece, Italy and Spain only pharmacists may be owners (albeit in some countries as co-owners) and may only own one pharmacy.

Generic substitution is allowed under various conditions (in 20 countries, thereof mandatory in 7 countries) and in 8 countries pharmacists must dispense the lowest priced medicine. Wholesaler discounts to pharmacies are formally allowed in all countries except the Czech Republic, Finland and Greece, although wholesalers in Greece typically give a discount to pharmacies from their allocated margin (information based on interviews).

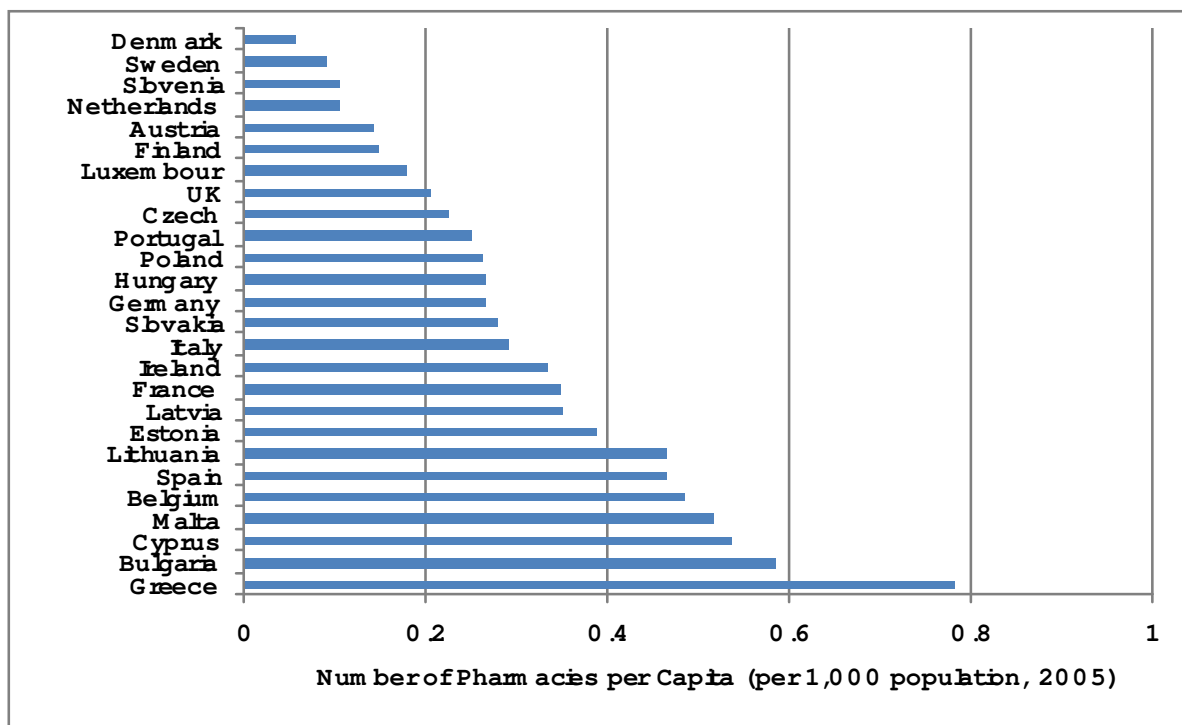
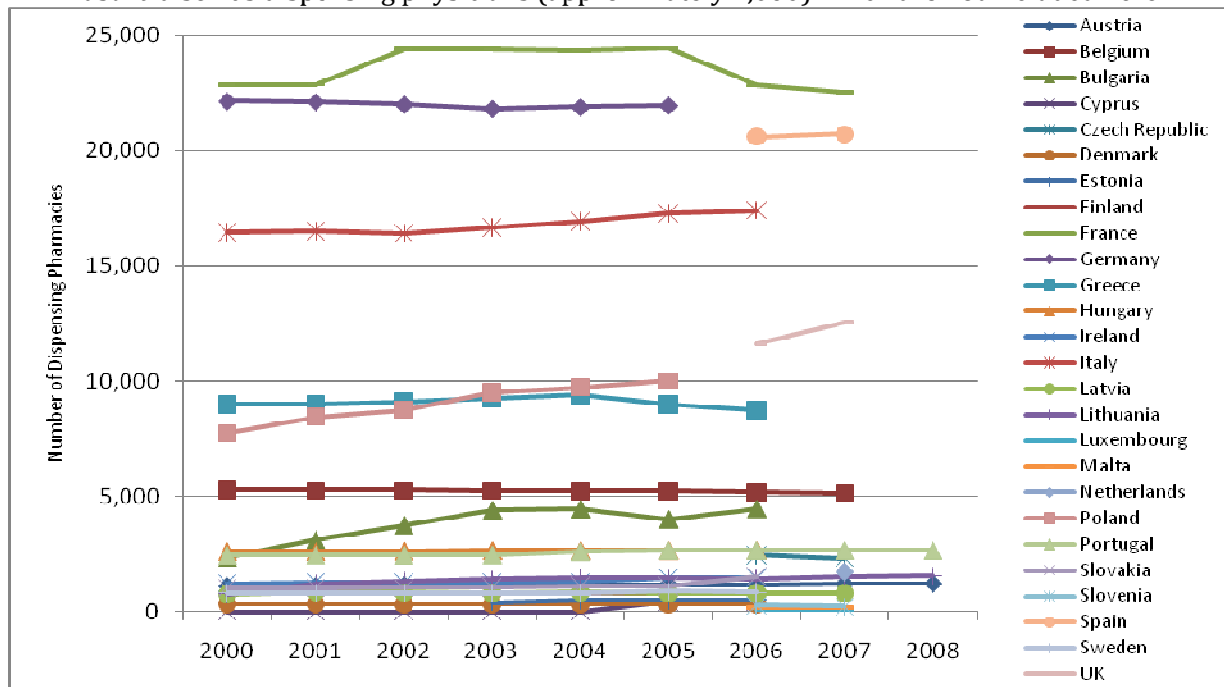
Besides community pharmacies, other dispensaries which are allowed to dispense prescription medicines to outpatients may be allowed. One reason for this is to guarantee medicines provision in remote (e.g. rural) areas. This is most commonly undertaken by dispensing doctors, who have been in place in Austria, France, Hungary, Ireland, the UK and the Netherlands. However, apart from Austria, their number has been declining and they do not play a major role in the retail sector. Only in Austria does the number of pharmacies equal the number of dispensing doctors (around 1,000 each). Furthermore, hospital pharmacists may be allowed, under specific conditions, for specific patients and/or specific products, to dispense to out-patients (e.g. in the Czech Republic, the Netherlands, Lithuania) (PHIS 2010). Branches of pharmacies under the supervision of a pharmacy (e.g. Austria, Germany) or outlets (e.g. “medicines chests” in Sweden) may be another option to address this issue. Additionally, dispensaries whose product range is limited to OTC products might be allowed and operate in a number of countries (e.g. Czech Republic, Poland, Portugal).

While distance selling of OTC products or ordering of OTC products with a community pharmacy which may subsequently deliver the ordered products as home deliveries is allowed in some countries (Belgium, Hungary, Poland, Portugal), the selling of prescription medicines over the internet is much more restricted (PPRI 2010). Only Denmark, Czech Republic, Germany, Netherlands, Slovakia, Sweden and the UK allow internet pharmacies to exist, defined as “the long distance purchase of Prescription-Only-Medicines (POMs) from Internet sources outside of the network of actual pharmacies”. In Germany, the internet pharmacy must have a special license, ensure proper storage and transportation, correct delivery, advice given to patients, less than two days delivery time, risk management system, track-and-trace of parcels and ensure availability of all medicines. In 2005, there were 1,420 internet pharmacies in Germany (PPRI-Germany, 2008). In the Netherlands, internet pharmacies must be attached to an actual pharmacy. In Sweden, patients have an electronic ID to access their electronic prescriptions, choose which medicines to order as well as examine previously prescribed medicines. Medicines are delivered to patients’ homes, post office or local pharmacy within 3-5 days. Counseling can take place at a local pharmacy or over the telephone via a call centre. In the UK, internet pharmacies must be legally constituted with a supervising pharmacist and a storehouse.

Other countries have allowed pharmacies to set up E-trade which include both OTC and POMs (Czech Republic, Denmark, Portugal Sweden). In Denmark, POMs may be ordered and paid for over the internet and can be sent to an address of a patient’s choosing or

picked up at the pharmacy. In Portugal, medicines can only be delivered to the registered home address, and websites of pharmacies are monitored for stating prices, delivery and payment conditions, geographical area of operation, delivery time, and pharmacy contact details. In 2008, 90 pharmacies were registered as providing this internet service in Portugal (PPRI-Portugal, 2008).

Figure 3.3: Number of community pharmacies across the EU27 region. Top panel presents pharmacies per capita, while lower panel presents total number of pharmacies. Please note: Austria also has dispensing physicians (approximately 1,000) which are not included here.



Source: PPRI Country Reports, ECORYS 2006 report, GIRP 2007, ÖBIG 2007 report.

Table 3.1: Description of degree of regulation of wholesalers and pharmacies across EU27 countries, 2010

	Pharmacist generic substitution allowed	Pharmacist must sell at lowest price	Wholesale rebate to Pharmacies	Regulation of Wholesale margins	Pharmacy chain allowed	Pharmacy ownership by non-pharmacist	Regulation of establishment of new pharmacies	Pharmacy ownership Regulation	Internet Pharmacy allowed
Austria	β	β			β	β/			β
Belgium	β	β							β
Bulgaria	β	β					β	β	β
Cyprus	β/	-		β			β		β
Czech Rep.		β	β	β/			β	β	
Denmark				β		β			
Estonia		β						β	β
Finland			β	β	β	β	β/		β
France		β			β	β			β
Germany					β/	β			
Greece	β	β	β		β	β			β
Hungary					β/	β/		β	β
Ireland	β	β					β	β	β
Italy		β			β	β			β
Latvia		-	β						β
Lithuania		-					β		β
Luxembourg	β				β	β			β
Malta		-	-					-	β
Netherlands				β			β	β	
Poland		-					β	β	β/
Portugal					β/		β		β/
Romania		β						β	β
Slovakia		-					β	β	
Slovenia		β			β	β			β
Spain		β/			β	β			β
Sweden				β			β	β	
UK	β			β					

Note: β/ implies the condition occurs only under certain regulations or in some special situations.
 Note regarding generic substitution: obligatory in the public sector, not allowed in the private sector

Note regarding regulation of wholesale margins: there is a joint markup for wholesale and pharmacy in the Czech Republic, margin only applicable in the private sector in Cyprus and Malta, plus only for locally-manufactured medicines in Cyprus

Notes regarding internet pharmacy: Denmark and Czech Republic – online pharmacy must be handled by an actual community pharmacy; in Poland online pharmacy is only allowed for OTC products; Belgium, Portugal, Hungary: no Internet pharmacies are allowed, but community pharmacies may offer the possibility of ordering medicines (only OTC in case of Belgium and Hungary) via Internet and are allowed to send them by mail order.

Source: Authors' compilations; ÖBIG 2010, PPRI Country Reports, PPRI 2010, GIRP Member State Database (June 2010).

3.3 Integration in Distribution

3.3.1. Horizontal Integration

Horizontal integration is defined as a fusion of entities pursuing the same line of business. There is little horizontal integration among wholesalers although there are a few operating at EU level. Increasingly, pharmacy chains are becoming more prevalent in Member States. In 19 countries pharmacy chains are allowed, again under specific condition in a few countries (Table 3.1). In Estonia, Lithuania and the UK more than 80 percent of the market is dominated by pharmacy chains, while in Ireland almost half of pharmacies belong to a chain. Previously in Sweden only one pharmacy chain existed, the state owned Apoteket, however, recent changes have opened up the market with over 14 chains sharing the pharmacy market.

3.3.2. Vertical Integration

Vertical integration is the fusion of entities who have complementary business interests. In the pharmaceutical value chain, this can mean fusion between wholesaler and retailer, or manufacturer wholesaler and retailer. Integration between wholesalers and pharmacies is a key trend, although it is bound by regulations in different countries. One prerequisite is whether pharmacies can be owned by non-pharmacists. In 18 countries non-pharmacists may own pharmacies, sometimes under specific conditions (e.g. having a pharmacist present, as is the case in Belgium and Portugal; or having a pharmacist being the (majority) owner of the pharmacy, as is the case in Austria, Denmark, Bulgaria, Czech Republic, Poland, and Romania). Some specific stakeholders (in particular prescribers or the pharmaceutical industry) may be explicitly forbidden to own pharmacies (e.g. Estonia, Sweden). In Austria, integration is allowed only if the operating pharmacist holds the majority of shares (51%) and has exclusive management power. Other countries where vertical integration is allowed, either with or without restrictions are: Belgium, Estonia, Ireland, Latvia, Lithuania, Malta, the Netherlands, Poland, Portugal (limited) and the UK. In Estonia, wholesalers and pharmacies cannot directly integrate but their subsidiary company can integrate. In Lithuania, most large wholesalers own pharmacy chains (i.e. Tamro wholesalers owns Farmacijos Projectai pharmacies). In Ireland and the UK, integration has occurred with some national and some European wholesalers. In Ireland, the German wholesaler Celesio owns both a local wholesaler (Cahill May Roberts Ltd) as well as a pharmacy chain (Unicare).

Changes in the prevailing distribution models as well as pressures on the market and the type of products that are dispensed mean that consolidation in this field can be significant.

Figure 3.4: Proportion of Pharmacy market share as source of delivery, including Full Line Wholesalers, Short Line Wholesalers and direct from Manufacturer, across EU27 region, 2010



Source: Authors' compilations from GIRP Member Database, 2010.

Note: Proportion of direct pharmacy sales may be under-represented. In the UK, Pfizer, GSK, AZ and Eli Lilly all use this route. Data not available for Bulgaria, Germany, Slovakia, Spain.

3.4. The changing nature of the distribution model

Of significant interest is the development of direct delivery to pharmacy from the pharmaceutical manufacturers, using a restricted number of wholesalers as sole agents to distribute products directly to pharmacy (Direct-To-Pharmacy or DTP), or, indeed, using wholesalers as logistics providers for the same purpose. Whereas the majority of pharmacy sales continue to originate from (full-line) wholesalers, in a number of countries the proportion of pharmacy sales originating directly from the manufacturer is over 10 percent (Denmark, Greece, Ireland, Luxembourg, Netherlands, UK) and can be over 20 percent (Czech Republic, France, Italy) (Figure 3.4).

In Austria medicines can be delivered directly to pharmacies, however, the majority of medicines are distributed via wholesalers, and in Bulgaria most manufacturers have their own wholesaling (via own development or acquisitions). In Hungary, a manufacturing license also incorporates a wholesaling license. In France, direct delivery occurs particularly for high turnover products, and in Italy manufacturers are allowed to deliver directly to the regions to discharged hospital patients and outpatient clinics (e.g. for oncology patients). In the UK, direct distribution occurred particularly for generic medicines (PPRI Country Reports 2006-2008; ÖBIG 2006) until recently, but, currently, this trend appears to be on the wane (Interviews with Stakeholders, September 2010). In

the UK, there has been a significant uptake of DTP arrangements over the past 3 years (Table 3.2). GSK was first, Pfizer second (now including Wyeth). With just Astra Zeneca and Eli Lilly these cover over 30% of the market. There are also optional offers by some companies to sell direct or via mainline wholesalers, eg Roche and Bonviva via Williams, Takeda and Prostag via Clarity DTP. Some companies distribute lines that tend to be low volume and high cost directly themselves, e.g. Novartis supply ten low volume for dispensing GP lines in the UK, which include Sandimmun and Roche two such (product) lines.

DTP distribution can take place via a variety of schemes. Sole agency is a typical option in this case, where the manufacturer would sell directly to their customers with an exclusive wholesaler acting as a distributor or a logistics service provider only. Under this type of Agency arrangements, the wholesalers never own the stock and, consequently, are not in a position to offer any discount on it. It is also not uncommon for manufacturers to have set up their own wholesale distribution channel for part of the portfolio (e.g. Novartis and Roche, as shown on Table 3.2).

Table 3.2
Examples of Agency model applications in the UK, 2010

Pharmaceutical Manufacturer	Wholesalers chosen as Distributors	Details of Discounts offered on DTP Schemes
ALK-Abelló	Alliance	EpiPen and EpiPen Junior only; Zero Discount (ZD) Products
Astellas	Alliance	Prograf, Advograp, Mycamine and Modigraf only; ZDs
AstraZeneca	AAH, Alliance	Two separate schemes (as below) and ZDs 1. Invoice Discounts and not cash rebates applied via both carriers and not volume related and not handled by Forte Pharma 2. Dispensing Doctor Retrospective Rebate Scheme that is volume related (tiered) is cash rebate (BACS) and is applied via the AstraZeneca Forte Pharma Team
GSK	AAH, Alliance	Access scheme offering a flat 12% across the board. (Note GSK vaccines and travel medicines is a separate division and not part of this GSK Schemes)
Eli Lilly	AAH, Phoenix	Three bands

		<ol style="list-style-type: none"> 1. 15% Celance, Prozac 2. 8.5% Cialis, Cymbalta, Efient, Humapen., Strattera, Yentreve Zyprexa 3. ZD Products: Humulin, Byetta Humatrope
MSD for Sinemet	Alliance	Temporary distribution arrangements for: Sinemet 62.5, Sinemet PLUS, Sinemet CR 200/50 and Half Sinemet CR during period of limited availability
Novartis Ten lines only	Novartis' own Patient Priority Supply Service	Afinator, Exjade, Glivec, Aclasta, Myfortic, Tobi, Sandimmun, Zometa, Tasigna, Sandostatin LAR
Pfizer	Alliance	<ol style="list-style-type: none"> Three bands: 1. Flat rate on Lipitor + Viagra at 25% 2. 8.5% on everything else except ZD Products 3. ZD products
Pfizer / Wyeth	Alliance	Wyeth Lines now as Pfizer DTP. Pfizer standard discount 10.5% except ZD Products. Rapamune syrup is the only oral Wyeth ZD Products
Roche Two lines only	directly through Roche Products Ltd only	Pulmozyme (dornase alpha) ampoules 2.5mg and Valcyte (valganciclovir) tablets 450mg x 60 in England, Scotland and Wales only.

Source: British Pharmaceutical Wholesalers' Association, 2010.

Very often, Reduced Wholesaler Model schemes (RWM) are used to supply pharmacies. In RWM (or Reduced Wholesaler Agreements, RWA), pharmaceutical manufacturers use a very small number of wholesalers (1-3) in the traditional manner to distribute products. In this case, wholesalers purchase the stock, therefore, they can offer a discount. Current evidence on practice suggests that a number of manufacturers have selected this route; in the UK Sanofi Aventis, Novartis, Janssen-Cilag, Roche, Novo Nordisk and Bayer Schering operate with RWM schemes, which, if put together, account for about 20% of the market. Examples of what is offered in these circumstances, are shown on Table 3.3. Further, wholesalers have introduced a number of additional surcharges in recent years. Most now have fuel surcharges, stock return surcharges and an underspend surcharge of £300 in the UK.

Table 3.3
Reduced Wholesaler Models and their terms, UK, 2010

Company	AAH	Alliance¹	Phoenix
Bausch & Lomb	4%	0%	Zero (4% if PSUK)
Bayer Diabetes	7.5%	8%	6% (+ 2 % for PSUK)
Bayer-Schering ²	6 %	8%	6% (+ 2 % for PSUK)
Boehringer Ingelheim	8%	7%	7% (+ 1.5 % for PSUK)
Ferring	6.75%	7%	6% (+ 1 % for PSUK)
BMS ³	usual ethical discount terms on qualifying lines	usual ethical discount terms on qualifying lines; Baraclude only via Alliance	-----
Janssen-Cilag	6%	7%	7% (+1.5% for PSUK)
Leo	8%	8%	7% (+ 1% for PSUK)
LifeScan One Touch	9%	8%	7 % (+1.5% for PSUK)
MSD	8%	7.5%	7% (+ 1.5 % for PSUK)
NAPP	7%	7%	7 % (+1.5% for PSUK)
Novartis ²	8%	8%	No direct contract but can supply at 8%
Novo Nordisk	-----	Your usual ethical discount terms on qualifying lines	Your usual ethical discount terms on qualifying lines
Roche ²	8%	7%	-----
Sanofi-Aventis	8 %	7%	7% (+1.5% for PSUK)
Schering-Plough	7.5%	7.5%	6% (+2% for PSUK)
Servier	7.5% from 1 st August	7% from 1 st August	6% (+1.5% for PSUK)
Shire	6.4% but Calcichew usual ethical discount terms and Xagrid ZD	6% but usual ethical discount terms on Calcichew	5% + 1% for PSUK But full ethical discount on Calcichew
Smith & Nephew	usual ethical discount terms on qualifying lines	usual ethical discount terms on qualifying lines	Your usual ethical discount terms on qualifying lines
UCB	7%	8% Neupro is via Alliance only	7% (+1.5% for PSUK)

Notes: ¹ (Alliance) Discount applied before invoicing. Therefore invoice price is net of discount.

² Arrangements above for Bayer do not include Bayer Consumer Care, for Novartis do not include Novartis Consumer Health and for Roche do not include Roche Diagnostics and for Wyeth do not include Wyeth Consumer Healthcare, Wyeth Vaccines nor SMA Nutrition. For Novartis, Table 3.2 outlines the ten lines that are subject to the Agency model.

³ BMS will continue to supply a few products direct to dispensing customers and homecare companies. These are aztreonam, etoposide phosphate, abatacept, atazanavir, dasatanib, efavirenz, etoposide, didanosine, and stavudine.

Source: British Pharmaceutical Wholesalers' Association, 2010.

DTP and RWM arrangements have implications for integration within the supply chain in the sense that selective agreements between manufacturers and wholesalers may force some of the latter to consolidate in order to face the emerging type of competition. At the same time, these arrangements imply in themselves a different type of vertical integration, whereby manufacturers bypass the traditional chain to supply direct to pharmacy (DTP) or select which wholesalers to work with (RWM), or, even form their own distribution vehicle (Table 3.2). In the DTP arrangements the discounting ability by wholesalers to pharmacy is removed, whereas in the RWM arrangements, it is maintained but may be influenced by the agreement between the manufacturer and the wholesaler.

3.5 Wholesaler and Pharmacy Expansion of Services

Pharmacies have increased their breadth of service to include diagnostic and counseling services. In 11 countries repeat dispensing is allowed (with the Netherlands charging an additional dispensing fee), and all countries but Cyprus and Slovenia offering medicine waste disposal (a charged service in Ireland) (Table 3.4). Ten countries offer medicines review services, and others offer minor diagnostics including blood pressure testing and weight (all but Belgium), cholesterol (13) and blood glucose (15). Medical interventions include emergency contraception (11), smoking cessation (all), diabetes management (all but Belgium, Ireland, Sweden), asthma management (all but Belgium, Slovakia, Slovenia, Sweden), hypertension management (all but Belgium, Ireland, Sweden), vaccinations (6) and home care services (10).

Other services comprise individual preparations (Austria), weekend services (Austria, Belgium charged), dossier pharmaceutique (France), needle exchange programme (Portugal), methadone/naltrixone/buprenorfine maintenance (Austria, Portugal), promotion of correct use of therapeutic and autovigilance equipment (Portugal), health information (Portugal), wound management (Portugal), nutrition services (Portugal), skin and hair examinations (Slovenia). In Ireland, Germany and the UK these additional services incur further charges.

Wholesalers are also offering more services to their clients (such as kitting, re-labelling, information services, patient services, clinical trial packaging, waste management and returns management), some of which are added on for competition but many are obligatory to meet licensing demands. As a result, most countries have fewer full line

wholesale companies which are supplying most of the markets needs. The potential for further mergers or integration at this time appears to be limited by country regulations and legal competition protection.

3.6. Concluding remarks

The trends presented and discussed in this section highlight:

- First, a diversity and fragmentation of wholesaling and retailing entities at EU level, as reflected by the market structure of both wholesaling, but, more importantly, retailing entities. Significant variation continues to exist in the density of wholesale and retail outlets in the EU, propagated by national regulation and historical patterns.
- Second, different densities in terms of number of wholesalers and number of pharmacies in the population in the member states, as well as different regulatory policies setting the operating framework for distribution (both wholesale and retail) outlets;
- Third, some consolidation in activities, particularly in pharmacies, as experienced by the phenomenon of horizontal integration through pharmacy chains, but also differential regulation regarding the extent to which such consolidation can take place
- Fourth, vertical integration has been on the ascendancy particularly with wholesaler groups taking over pharmacies or pharmacy chains, although the opposite is also possible.
- Fifth, the frequency and influence of schemes such as Direct To Pharmacy Distribution (DTP) through sole agency or reduced wholesaler models (RWM) or treating wholesalers purely as logistic providers has risen considerably in the past 5-7 years; this trend can alter the rules of distribution, particularly where the public service obligation is not present. Through a variety of schemes manufacturers are in a position to bypass wholesalers and sell directly to pharmacies, or use wholesalers as logistics providers only.
- Sixth, elements of diversification (expansion of services) by both wholesalers and pharmacies, particularly where there is a squeeze on margins.

Table 3.4

Description of additional services provided by pharmacies across the EU27 countries. Starred (*) services have a charge attached to the service, services with a 'S' are only available at some pharmacies

	Dispensing Prescriptions	Repeat Dispensing	Disposal Waste Medicines	Medicine Use Review	Emergency Contraception	Blood Pressure Measurement	Cholesterol Measurement	Glucose Measurement	Weight Measurement	Pregnancy Test	Smoking Cessation	Diabetes Management	Asthma Management	Hypertension Management	Vaccination	Homecare Services	Night Services	Other
Austria		β		β	β					β		-	-	-	-	S		
Belgium	*			β		β	β	β	β	β		β	β	β	β			*
Cyprus			β	β			β								β	β/		-
Czech Rep.										β					β	β	β	-
Denmark	*	β		S		S	S	S	S	β		S	*	S	β	β	S	-
Finland	*			S						β	S			S	β			-
France																		
Germany	*	β			*	*	*	*	*	*	*	*	*	*	β			*
Ireland		β	*S	β	β	*S	*S	*S	*S	*S	*S	β	S	β	S	β	β	-
Italy				β							S	S	S	S	β	S		-
Netherlands	*	*																*
Poland		β	S	β	β		β	β		β	S	S	S	S	β	β		-
Portugal													S	S	S			-
Slovakia		β	S	β		S	S	S	S	β	S	S	β	S	β	β	S	-
Slovenia			β	S		S	S	S		β		S	β	S	β	β	S	-
Spain		β		β											β			-
Sweden				S		S	β	β	S	β	S	β	β	β	S	β	S	-
UK							*	*	*	*		*	-	-				-

Source: Authors' compilations; PGEU Member Database, 2010.

Note: The starred (*) services in the UK are all offered on the NHS or via private health insurance.

4. Distribution Margins

4.1. Evidence from the literature

Comparison of distribution margins between countries remains scarce in the academic literature. An examination of 2002 prices of eight newly reimbursed medicines in Belgium, Denmark, Finland, France, Ireland, Netherlands, Spain, Sweden and the UK found large price gaps between countries, with Ireland consistently recording the highest wholesale prices (81% price gap for some medicines) and Spain and Belgium the lowest (Marikainen et al, 2005). The highest net PRP were recorded for Ireland (124% price gap), followed by Finland, while the lowest net PRP was found in Belgium, France and the Netherlands. The addition of VAT increased the range of prices, but the ordering of countries remained the same. The authors concluded that wholesale prices appeared to be highest in countries where manufacturers have free pricing, however, this did not dictate final PRP.

Another examination of margin effects on 2004 prices of 20 branded drugs in Belgium, France, Italy, Germany, Netherlands, Spain and the UK found Italy had the lowest EFP while Germany had the highest (Garattini et al, 2008). The combination of wholesale and pharmacy margin/markups recorded the lowest values for the Netherlands and the UK while Spain had the highest. The highest retail price was found in Germany and Belgium, and the lowest in the UK and the Netherlands. The authors suggested that the lower impact of distribution margins in the Netherlands and the UK might be due to liberalization of the distribution sector including less restrictions and allowance of pharmacy chains. Another study comparing pharmaceutical prices in Austria to other European countries found the price range between Austria and other European countries was higher at the pharmacy purchasing price level with regard to the ex-factory price level (ÖBIG 2004).

The examination of the effect of distribution margin/markups on the generic market versus branded market also has limited literature. Simoens in his analysis of the Polish generic market believes that the regressive pharmacy margin currently applied in Poland has improved generic dispensing but still has not completely removed the incentive to dispense branded medicines (Simoens, 2010).

There is increasing interest in developments in the wholesale market. Wholesaler margins are continually squeezed downwards by pharmacies, in addition to lower manufacturing prices and development of the lowest cost generic market (Tuma, 2005), forcing wholesalers to expand into offering more services to their primary customers. The past decade has seen wholesaler expansion, via mergers and acquisitions, and, as a consequence, overall wholesaler numbers have declined. In addition, more wholesalers are entering pan-European alliances or acquisitions (Macarthur, 2007).

Likewise, pharmacies are facing increasing competitive environments. The development of pharmacy chains places strain on independent pharmacies, in addition to the very recent development of internet selling (Macarthur, 2007).

4.2. Summary of Wholesale and Pharmacy Margins

There are a number of different types of margin/markups, notably regressive, linear or percentage, flat fee, or a combination thereof. The pharmacy sector can also apply for fee-for-service remuneration of specific services. The regressive margin, most common in the EU as seen below for both wholesaling and retail (pharmacy) operations, may be composed of a fixed percentage which decreases as the price to which it refers increases. Another approach may be a linear or percentage markup where an equation is developed that is applied to all price ranges or a flat percentage is applied to all price (usually starting from EFP) ranges. These generally do not have a maximum fee.

Usually, there are distinct markup/margins for the wholesale and the pharmacy sector, however, in the Czech Republic there is a joint maximum markup allowed which is shared by the wholesaler and the pharmacy.

4.2.1 Wholesale Margins across EU27

The majority of EU27 countries have regulated wholesale (WS) margins, with the exceptions of Denmark, Finland, Netherlands, Sweden and the UK who enter into private negotiations with manufacturers (Table 4.1 and Appendix 2). Likewise, only a minority of countries (Cyprus, Luxembourg, Malta) have different WS margins for different classes of drugs be it locally manufactured versus imported (Cyprus), depending on the country of origin (Luxembourg), public versus private market (Malta) (see footnote Table 4.1 for details on markups/margins for reimbursable medicines). The most common distinction, however, is that there are regulated markups/margins for reimbursable medicines (e.g. FR, IE, IT, LT, PL, SK), while non-reimbursable medicines are not regulated.

The type of margin applied may be linear, referring to a flat rate regardless of price, or regressive, referring to decreasing margins with increasing EFP. More than half of the EU27 Member States apply regressive margins (14 countries), with no clear pattern in the preference for the quantity of regressive margins chosen between countries (Table 4.1). France is the only country where the regressive margin is organized in a way that the different scales are cumulative, where the first regressive category will apply its margin, the second regressive margin is applied only to the portion above the first regressive category (to which applies the first margin), and so forth.

The costs of wholesale distribution are affected by a number of factors. Slow moving medicines incur greater storage costs than fast moving medicines, compounded by whether the product has special storage and handling requirements (as in the case of blood

products, narcotics and cold chain products), the shelf life and risk of product expiration. The method of ordering also affects costs with telephone ordering incurring greater costs than electronic orders. Preparations costs depend on the number of units per order-line, and delivery costs depend on the number of units per delivery. Finally, the stockholding function itself is a significant financial burden to permanently stock full range of medicines.

In most countries, the wholesale margin is based on the 'solidarity' principle, which covers the cross subsidization between types of products. Many generic medicines are now so inexpensive fixed costs are difficult to recap, while innovative expensive medicines often have higher fixed costs due to storage difficulties described above yet often have a cap or are distributed directly. For example, in France, wholesalers generate 80% of their revenue from only 12% of prescription medicines while for 20% of their revenue they must distribute 88% of the prescription medicines.

Table 4.1: Overview of wholesale distribution margin/markups, types, regulations and discounts/rebates for reimbursable medicines in the EU27 (March 2010).

	Regulated	Different Margins: Different Drug Classes	Regressive ≤ 4 Categories	Regressive: 5-9 Categories	Regressive: ≥ 10 Categories	Linear Markup	Average WS Margin† (% PPP)	Discounts, Rebates to Health Insurance: Mandatory	Discounts, Rebates to Pharmacies: Commercial
Austria		A	-	-		β	6.5 - 13.4% ²⁰⁰⁸	β	
Belgium		β		-		β	8.45% ^{T, 2007}	β	
Bulgaria	PM	β		-		β	7-10% ^{T, 2009}	β	
Cyprus	PR	B	-	-			na	β	
Czech Rep.	+ ph.	β	-	-		β	4.3% ^{T, 2007}	β	
Denmark	β	n.appl.	Private Negotiations, Unregulated				6-7% ^{T, 2009}	β	β
Estonia		β	-	-		β	na	β	
Finland	β	n.appl.	Private Negotiations, Unregulated				3.0% ^{T, 2008}	β	
France		β	+ ACC	-	-	β	6.2% ^{T, 2007}	β	
Germany		β	-	-		β	4-6.1% ^{T, 2007}	H	
Greece		β	-	-			4% ^{T, 2007}		
Hungary		β				β	6.04-6.36% ^{T, 2007}	β	
Ireland		C	-	-			Na		
Italy			-	-			6.65% ^{2009, 1} 3% ^{August 2010}	β	
Latvia		β	-	-		β	3.34% ²⁰⁰⁸	β	
Lithuania		β	-	-		β	8-9% ^{T, 2005}	β	
Luxembourg		D	-	-			Na	β	
Malta	PR	E	-	-			15% ^{PR, 2009, 1}	β	
Netherlands	β	n.appl.	Private Negotiations, Unregulated				13-24% ^{T, 2007}	β	
Poland		β	-	-			9.78% ²⁰⁰⁷	β	
Portugal		β	-	-			6.87% ²⁰⁰⁷	β	
Romania		β		-		β	10-14% ²⁰⁰⁷	β	
Slovakia		β	-	-		β	n.appl.	β	
Slovenia		β	-			β	8-9% ^{T, 2007}	β	
Spain		β		-		β	3.5% ^{T, 2007}	β	
Sweden	β	n.appl.	Private Negotiations, Unregulated				2-3% ^{T, 2009}	β	

UK	β	F	Private Negotiations, Unregulated	12.5% ²⁰⁰⁷	β
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Notes: EFP: ex-factory price; LM = locally-manufactured medicines; n.appl. = not applicable; PM: prescription medicines; PR private market medicines; T = total market;

† As more than one source was consulted to find the average margin/markup, different sources present different average margin/markups. In order to reflect the diversity in average margin/markups, a range is presented rather than creating our own average which would dilute this diversity. As stated in the heading, the margins refer to the reimbursement market, unless otherwise indicated.

+ ph.: a joint markup for wholesale and pharmacy which is shared by the actors in two sectors

+ACC: Applied in a cumulative way.

¹ This is the official mark-up; the average mar-up may be different due to discounts to pharmacies.

A: Different kind of markups for different section of the positive lists (“Red box” versus “Green” or “Yellow Box” of the “Erstattungskodex

B: Locally produced generics have higher margins than imported drugs, plus no margins in the public system;

C: High Tech Drug Scheme, controlled drugs and refrigerated drugs have higher margins than General Medical Services scheme and community drug scheme;

D: Different margins applied to Belgian imports than other countries;

E: Tendering for public National Health Service (NHS) drugs, private negotiations for private drugs;

F: Branded medicines, generic medicines categories A-C+E+W have different maximum margins; H: In 2011, Pharmaceutical Market Restructuring Act comes into action, requiring pharmacies to contribute €200 million annually through a discount to sickness funds. Wholesalers will give sickness funds a discount of 0.85% EFP plus wholesalers margins are capped at €72, causing loss for medicines greater than €8,470.50 (2009)

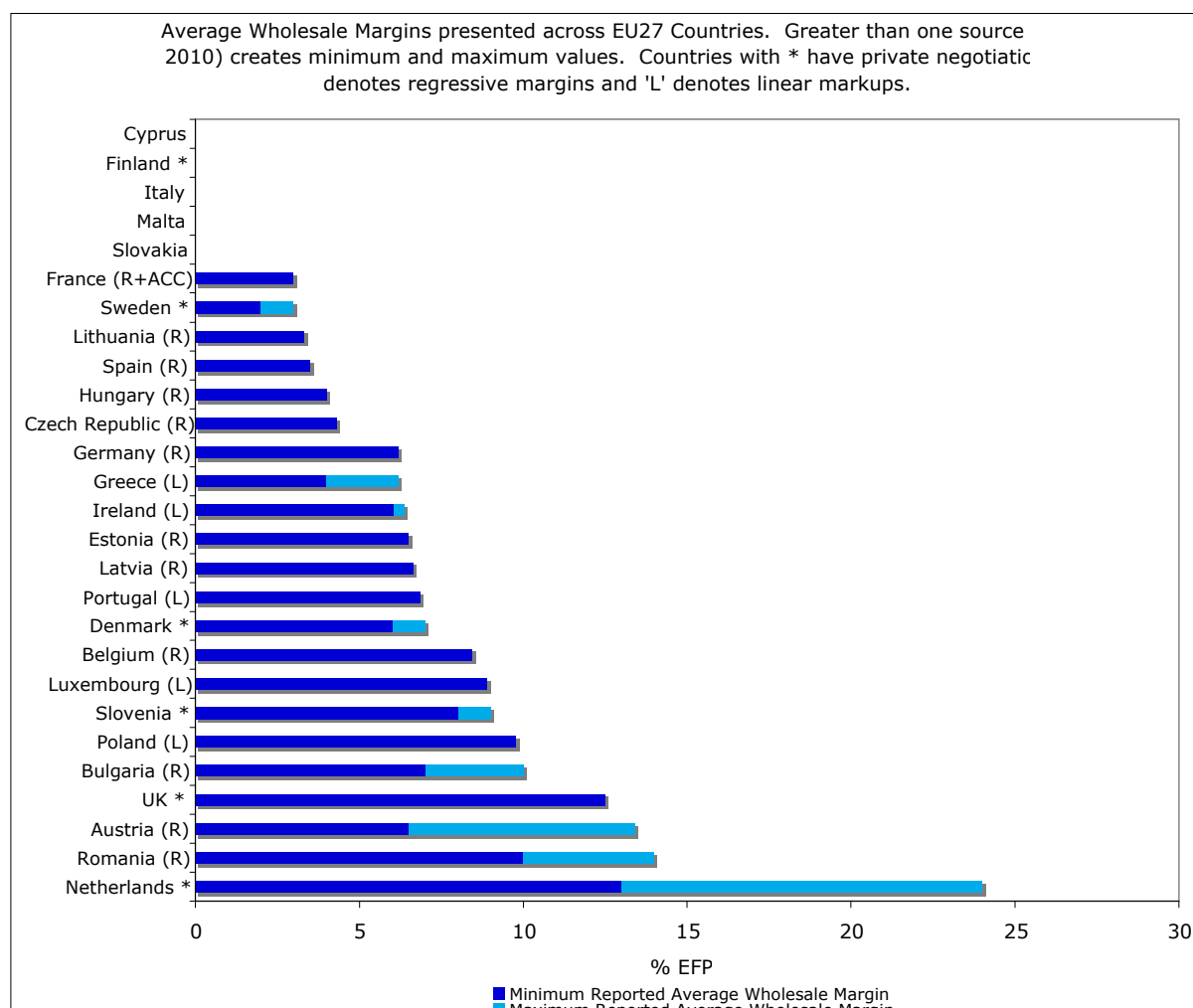
Source: AESGP 2009, GIRP Member Profiles, ÖBIG 2007, PPRI Country Profiles, for updated information on markup/margin regulation GÖG/ÖBIG survey with authorities and stakeholders.

Countries with regulated wholesale mark-ups which are regressive apply flat rate linear markups ranging from 0-20% EFP, where the same rate applies regardless of the EFP.

The average WS margin applied to all medicines across EU27 ranged from 3-23% (Figure 4.1) (AESGP 2009, GIRP Member Profiles, , ÖBIG 2007, PPRI Country Profiles). There does not appear to be any pattern between margin type and resulting average margin per country, however, countries with unregulated margins appear to be on the highest third of the list (Netherlands, UK), although Sweden and Denmark appear on the lowest third of the list.

Figure 4.1

Average wholesale margins/markups presented across EU27 Countries. More than one source (2007-2010) creates minimum and maximum values. Countries with * have private negotiations, 'R' denotes regressive margins and 'L' denotes linear markups.



Source: Authors' compilations and AESGP 2009, GIRP Member Profiles, ÖBIG 2007, PPRI Country Profiles.

4.2.2 Pharmacy Margins across EU27

Pharmacy margins are regulated in a way similar to wholesale margins, with all EU countries having regulated pharmacy margins in place, however the UK is applying “softer” regulations (officially unregulated). Apart from Cyprus and Malta, where margins are only applicable in the private (non-reimbursed medicines) sector, these margins are relevant for the reimbursement market in all other countries. Some countries apply their margin regulation to the entire market (e.g. Estonia, Greece, Spain, Latvia), or have one stream of regulation for the reimbursement market and another scheme applying to the non-reimbursement market (e.g. Austria, Belgium).

As with WS margins, across the EU countries, pharmacy margins are either regressive or linear in nature or organized as a fee-for-service remuneration. The majority of countries apply regressive margins, particularly with systems using four or less categories (Belgium, Bulgaria, France, Spain, Sweden), five to nine categories (Czech Republic – joint markup for wholesale and pharmacy, Estonia, Finland, Hungary, Latvia, Lithuania, Romania), but less likely to apply more complex ten or greater categories (Austria, Poland) (Table 4.2 and Appendix 2). These regressive markups may be calculated based on the pharmacy purchase price (PPP) or calculated as a margin of the pharmacy retail price (PRP). The number of countries applying a linear markup added on the pharmacy purchase price is rather few (e.g. Cyprus, Portugal).

In some cases, a significant proportion of pharmacy income comes from fixed dispensing fees, notably Belgium, Denmark, Ireland, Netherlands and the UK (Table 4.2). For the majority of these countries with dispensing fees, fixed dispensing fees are an additional source of pharmacy income added to the pharmacy retail margin, with the exception of the Netherlands and the UK. Usually, the pharmacy remuneration is product-based, in particular if it is organized as a percentage markup on the pharmacy purchase price or percentage margin of the pharmacy retail price. Another option would be a fee-for-service, which a few European countries have; in the European Union arena it is only the case in Slovenia.

In the European countries, the pharmacy markup / margins are regulated as maximum markup/margins, meaning that no higher markup / margins may be applied. In most, in particular Western European countries, these maximum markups are fully utilized. However, in some Central and Eastern European countries, in particular in the OTC sector, lower than the officially allowed pharmacy markups/margins are applied which leads to the different prices of a product in different pharmacies (PPRI 2008). Commercial discounts from wholesalers to pharmacies are allowed in several countries; so are commercial discounts granted by pharmacies to patients. However, there may be

limitations. For instance, the discount on generics granted by a pharmacy to customers is limited at 17% (PPRI Query 2010).

Additionally, some countries apply mandatory discounts which the pharmacy must grant to the public payer (see section 4.2.3). From the pharmacists' perspective, this is seen as a reduction in the pharmacy revenue.

The regressive margin scheme which several countries apply implies an incentivizing factor for higher-priced medicines, as the percentage markup /margin rates for these medicines are lower than for lower-priced medicines. However, a specific financial incentive linked to the markup/margin scheme for generics or other lower-priced medicines (e.g. parallel imported medicines) is not at all common in the EU countries. Only in France, the pharmacy markup for generics is designed in a way that in fact the pharmacy receives the same amount in Euro when dispensing a generic as for the original product of the same active ingredient (same cluster).

Pharmacy markups/margins, along with the wholesale markups/margins are a policy area which is rather often targeted in times of limited budgets. For instance, Belgium introduced a new pharmacy remuneration scheme in April 2010, Spain modified the pharmacy remuneration in July 2010 (increasing the number of scales in the regressive scheme from two to four) and Italy at the end of July 2010 (cut of wholesale margin).

For other prescribers who are allowed to dispense prescription medicines (usually in the reimbursable market), regulation on their remuneration exists (e.g. for dispensing doctors in Austria, for hospital pharmacies dispensing to out-patients in France, see Table 4.2).

Table 4.2: Overview of pharmacy margin/markups/types, regulations and discounts/rebates for reimbursable drugs in the EU27 (March 2010).

	Regu- lated	Different Margins: Different Drug Classes	Regressive ≤ 4 Categories	Regressive: 5-9 Categories	Regressive: ≥ 10 Categories	Linear Mark Up: Flat Rate	Dispensing Fees	Other Fees	Average Pharmacy Margin† (%PRP)	Discount, Rebates: Manda- tory	Discount, Rebates: Commer- cial
Austria		PR, SF	-	-	-	-	15%PR	DD	19.16% ²⁰⁰⁸		
Belgium		β	-	-	-	-	€3.88pp	R, INN	na	β	
Bulgaria		β	-	-	-	-	β	β	18-22% ^{T,2007}	β	
Cyprus	β/ +WS	PR, P	-	-	-	-	β	β	na	β	
Czech Rep.		β	-	-	-	-	β	β	na	β	
Denmark		β	-	-	-	-		AF	19.3% ²⁰⁰⁹	D	β
Estonia		β	-	-	-	-	PROG	β	19% ^{T,2009}	β	
Finland		β	-	-	-	-	€0.42pp	β	23.6% ²⁰⁰⁸		β
France		B, G	+ACC	-	-	-	€0.53pp	H	na	β	
Germany		β	-	-	-	-	β	β	24% ²⁰⁰⁴		na
Greece		β	-	-	-	-	β	β	na		na
Hungary		β	-	-	-	-	β	β	19.46% ²⁰⁰⁵	β	
Ireland		S	-	-	-	-	V	β	na	β	na
Italy			-	-	-	-	β	β	na	C	na
Latvia		β	-	-	-	-	β	β	19% ²⁰⁰⁸	β	na
Lithuania		β	-	-	-	-	β	β	na	β	
Luxembourg		I	-	-	-	-	β	β	46.7-50.2% ²⁰⁰⁷	β	
Malta	β/ +WS	PR, P	-	-	-	-	β	β	20% ^{PR}	β	β
Netherlands		β	-	-	-	-	€7.28pp	β	na	C	
Poland		β	-	-	-	-	β	β	na	β	
Portugal		β	-	-	-	-	β	β	18.25% ²⁰⁰⁸	β	
Romania		β	-	-	-	-	β	β	12-24% ²⁰⁰⁸	β	na
Slovakia		β	-	-	-	-	€0.48pp	β	21% ²⁰⁰⁷	β	
Slovenia		Points	-	-	-	-	€1.4-2.8pp	β	€2.10pp	β	
Spain		β	-	-	-	-	β	β	na	C	
Sweden		Off-P	-	-	-	-	β	OP	21.3% ²⁰⁰⁸	β	
UK	β/ +WS		-	-	-	-	€1.52pp	HC	na	C	

Notes: † As more than one source was consulted to find the average margin/markup, different sources present different average margin/markups. In order to reflect the diversity in average margin/markups, a range is presented rather than creating our own average which would dilute this diversity. As stated in the heading, the margins refer to the reimbursement market, unless otherwise indicated.

PR, SF: Higher margins are applied to Private clients than Sickness Fund clients;

PR, P: Pharmacy markups only in the private sector (non-reimbursable medicines), no markups in the public sector;

B, G: Generic medicines must provide same remuneration to the pharmacy as Branded medicines;

S: Different Schemes apply different margins, with the High Tech Drugs Scheme a flat fee of €49.64 monthly;

I: Imports outside Belgium and Luxembourg have higher margins;

Points: Fee-for-service remuneration on the points attached to the prescription;

Off-P: Off patent medicines have an additional €1.04 added on when generic competition is available

+ WS: a joint markup for wholesale and pharmacy which is shared by the actors in two sector

+ACC: in a cumulative way.

pp = per pack; 15%PR: For private customers, pharmacists and dispensing doctors are entitled to add a surcharge of 15% on the prices of medicines calculated according to the pharmacy remuneration regulation.

PROG: Progressive dispensing fee (DF). If PPP is <€1.28 then DF is €0.38pp, if PPP is €1.29-44.73 then €0 DF, if PPP is >€44.74 then DF is €5.11pp;

V: Varies with item and drug scheme. Pharmacists are paid €5 for the first 1667 items dispensed, €4.50 for the next 833 dispensed and €3.50 for all additional item dispensed in a month. There are a few additional fees varying with item and drug scheme.

A: Consists of linear mark ups which are made regressive due to statutory discounts (urban/rural, high/low turnover)

DD: For dispensing doctors the same remuneration regulation applies for pharmacies;

R: when public price is different than the reimbursement price, the patient pays the difference to a maximum of €10.80;

INN: patient pays €1,19 for dispensing a INN prescription or a Chapter IV drug;

AF: Additional fees for telephone prescriptions (DKK4.80), after hours purchasing (DKK 12.00), delivery fees (DKK12.00), H: Specific remuneration (€28) for hospital pharmacy when dispensing to out-patients (specific medicines are allowed to be dispensed);

OP: Off patent charge of SEK10 (€1.04) for medicines with no established generic competition;

HC: Health counseling services

C: clawback; D mandatory rebates given on public expenses for prescription medicines only (no commercial rebates)

Sources: AESGP 2009, ÖBIG 2007, PPRI Country Profiles, GÖG/ÖBIG survey with authorities and stakeholders

4.2.3 Discounts, rebates and clawbacks across EU27

Discounts and rebates in all parts of the distribution chain are commonplace and part of everyday practice. They are typically classed into commercial and non-commercial. Commercial discounts are offered by manufacturers to wholesalers, by wholesalers to pharmacies and by manufacturers to pharmacies. In some cases discounts are offered from pharmacies to patients. Non-commercial discounts, also known as (mandatory) rebates, are visible, usually based on a legal act, and constitute an indirect measure of further price reduction on the statutory and/or negotiated prices of medicines.

Commercial discounts

Commercial discounts also occur in transactions between manufacturers and pharmacies in DTP arrangements. These types of discounts are invisible and almost impossible to measure with any degree of accuracy. In some cases the authorities launch an inquiry on the level of discount in order to calculate the extent of the clawback, i.e. part of the discount that accrues to the state (UK, and, to a certain degree, the Netherlands).

Many countries allow commercial rebates or discounts, negotiated between manufacturers and wholesalers or between wholesalers and pharmacies (Table 4.1). In some cases discounts are part of a stakeholder's remuneration (e.g. UK, the Netherlands). In other cases they are formally disallowed, but in practice occur as part of commercial practice (e.g. Germany, buy three for the price of two, or offer a discount if payments from pharmacies to wholesalers are made on time).

Mandatory wholesale rebates and discounts

Three countries (Germany, Greece, Ireland) have mandatory wholesale level rebates or discounts required by health insurance; these are visible and form part of the requirement by the relevant stakeholders to health insurance. In Germany, manufacturers must offer a 6% discount to wholesalers for drugs which are not subject to reference pricing. In rural areas of Greece where population averages less than 4,000 inhabitants per town, wholesalers must offer pharmacies a discount of 4% PPP, and in turn the manufacturer must offer the wholesaler a discount of 0.4% EFP to compensate. In Ireland, the manufacturer must offer a rebate of 3% PPP to the Primary Care Trust (PCT) Schemes for all drugs dispensed under the General Medicines Scheme (GMS).

Mandatory pharmacy rebates and discounts

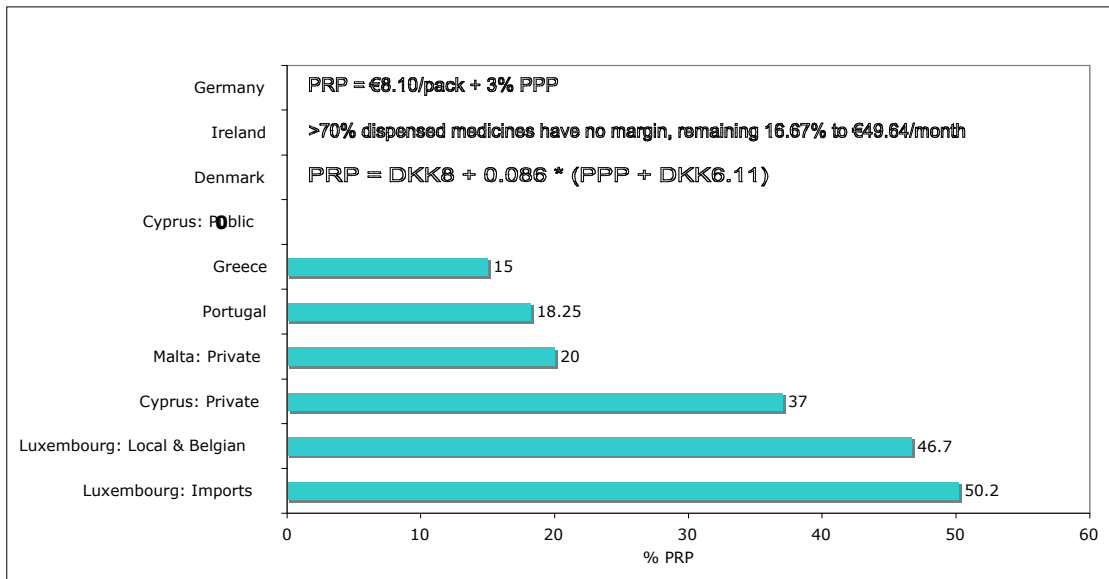
Pharmacies may also be obliged to offer discounts or rebates to public payers such as health authorities or health insurance funds (Austria, Denmark, Finland, Germany, Greece, Italy, Spain, UK). In Austria, pharmacies generating annual turnover greater than the median community pharmacy turnover with Sickness Funds (SF) must grant a 2.5% discount on products priced less than €200 (at PPP level) to the SF.

In Germany, off-patent drugs have a 10% EFP discount from pharmacies to the Social Health Insurance (SHI) funds, in addition to rebates of €2.30/pack for prescription only medicines (POM) and 5% for non-POM. Manufacturers must also offer the SHI a 10% rebate for generic medicines. In Spain, the deductions depend on monthly pharmacy turnover (based on PRP, including VAT), and account for approximately 4% of sales. Italy also has a pharmacy clawback calculated based on the pharmacy turnover and location of the pharmacy (urban/rural), which makes their linear mark-up system regressive via these clawbacks.

In Denmark, there is a 'solidarity contribution' that is re-distributed nationally to level out pharmacy earnings based solely on pharmacy sales (regardless of its population base) in order to ensure rural access to pharmacies.

In Finland, pharmacies grant war veterans a 10% discount, and private pharmacies pay the state 6.6% of their turnover (or to the university if they are a university pharmacy). In the UK and the Netherlands, pharmacies have an amount deducted from their reimbursement (approximately 10%, known as clawback) depending on its turnover. Further, reimbursement prices are reviewed depending on pharmacy margins.

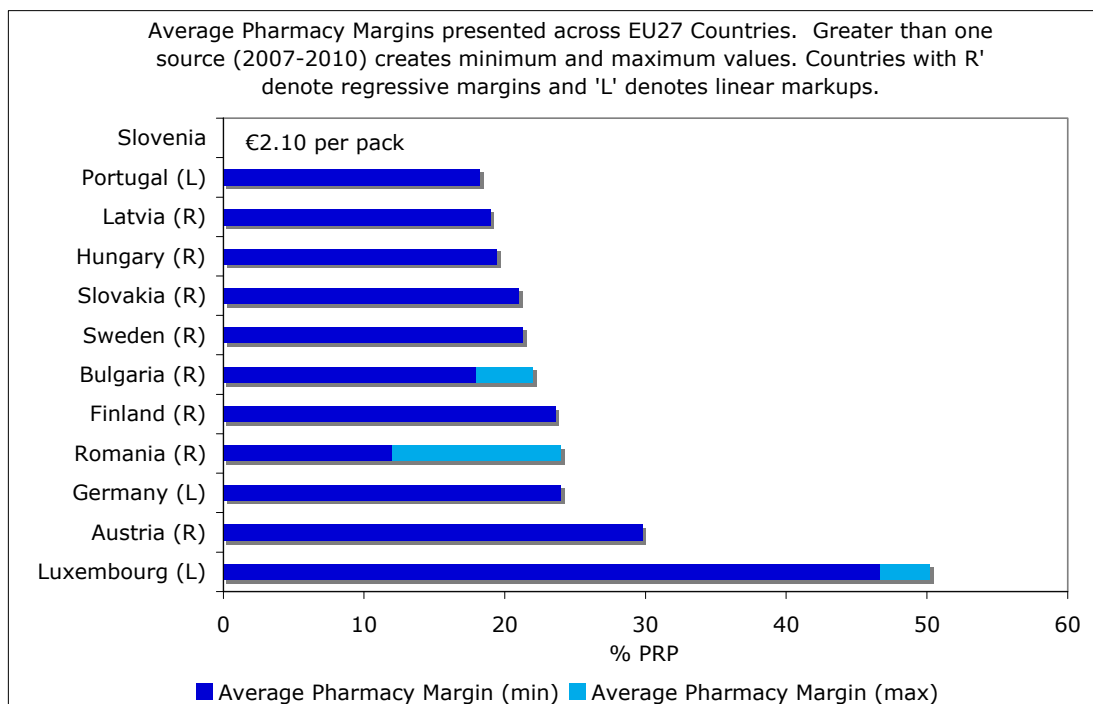
Figure 4.2: Comparison of flat rate linear pharmacy markups across EU27 Member States.



Source: Markup/Margin regulation as described in Table 4.2.

Figure 4.3: Average pharmacy margin/markups presented across EU27 Countries.

Greater than one source (2007-2010) creates minimum and maximum values. Countries with * have private negotiations, 'R' denotes regressive markup/margins and 'L' denotes linear markups.



Source: Authors' compilation and AESGP 2009, ÖBIG 2007, PPRI Country Profiles, GÖG/ÖBIG survey with authorities and stakeholders

4.3. Concluding remarks

The discussion from the preceding sections has highlighted that:

- First, the majority of Member States applies regulated margins to both or the pharmacy sector only for the reimbursement market. Often, markups/margins are applied for all medicines. They are designed as maximum markups/margins.
- Second, regressive markups/margins are very common, but some countries also apply linear markups/margins. For pharmacies, dispensing fees are used in a few countries, and in one country (Slovenia) pharmacies are funded on a fee-for-service remuneration.
- Third, average wholesale margins range from 2-24% of PRP (low in Sweden, high in the Netherlands, both unregulated private negotiations), with the majority ranging between 4-8% of PRP.
- Fourth, considerably less information is available regarding the average pharmacy margin in a country, however, for the 15 countries for which average pharmacy margins could be surveyed, the range is 12-50% of PRP (low in Romania, high in Luxembourg).
- Fifth, what is made apparent in this section is the diversity of the methods of establishing wholesale and pharmacy/retail remuneration. There are different markup/margin schemes for reimbursable and non-reimbursable medicines in a few countries, specific schemes for other retailers of prescription medicines in the very few countries in which such other retailers operate and a specific incentive for dispensing generics in one country (France).
- Sixth, discounts and rebates play an important role in defining the precise amount of wholesale and pharmacy remuneration. On the one hand, in several countries commercial discounts (offered by manufacturers to wholesalers, by wholesalers to pharmacies, by manufacturers to pharmacies, and in some cases by pharmacies to patients) are granted, and in a few cases they are limited by regulation. The exact amount of these discounts and rebates is confidential. On the other hand, wholesalers and, in particular, pharmacies are obliged to grant discounts and rebates to public payers in nine countries (known as “clawback” or “solidarity contribution”).

5. Impact of Wholesale and Retail Margins on the Prices of Prescription Medicines: A Payer Perspective

5.1 Drug Selection and Methodology

In order to assess the impact of wholesale and retail distribution margins/markups on the prices of prescription pharmaceutical products that health care systems pay in the EU Member States, an analysis of pricing data was conducted. For this purpose, seven molecules and their prices were selected across EU-27. Prices were available at ex-factory (EFP) level, wholesale (pharmacy purchase price, PPP) level, and retail (pre-VAT net pharmacy retail price, net PRP) level. The highest branded and the lowest-priced product (generic or parallel imported versions available for 6 out of the seven molecules) were selected for each molecule and across EU-27. The available price observations related 15 June 2009 and price information was obtained with the assistance of the Member States.

Based on the prices of the medicines selected, we classified these as lower-priced (LP), medium-priced (MP) and high-priced (HP). The medicines were selected based on their price levels, but also based on their availability across EU27, in order to ensure the widest possible levels of comparability.

Four lower-priced (LP) medicines selected from the broad therapeutic classes of

- hypertension (HT) (LP-HT-50 mg 28 days),
- gastroenterology (GERD) (LP-GERD-20 mg 28 days),
- depression (D) (LP-D-20 mg 30 days) and
- dislipidemia (HC) (LP-HC-20 mg 28 days).

Two medium-priced (MP) medicines selected from the broad therapeutic classes of

- cardiovascular disease (CVD) (MP-CVD-75 mg 28 days) and
- psychiatry (S) (MP-S-10 mg 28 days).

One high-priced (HP) medicine was selected from the therapeutic class of

- autoimmune diseases (A)(HP-A, 25mg 4 day pack, branded only)

Not all pack sizes were the same across countries, so the most common pack size was chosen and in some cases data were adjusted upwards or downwards as needed using unit (pill or capsule) price. This ensured that the price per pack was uniform across all Member States for which data was available. The one month pack size is the most dominant in this analysis, however, for some chronic conditions larger pack sizes may be available (i.e. 3 months) which may have

even lower EFP. It is important to note that these medicines are not completely representative of the entire market, however, they do provide an example of what occurs in the distribution chain with some medicines in specified countries.

The distribution information presented in Section 4 was conjoined with the data in this section in order to understand the impact of wholesale and retail margins on final net retail prices payable by public payers. The prices received from the Member States were benchmarked against the distribution database discussed in the previous section for cross-comparison purposes and found to agree within a 95% confidence interval. A number of caveats applied in conducting this analysis, for instance:

- It became apparent that in the price data received, certain countries had not added dispensing fees (Belgium, Netherlands, Poland, UK) when very low priced generics were examined as the retail price was lower than the dispensing fees, thus dispensing fees were added to prices in these countries.
- In certain cases ex-factory (Denmark, Cyprus, Finland, Luxembourg, Netherlands, Sweden, UK) or wholesale (Czech Republic) prices were not included as due to the pricing and markup/margin regulatory framework (e.g. joint markup in the Czech Republic, not regulated wholesale markup, see Table 4.1), in which case they were extrapolated using the country average margins from the distribution database (Tables 4.1, 4.2).
- The Austrian prices given reflected only the private client prices and not the public prices to which a different pharmacy remuneration system is applied.
- In Italy, very expensive medicines are now distributed via hospitals and local health units.
- It was impossible to extract wholesale or retail prices for Malta, as only final retail prices were given.

In the section that follows the impact of distribution margins/markups across EU27 is presented. For simplicity, figures in this part of the report include data for 3 medicines, showcasing the high-priced medicine for auto-immune conditions (HP-A), a mid-medicine priced for psychiatry (MP-S) and a lower-priced medicine for dislipidemia (LP-HC) medicines from the sample. Appendix 3 pictorially shows price build-ups for all medicines, including their construction and Member State ranking along each stage of the process. For a number of cases, particularly pertaining to generic medicines, prices are not available for all Member States, as the medicine in question may not have become generic. All prices were translated into Euros using the second quarter average exchange rates where applicable.

5.2 Results of Price Comparisons

5.2.1 Branded Medicines

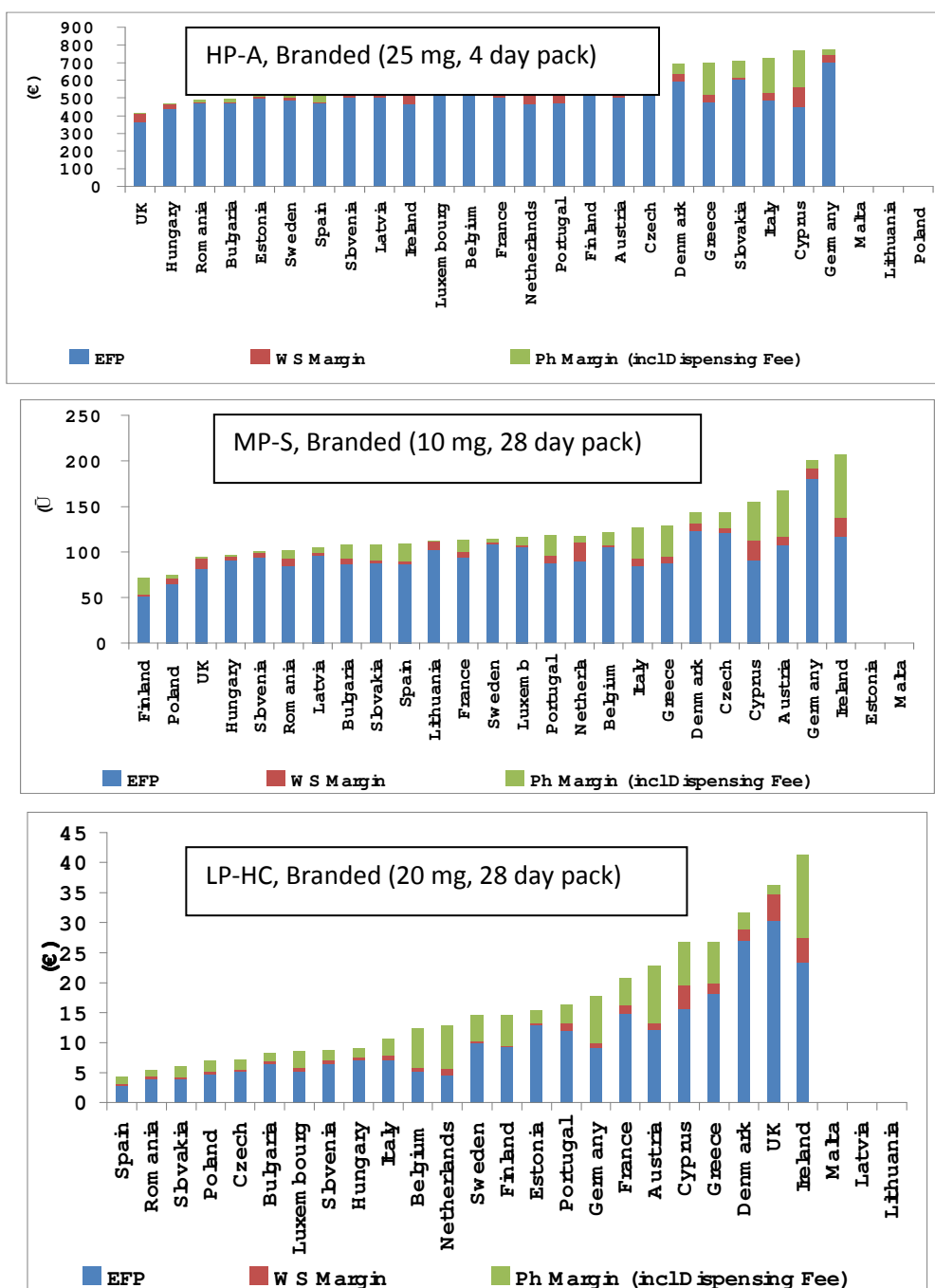
As discussed in the methods section, the prices of the branded medicines selected originate from the highest priced brand for each selected medicine in each country. The price gap at EFP levels and the various margins/markups, presented in (a) absolute values and (b) as percent of net Pharmacy Retail Price (PRP), can be significant between countries.

For expensive medicines such as HP-A, the price gap between the *highest* and *lowest* priced countries in absolute terms is 93% for EFP, and 79% when wholesale margin/markups are added, 85% when pharmacy margin/markups are added (Figure 5.1). For mid-priced medicines, the price gap between the *highest* and *lowest* priced countries respectively in absolute terms is 104% and 250% for absolute EFP, 97% and 260% wholesale margin/markup, 144% and 187% pharmacy margin/markup. For low priced medicines, the price gap between *highest* and *lowest* priced countries respectively is 364% / 2,206% / 410% / 968% for absolute EFP, 354% / 2,183% / 441% / 1,029% wholesale margin/markup, 284% / 1,855% / 325% / 873% pharmacy margin/markup respectively.

The impact of distribution costs and taxation on health systems and payers also seems to vary significantly by drug cost category. For branded LP-HC, the cost to payer can be as high as 60% of the retail price, while the average cost to payer lies in the region of 30 – 40% of retail price (Figure 5.1). For branded MP-S and HP-A, the cost to payer is somewhat less, the highest being 35% and 43% respectively, although, typically, the average lies between 25 – 35% (Figure 5.1).

Figure 5.1

Presentation of branded HP-A (expensive), MP-S (mid-priced) and LP-HC (low priced) ex-factory price (EFP), wholesale (WS) margin/markup, pharmacy (Ph) margin/markup across 27 EU Member States; prices as of 15 June 2009.



Note: Data for Malta, Latvia and Lithuania not available.

Source: Authors' calculations from pricing data received from Member States.

Branded Medicines: Highest and lowest absolute price levels

This section and the next provide a brief account of where prices (in absolute and relative terms respectively) are highest and lowest. Similarly, they provide an account of the highest and lowest wholesale and retail margins in Euro terms with a view to enabling a comparative account.

Among the 7 selected medicines, identification of the top three net PRP and its constituents (EFP, wholesale and pharmacy margins), found a number of patterns between Member States. The EFP was highest in most of these countries (Denmark 5 medicines, Germany 3, Bulgaria 2) with the addition of Ireland (3), Czech Republic (3) and Estonia (3). Lowest EFPs were found most frequently in the UK, Finland, Romania, Spain, Hungary, Poland and Slovakia.

Wholesale margins were (in absolute Euro terms) highest in Ireland (7 cases), Cyprus (7) and the Netherlands (4), while pharmacy margins were (in absolute Euro terms) highest in the Netherlands (6 cases), Ireland (5), Belgium (3), Germany (2) and Greece (2). Wholesale margins were lowest in Finland (5 cases), Sweden (4), Czech Republic (2), Estonia (2) and Spain (2). Pharmacy margins were lowest in the UK (6 cases), Lithuania (4), Slovenia (4), Romania (2) and Spain (2). For the UK, the pricing situation reflects the impact of exchange rates combined with one price cut, which is reflected in the pricing data for the selected molecules.

Overall, the general trend is for high or low EFPs to be transferred through to the final net retail (PRP) price. Countries with high wholesale margins also appear to have high pharmacy margins (i.e. the Netherlands and Ireland), while this does not hold in the case of low wholesale margins. Denmark and Germany have the highest EFPs and PRPs, while the UK, Finland, Romania and Spain the lowest.

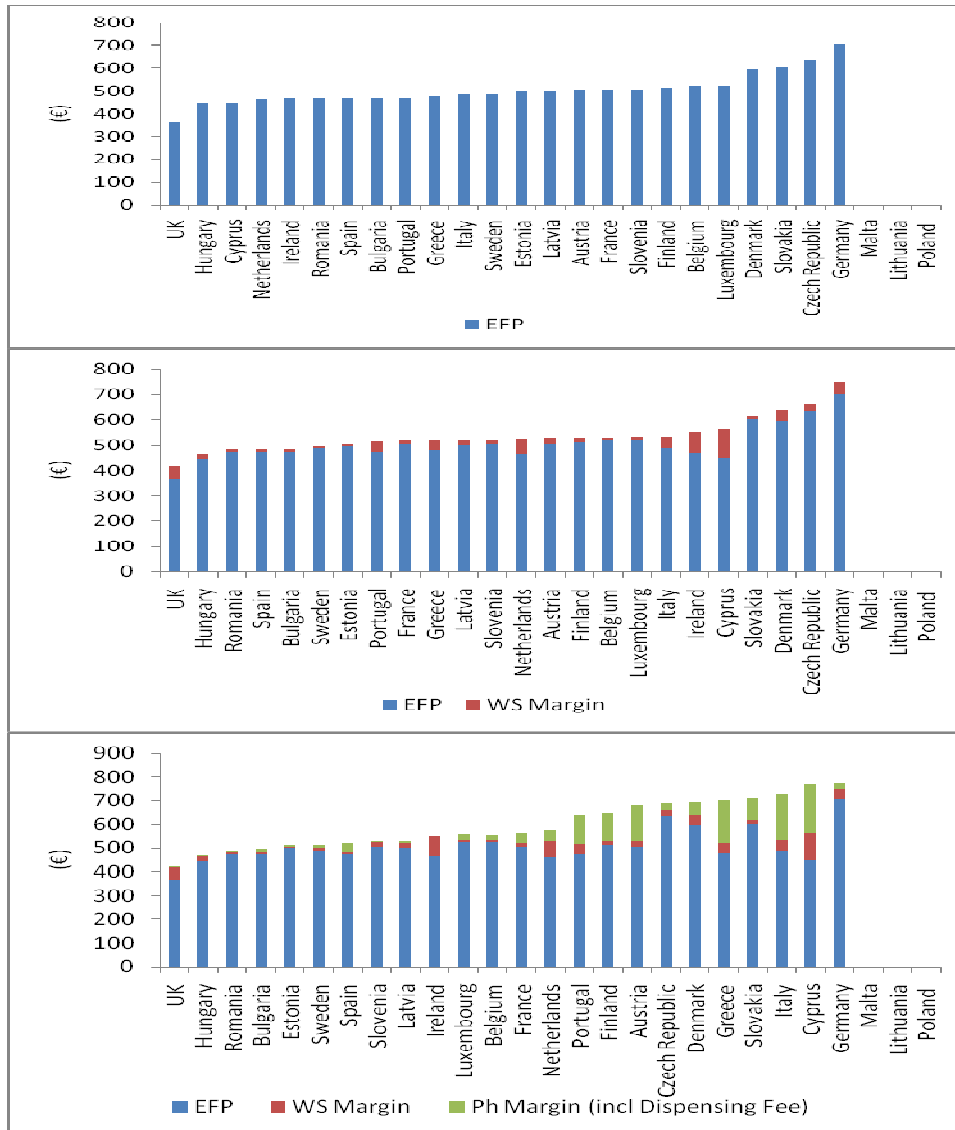
Total impact of distribution costs: branded medicines

The final net average costs of distribution for HP-A is €89.75 (range €11.50-320.77, Estonia – Cyprus), for MP-CVD €13.18 (range €4.43-35.18, Slovenia-Austria), for MP-S €25.13 (range €5.98-89.96, Hungary-Ireland), LP-HT €7.09 (range €1.81-14.02, Lithuania-Ireland), LP-GERD €9.83 (€1.22-20.97, Spain-Ireland), LP-D €6.36 (€1.50-13.34, Lithuania-Germany), LP-HC €5.34 (€1.41-17.93, Spain-Ireland). These wide ranges in total net distribution margins reinforce the notion of significant variation in distribution costs between EU Member States.

Closer examination of the ranking of countries during the build-up of prices from EFP to PPP to net PRP shows that the impact of margins can change the final price to payers significantly. Examination of HP-A (Figure 5.2) shows that although the highest and lowest ranked countries remain the same during the process, some countries can decrease significantly in their rankings (i.e.

Luxembourg) and others can increase (ie Greece, Italy) due to lower or higher respective influence of margins on EFP. Appendix 3 shows similar graphs for each medicine, both branded and generic.

Figure 5.2
 HP-A: Building of EFP (1st panel), PPP (2nd), and net PRP (3rd) across EU27 Member States, with ranking of Member States during each stage of the process, as of 15 June 2009.



Note: Data for Malta, Lithuania and Poland not available.

Source: Authors' calculations from pricing data received from Member States.

5.2.2 Generic Medicines

The prices of generic medicines across the products selected originate from the lowest priced generic product in the country. HP-A is not presented as it is only available as an originator. As with branded medicines, the range of prices and margins/markups are significant between the Member States, particularly for wholesale margins and low priced medicines (Figure 5.3).

For MP-CVD and MP-S, the price gaps between the *highest* and *lowest* priced countries respectively are 252% and 353% absolute EFP, 256% and 365% wholesale margin/markup, 243% and 363% pharmacy margin/markup respectively. For LP-HT, LP-GERD, LP-D and LP-HC, the price gaps are 7483%/3175%/1811%/8610% gross EFP, 7807%/2797%/1648%/9177% wholesale margin/markup, 782%/1117%/622%/1838% pharmacy margin/markup, respectively. These wide variations mimic the variations found in the branded versions albeit exponentially.

The impact of distribution costs on health systems and payers also seems to vary significantly in the generics case as it does in the branded medicines case, although the variation in this case is far greater than in branded medicines (as shown on Figure 5.3). The structure of wholesale and retail margins does mean that in certain (extreme) cases the impact of distribution costs and taxation exceeds 90% of the total cost to payer and the average seems to be higher than in the case of branded medicines.

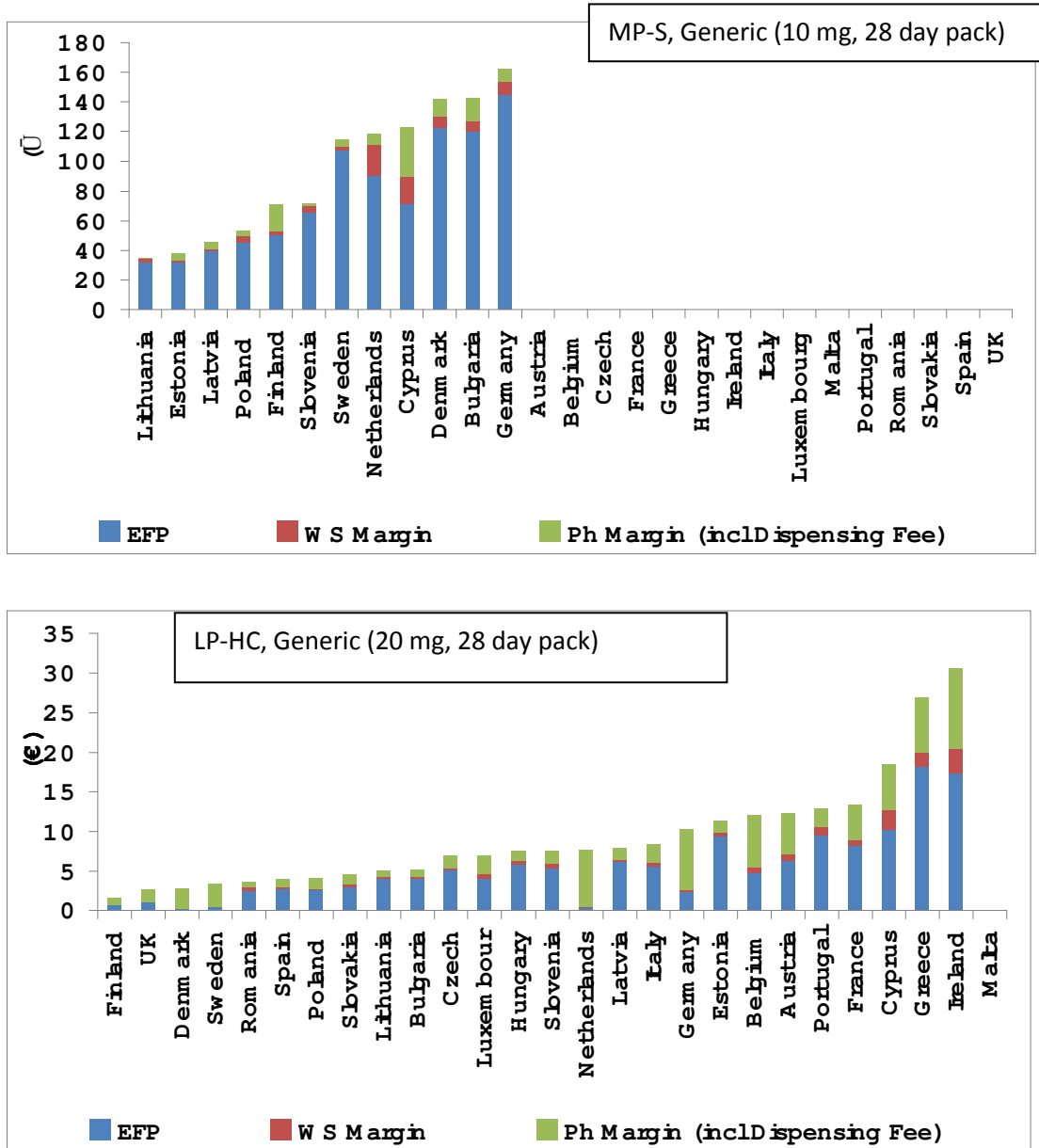
Generic Medicines: Highest and lowest absolute price levels

Identification of top three absolute prices found high EFP in Germany (3 medicines), Greece (3), as well as Cyprus (3) and Denmark (3). High wholesale margins were found in Cyprus (4 medicines), Ireland (3) and the Netherlands (3), while high pharmacy margins were found in Germany (4), Ireland (3), Denmark (2) and the Netherlands (2).

Lowest EFP were found in Sweden (4), Netherlands (3), Bulgaria (2), Denmark (2) and Estonia (2). Lowest wholesale margins in generics were found in Sweden (5 medicines), Finland (3), Czech Republic (2) and Latvia (2), while lowest pharmacy margins were identified in Lithuania (4), Romania (3) and the Netherlands (2).

Overall, high EFPs are usually transferred all the way through to high gross PRP (Denmark, Germany, Greece), as well as reflected in high wholesale (Cyprus, Ireland) and pharmacy margins (Denmark, Germany). This trend was also found in countries with low EFP (Sweden, Denmark, Estonia).

Figure 5.3: Presentation of generic MP-S and LP-HC ex-factory price (EFP), wholesale (WS) margin/markup, and pharmacy (Ph) margin/markup across 27 EU Member States, as of 15 June 2009



Note: Data for several Member States not available.

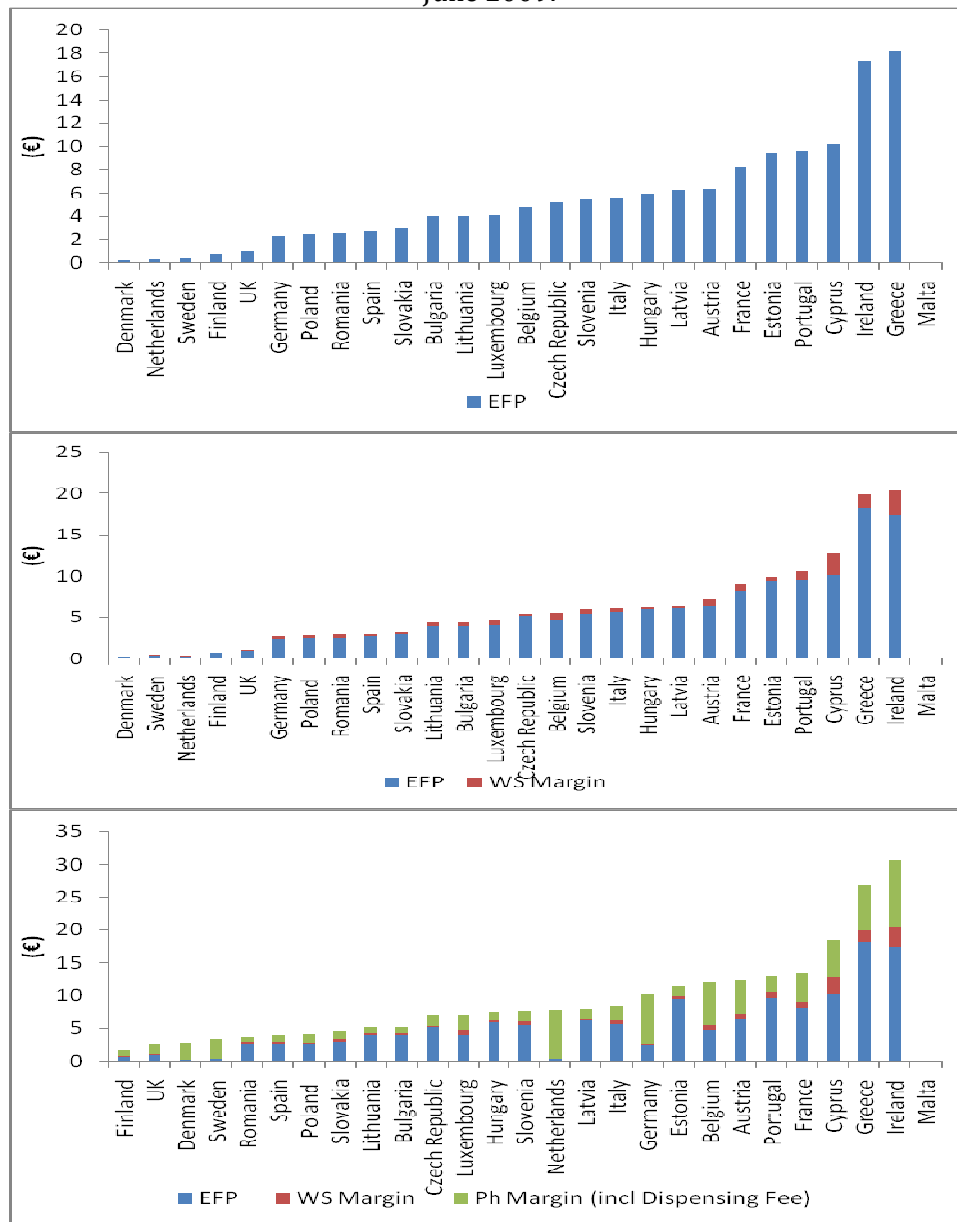
Source: Authors' calculations from pricing data received from Member States.

Total impact of distribution costs: generic medicines

The net average distribution costs for MP-CVD were €8.60 (range €3.42-15.64, Hungary-Netherlands), for MP-S €16.21 (range €3.10-51.06, Lithuania-Cyprus), for LP-HT €4.24 (range €1.05-10.52, Romania-Netherlands), LP-GERD €4.70

(€0.94-13.76, Spain-Ireland), LP-D €4.86 (€1.30-14.18, Bulgaria-Belgium) and for LP-HC €3.76 (€0.87-13.27, Finland-Ireland). Again, as with branded medicines, it appears there is significant variation between EU Member States in their distribution costs.

Figure 5.4 LP-HC (generic): EFP, PPP, and net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for Malta not available.

Source: Authors' calculations from pricing data received from Member States.

Examination of the least expensive generic medicine presented, LP-HC, also finds that the impact of distribution costs has significant impact on the final price to payers (Figure 5.4). Furthermore, for a number of countries, it appears that the distribution costs consume the majority of the final net price (Belgium, Denmark, Germany, Netherlands, Sweden, UK). In the case of Belgium and Germany, their overall net PRP is in the top third prices, the Netherlands is approximately middle of the range, while for the remaining countries they offer some of the lowest net PRP in the EU. It could be, in these cases, that the proportional greater distribution costs in relation to the EFP are needed to offset the lesser profits gained by their branded counterparts.

In addition, as with the branded medicines, although the majority of countries rank the same throughout the exercise there are some that change dramatically during the process. For example, the Netherlands have one of the lowest EFP, however, the addition of wholesale and pharmacy margins immediately push it up to middle of pack. There are other countries which also change from the top third to the lower third (or vice versa) although not as dramatically as the Netherlands.

5.3. Concluding remarks

There are a number of messages to take away from this price comparison and build-up.

- First, it appears that there is a wide range in prices at each stage of the exercise from EFP to gross PRP between EU27 Member States. This price spread is significantly more apparent in generic medicines than it is in branded, and far more apparent in less expensive medicines than more expensive medicines. This evidences the impact of regressive margin/margin schemes which are in place in several countries.
- Second, although EFP appears to some extent to predict approximately the final gross PRP to the payer, this is not always the case. Countries such as Greece, Italy and Luxembourg for branded medicines, and the Netherlands for generic medicines saw dramatic changes in their ranking with addition of wholesale and pharmacy margins.
- Third, it appears that the application of distribution margins may be different between branded and generic medicines, in some countries in particular. Countries with consistently low EFP, in some cases less than 5 percent of the final gross PRP, were Belgium, Denmark, Germany, Netherlands, Sweden – of interest these countries also had low relative EFP for their branded counterparts.

6. Diversity in the Distribution System and Issues Arising

It emerges from the previous sections that there is a significant level of diversity in the operation of both wholesaling and retailing across the EU. The following paragraphs summarise a number of interesting cases based on individual Member State experience and outline some of the issues they face. The selection of Member States for this purpose has been arbitrary, but has been facilitated by recent developments in distribution.

6.1. United Kingdom

6.1.1. Key trends

Wholesale margins in the UK are unregulated and determined through private negotiations between manufacturers and wholesalers. It is estimated this margin is no more than 12.5% (an unwritten “agreement” but widely understood to be the case). The pharmacy margin is also unregulated (formally), and a flat dispensing fee of €1.52 is one the margins added to pharmacy remuneration (see below). Other fees may also be collected via additional services, such as low-level diagnostics and basic counseling services. Pharmacy remuneration is determined, in fact, negotiated between government and pharmacy and includes payment terms alongside service provisions.

Application of margins across the seven selected molecules and the resulting branded and generic products, found that generally the UK has the lowest or amongst the lowest-third prices across the Member States for both branded and generic medicines¹, with the exception of branded LP-HC (Appendix 3). Generally, regardless of price class, a low EFP transfers through to a low net and gross PRP.

Pharmacy remuneration is covered by the Contractual Framework (operating since 2005) and pays pharmacies via a *global sum* budget from the Department of Health (DH) through fees and allowances (£1,049 million 2008-09), via *practice payments* in the form of dispensing fees in larger pharmacies and monthly payments from Primary Care Trusts (PCT) in smaller pharmacies (£664 million 2008-09), and via *retained margins* from the difference in price between the PPP and the NHS reimbursement price and set at £500 million annually (£770 million, 2008-09) (NAO, 2010). The majority of pharmacies are paid via

¹ This is a fairly recent development (evolving gradually over the past 3 years), reflecting a combination of two effects: first, two consecutive PPRS agreements, one in January 2006 and one in January 2009, both of which were associated with an across the board price cut; second, during this period, sterling depreciated significantly against the Euro, from €1.42 per £ to less than €1.1 per £. This combined effect made UK prices among the lowest in the EU in 2009, compared with among the highest 7-8 years earlier.

the practice payments, and only a small minority of isolated small pharmacies are paid via the essential small pharmacies scheme. The UK is, along with the Netherlands, one of the countries that explicitly allows discount income as part of overall pharmacy income. As part of this process, the government also retains part of the discount income through a process known as the clawback.

The higher than expected retained margin income is principally related to lower than forecasted PPP due to pharmacy incentives to drive purchase prices down. With new information, the retained margin calculation drives NHS reimbursement prices down, which then encourages further discounts by pharmacies. This regulatory lag is implicitly included in the agreement between the Pharmaceutical Services Negotiating Committee (PSNC) and the Department of Health.

6.1.2. Issues in distribution

The main wholesalers in the UK are Celesio, Alliance Healthcare, Phoenix and Mawdsley-Brooks. National wholesalers occupy the main source of pharmaceuticals (93%), while regional wholesalers are a minority. However, approximately 11% of medicines are delivered by short-line wholesalers (GIRP Database, 2010). The wholesale distribution model has undergone significant changes in the past 4-5 years with the evolution of agency and reduced wholesaler arrangements. One of the implications is that, as a result, full-line wholesaling is declining and short-line wholesaling is on the ascendancy. Wholesalers typically offer up to half or – according to meetings with them – more of their margin (of 12.5%) to pharmacy for branded medicines.

The UK offers one of the least restrictive government environments of pharmacies between Member States: discounts from wholesalers to pharmacies are allowed, chains and non-pharmacy ownership are allowed, and no control of location exists (only for non-NHS contracts). Further, most pharmacies offer additional services such as blood glucose testing and emergency contraception, sometimes at no cost to the patient.

6.2. Greece

6.2.1. Key trends

Greece applies a flat wholesaler markup of 8.43% EFP to all reimbursed medicines, in addition to a flat pharmacy markup of 35% PPP. Mandatory discounts are applied to manufacturers, wholesalers and retailers based on rural location (population <5,000). No additional dispensing fees or other fees are collected.

Application of Greek margins across the seven molecules finds generally that Greece has the highest or amongst the highest generic prices across the Member States, although a number of generic medicines were not represented by Greece in the dataset. These high generic prices start with the EFP and continue all the way through to the net and gross PRP. The expensive class example of HP-A found a mid-range EFP, however, the application of wholesale and pharmacy margins created a top 5 finish, suggesting a high impact of distribution on insurance costs of medicines.

6.2.2. Issues in distribution

The five largest wholesalers in Greece are Alapis SA, Sypfa Salonica, Stroumsas I SA, Prosyfape and Syneterismos Peiraios. Approximately 15% of medicines bypass the wholesalers and are directly delivered to the pharmacies which is amongst the highest rate between Member States (GIRP Database, 2010). Wholesalers seem to have a spatial (geographical) monopoly, originating from the geographical peculiarities of the country (over 65% being mountainous and difficult to have easy road access; several thousand islands, many of which are inhabited with small populations), although it is not certain how recent developments and infrastructure investment have been taken into account in re-shaping that policy.

Pharmacy ownership remains very restrictive, with only pharmacists allowed to be owners, no chains are allowed and locations strictly regulated. Despite that, the country has the largest density of pharmacies within the EU. Pharmacies are the only licensed vendors for both prescription only and over-the-counter medicines, including food supplements. Based on interviews with wholesalers, a significant part of their margin (approximately 2/3) is passed on as a discount to pharmacies. Pharmacies have also set up cooperatives, ie wholesaler arrangements to enable them to procure cost-effectively from suppliers of medicines. Some of the largest wholesalers are cooperatives.

6.3. Spain

6.3.1. Key trends

Spain has regressive margins both for wholesale and pharmacy remuneration. Prior to July 2010, two scales would apply to each of wholesale and pharmacy remuneration: for medicines with a manufacturer price of up to €91.63, there was a margin expressed as a percentage of the wholesale and pharmacy retail price respectively; and for higher priced medicines a fixed amount was added. In July 2010, the pharmacy margin scheme was changed, by adding two further scales (the first applying to medicines priced between € 200.- and € 500.- and the second applying to medicines priced above € 500.-) to which a fixed

remuneration sum was added. This is one measure in reaction to the financial crisis, in addition to price cuts for generics and discounts for higher-priced medicines (see below).

Average wholesale margins are between 3-5%. Only commercial discounts may be applied between wholesaler and pharmacy.

At pharmacy level, Spain applies a clawback system, with pharmacies making payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices. This clawback system has been in place since August 2000, while changes to the operation of the system came into effect in 2004, in February 2005 and May 2008 and, more recently, in July 2010.

This latest change in July 2010 to address the financial crisis provided, instead of price cuts, for discounts by the stakeholders to the regions for original products (7.5%) and orphan medicines (4%). While the discounts entered into force in June 2010, it took, according to Spanish experts, some months until the decision about the exact sharing of the burden for each of the stakeholders was reached. The exact handling of the implementation was still unclear at the end of 2010.

Application of margins across the seven molecules found Spain to be consistently amongst the lowest for branded LP-HT, MP-S (plus generic version) and LP-HC which all represent low-priced medicines, as well as the lower third for expensive HP-A. The remaining medicines, both branded and generic, were generally close to the average amongst EU Member States. Further, most medicines followed generally along the same path, with no huge swings from EFP to net and gross PRP.

6.3.2. Issues in distribution

The five largest wholesalers in Spain are Cofares, Alliance Healthcare, Hefame, Cecofar and Federacio. Regional wholesalers (55 companies) command the largest part of the market share at 58%, in comparison with other Member States where national wholesalers are the minority, yet occupy the position of key distributors (GIRP 2010). Most of these regional wholesalers are owned by pharmacist-owned co-operatives controlling 75% of the market; only one wholesaler is owned by a foreign entity (SAFA; 14% market share).

There are several restrictions in operation of the distribution channel, as such there is no vertical or horizontal integration – all pharmacies are owned by pharmacists and no pharmacies are part of a chain (ÖBIG, 2006). However, there are buying groups (approx. 25 groups, each with 50 members) to help with purchase prices. Further, the market is very fragmented (expressed by the dominance of regional wholesalers) partly reflecting the organizational structure of the country with emphasis on the autonomous communities (regions). The number of pharmacies per inhabitant has increased significantly over the past

decade, which means existing pharmacies may be having issues with sufficient medicine stocks.

6.4. Sweden

6.4.1. Key trends

Sweden has an unregulated, privately negotiated wholesale market, which is estimated on average at 2-3% of EFP. No mandatory discounts exist but commercial discounts do exist from wholesalers to pharmacies. The pharmacy margins on the other hand are regressive, using 4 categories ranging from less than €8.08 to greater than €646.40 PPP, with an average of 21.3%. No pharmacy dispensing fees exist and VAT on public reimbursed medicines is zero.

Examination of margins across the seven molecules found generic medicines were the lowest or amongst the lowest prices from EFP through to net and gross PRP. Branded medicines tended to remain in the middle of the pack all the way through the margin building exercise. The expensive HP-A began with a mid-range EFP and ended in a bottom 6 net PRP and bottom 3 gross PRP price.

6.4.2. Issues in distribution

The two main wholesalers in Sweden are Tamro and KD who occupy 95% of the market share (no regional wholesalers exist). It has a single-channel distribution system, which is nearly unique across EU Member States; such a model of organizing wholesale distribution can only be found in Sweden and Finland. In a single channel system the wholesaler has the exclusive right to distribute medicines for a manufacturer. It has been evidenced that wholesalers in single-channel systems have a stronger market power than the ones in multi-channel systems (ÖBIG 2003). This might impact prices and raises concerns regarding the lack of competition in this sector.

Sweden is one of the few countries that allows internet distribution².

From 1971 to 2009 the Swedish state owned all pharmacies, as only a state owned pharmacy chain (“Apoteket”) existed. Sweden was one of the few countries world-wide with a pharmacy monopoly. Many attempts (approx. 30 commissions) have been undertaken to abandon the monopoly, but these were unsuccessful. In addition, the Swedish pharmacy monopoly has been challenged by the European Commission. After the general elections in 2006, the Swedish government decided to implement a new commission aiming to deregulate the

² Alongside the UK, the Netherlands, Germany, the Czech Republic, Denmark, Slovakia, and Poland (see Table 3.1.)

pharmacy sector by 2009. In July 2009 the new regulation developed in collaboration with the pharmaceutical industry went into force.

Since then many players have entered the pharmacy sector as “anyone” can own a pharmacy, except for prescribers and pharmaceutical companies. Some chains have also entered this market. Some government-owned pharmacies still remain organised in a franchising system. Two DocMorris pharmacies have already emerged in Sweden and some food chains also own pharmacies. By June 2010 about 50% of the state pharmacies were sold to other owners and the remaining 50% are still and continue to be under public control. An increase in numbers from 800, prior to the deregulation to 1,300 is expected to change due to market stabilization.

The goals of the deregulation in Sweden, which some experts prefer referring to as “re-regulation”, are increased accessibility (to extend opening hours), better service and more differentiated services. Among the goals and mission given by the Swedish government to the Dental and Pharmaceuticals Benefits Agency (TLV), which is in charge of the implementation of this policy, it is also to adjust the pharmacy/retail margin.

7. Discussion – A Stakeholder Appraisal

This section considers the stakeholder implications in 5 areas relating to distribution policy: first, the changing market structure; second, the recent developments in the distribution model in some countries; third, the policies on distribution margins and their implications; fourth, the impact of distribution margins and markups on retail prices; and, fifth, the likely differential impact of margins on brands versus generic medicines. It draws on the evidence presented in the previous sections and more widely on meetings and semi-structured interviews conducted with a variety of stakeholders, ranging from patient groups, health insurance organizations, wholesalers and wholesaler associations, pharmacists and pharmacy associations, and manufacturers and manufacturer associations from a number of countries (UK, France, Spain, Sweden, Greece, Belgium, Switzerland, the Baltics, and The Netherlands).

7.1. The changing market structure

7.1.1. Key issues

The majority of countries have regulated wholesale and pharmacy margins, with the exception of Denmark, Finland, Ireland, Netherlands, Slovenia, Sweden and the UK for the former and Ireland, Netherlands and the UK for the latter. Despite this regulation there appears to be fragmentation nationally and at EU level with regards to its organization and structure. Some countries have monopolistic or near monopoly conditions in wholesaling or retailing, or both (ie Denmark, Sweden), while others have much higher than average numbers of wholesalers (i.e. Italy, Spain, Greece) or pharmacies (Greece, Spain, Italy) relative to their population.

Significant horizontal integration has occurred particularly in the wholesaler industry, to the extent that many wholesalers operate throughout regions of the EU and the number of wholesalers operating has decreased significantly over the past decade. Pharmacy chains now exist in almost half (13) of the EU, while the remainder still have strict regulations on pharmacy ownership, usually entailing rules where either a pharmacist may own only one pharmacy or where the pharmacist must own a minimum of 51% of the pharmacy. Despite the development of pharmacy chains, or the liberalization of location, in most countries the total number of pharmacies has remained relatively stable during this decade. Where pharmacy horizontal integration is hindered by national regulation, cooperative purchasing schemes have arisen to achieve economies of scale and better procurement terms from wholesaling entities.

A further trend relates to ongoing developments in vertical integration in the industry. In a number of cases, wholesalers and pharmacies have merged to form vertically integrated entities and take advantage of any scale economies in the wholesale and retail markets. In most cases, such actions are initiated by wholesalers, seeking to access the retail market and potentially have access to patients and their needs, whereas in others, the opposite occurs and retail groups acquire wholesale entities in order to strengthen their backward links and procure more efficiently.

In recent years, manufacturers have assumed a more active role, indirectly intervening in the distribution chain and shaping its structure; as a result of these “interventions”, in some EU countries 5-20% of prescription medicines now bypass wholesalers and are directly delivered to the pharmacy.

Wholesalers and pharmacies both offer more services than previously due to this increased competition. In the majority of cases, these extra services are not charged but absorbed by the relevant company as a business cost. In a number of countries, pharmacies are allowed to offer internet dispensing of prescription medicines, in some cases independent of a ‘bricks and mortar’ pharmacy.

7.1.2. Stakeholder perspectives

Manufacturers

Manufacturers would in principle be interested in a supply chain that guarantees the efficient distribution of their products for the intended markets and at reasonable cost. Access to patient information at the micro level (i.e. in individual communities) would be key and an area worth investing in. In an era of logistics and stock management being driven remotely by advances in information and communication technology (ICT), the value-added of certain components of the distribution chain have often been questioned in relation to the services provided and the overall cost of these services.³ As a result, it is not surprising that manufacturers explore alternative (wholesale) distribution arrangements.

Wholesaling

Wholesalers feel squeezed by current practices as well as some recent developments. Current practices in wholesaling suggest that wholesalers typically offer a proportion (in some cases significant) of their allowable margin as a discount to pharmacy. Interviews with wholesaler stakeholders alluded to

³ Interviews with 4 leading manufacturers.

actual margins ranging between 1.5 – 3.5%. Pharmacy chains may have greater negotiating power and can, as a result, benefit from a higher discount from wholesaling, although the extent to which this is true at aggregate level is unclear and can be the subject of further scrutiny.

Competition among wholesalers for the retail business has intensified in recent years by developments in IT and logistics, as well as the entry of manufacturers who are increasingly interested in establishing direct vertical links with the retail business. In some cases, this is resulting in the map of players on the market being re-drawn with consolidation of existing entities and entry of others or a re-definition of activities by existing players.

These dynamic developments can have a significant impact on wholesaling and the competitive advantages it has in the distribution of medicines. Interviews with wholesalers and other stakeholders indicate that the traditional full-line wholesaling model (stocking the widest possible gamut of pharmaceutical products, easy access to stock by and timely & frequent delivery to retailers) is under dispute – indirectly - in a number of Member States, particularly those where the environment is more flexible regarding ownership and integration. As a result, if wholesaling is to survive it will probably need to develop further competences and links downstream strengthening existing advantages.

Pharmacy

Retail market structure remains diverse across EU Member States, as does the regulatory environment relating to ownership, procurement and ability to integrate both horizontally and vertically.

Greater efficiencies can be achieved by joint procurement and this can materialize through a horizontally or a vertically integrated structure or a cooperative. Countries where horizontal or vertical integration are limited by current legislation are taking advantage of the “cooperative solution”, e.g. Spain, France and Greece.

Redefining the role of pharmacy is a great pursuit, particularly in what concerns health promotion, prevention, aspects of disease management and monitoring. There may be considerable benefits to society and the health care system from this development in terms of quality, access and cost. Pharmacy chains are likely to benefit more from this development in terms of volume, facilities within pharmacy and network or population coverage. Yet, the willingness of health authorities to pursue this remains sluggish. As evidence from the UK suggests, ‘... *the new pharmacy contract involves more monitoring, survey and audit; none of which is supported by the Department of Health (DoH) or Primary Care Trusts (PCTs). PCTs do not provide support for health promotion campaigns or clinical governance, and the contract never delivered what it promised...*’

An important competitive advantage of pharmacy, making it an attractive target to pursue further consolidation in the field is its direct relationship with the patient population and the use by the latter as a source of information and advice. This is already driving developments in some Member States and further developments are still to come.

Patients

Patients are in principle neutral to consolidation in the distribution sector, so long as access and availability of medicines are not compromised and the range of available services increases at no additional cost to them. Increasing services at pharmacy level could prove beneficial particularly if they are offered in a timely fashion and avoiding waiting times. In some instances, patients have raised questions about access to services and the length of time it takes for them to access a pharmacy. This is particularly important for elderly and vulnerable patients in rural areas. Where these phenomena exist action could be taken by the competent authorities to ensure that access remains at acceptable levels. Where pharmacy chains occupy a significant proportion of retail distribution access problems in rural areas could be addressed by operating chain outlets in problem areas.

Insurers and payers

From a payer perspective, greater consolidation could mean lower distribution costs because of economies of scale in procurement and distribution, taking advantage of common networks and more efficient operations. In theory, consolidation would imply lower fixed costs, but it is questionable whether compressing these can be achieved *ad infinitum*. It may even be doubtful whether cost reductions can be achieved in the first place given the changing patterns in the distribution of medicines and the increasing proliferation of agency and reduced wholesaler models.

But even if these models are not taken into account for a moment, it is likely that the environment in the distribution chain is becoming more competitive with payers demanding greater generic dispensing (and, therefore, at a lower overall margin) and driving the market for generic products, as it has recently been seen with outpatient tendering in some countries (the Netherlands, Germany and Hungary, among others). Such developments are unlikely to enable further sustainable reductions in margins without having an impact on market structure of distribution.

Additional services that can be provided by retail pharmacies could go some way to maintain existing structures, yet, it is not always clear what additional value these services create and what an adequate remuneration is as a result. For instance, health promotion campaigns, monitoring, audit, or clinical governance

could be undertaken by pharmacies, yet, a number of stakeholders at national and regional level have suggested that they cannot support financially these services.

In an environment characterized by consolidation, payers need to be mindful that access to pharmacies is maintained overall, particularly in rural areas, which are, in principle, under-provided. In areas where there seems to be a problem, rural pharmacies can be offered financial incentives to continue operating for the benefit of the wider community they serve.

7.2. Changes to the prevailing distribution model

7.2.1. Issues in supply chain arrangements

Some of the changes outlined in the previous section on market structure relating to horizontal integration (among retailers or among wholesaler entities) and vertical integration (between agents across the distribution chain) are to a certain degree also propagated by changes in the type of the distribution model over the past 3-4 years with the emergence of agency and reduced wholesaler arrangements in some countries as discussed in section 3.

Both types of models are gaining momentum in a number of EU countries for an increasing number of products, particularly expensive prescription drugs. This development does not necessarily contravene the public service obligation.

Article 81 of Directive 2001/83/EC outlines the public service obligation requirements (and potential limitations thereof) suggesting that "... with regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities. Further, in the Official Journal of the European Union "... the holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition" (L136/50 EN 30 April 2004).

The interpretation of the above varies in the Member States, with the “public service obligation” at times being called into question, although, by and large, it does not restrict the parallel operation of different distribution models. To that end, agency (or Direct-To-Pharmacy, DTP) arrangements can co-exist with reduced wholesaler arrangements, where manufacturers can completely (in the case of agency) or partly (in the case of a reduced wholesaler model), or a combination thereof, bypass the traditional chain to supply pharmacies directly. At the same time, they limit (in the case of a reduced wholesaler model) or altogether eliminate (in the case of the agency model) the discounting ability by wholesaler to pharmacy. From a practical perspective the developments on this front have meant that the concept of a full-line wholesaler is redundant, as for example, different distribution arrangements may be in operation for different products within a manufacturer’s portfolio.

Indeed, as Table 7.1 shows by drawing on the UK environment, manufacturers may have more than one type of relationship with wholesalers. Reduced wholesaler arrangements exist in 18 out of 23 main manufacturers in the UK and the remaining 5 manufacturers have agency model arrangements with 3 major pan-European wholesalers (Alliance Healthcare, AAH and Phoenix). This reduced wholesaler relationship is present for all prescription medicines in 3 cases and for all products in 4 cases, while the remaining 11 cases are applied to selected products. The agency model is present for selected products in 3 cases, for all products in one case and prescription medicines in another case. Of the 23 manufacturers, 22 have relationship with Alliance Healthcare, 17 with AAH and 13 with Phoenix.

The above has given rise to a number of issues for the different stakeholders; these relate to the type of complex arrangements that are in place, the access issues that arise, the income and profitability of different stakeholders, the efficient operation of the market, the effects on competition and the likely impact of product shortages. These are explored in the paragraphs that follow from a stakeholder angle.

Table 7.1

Overview of supply chain arrangements between manufacturers and pan-European wholesalers, April 2010

Manufacturer	Effective from	Type of Arrangement	Products Available	Alliance Healthcare	AAH	Phoenix
Pfizer	Mar 2007	Agency model	All prescription medicines			
NAPP	Oct 2007	Reduced wholesaler	All products			
Sanofi-aventis	Nov 2007	Reduced wholesaler	All products			
Astellas	Nov 2007	Agency model	Selected products			
AstraZeneca	Feb 2008	Agency model	All products			
Novartis	Aug 2008	Reduced wholesaler	All prescription medicines			
GlaxoSmithKline	Nov 2008	Agency model	All prescription medicines			
Janssen-Cilag	Jan 2009	Reduced wholesaler	All prescription medicines			
Roche Products Ltd	Jan 2009	Reduced wholesaler	Selected prescription medicines			
Novo Nordisk	Mar 2009	Reduced wholesaler	All products excluding NovoSeven			
UCB	Apr 2009	Reduced wholesaler	Neupro only			
Smith & Nephew	July 2009	Reduced wholesaler	All wound management products			
Eli Lilly	July 2009	Agency model	Check with manufacturer			
Bayer Schering Pharma	July 2009	Reduced wholesaler	Selected products			
Bristol Myers Squibb	Aug 2009	Reduced wholesaler	Selected products			
Merck Sharpe & Dohme	Oct 2009	Reduced wholesaler	All MSD products			
LEO Pharma	Oct 2009	Reduced wholesaler	All products			
UCB	Nov 2009	Reduced wholesaler	All products (except Neupro)			
Lifescan UK	Dec 2009	Reduced wholesaler	One Touch Ultra and Finepoint			
Ferring Pharmaceuticals	Jan 2010	Reduced wholesaler	All products			
Medac	Mar 2010	Reduced wholesaler	Metoject			
LALK-Abello Ltd	Apr 2010	Reduced wholesaler	Epi-Pen and Epi-Pen Junior			
Shire	May 2010	Reduced wholesaler	Selected products			

Source: British Association of Pharmaceutical Wholesalers, September 2010.

7.2.2. The changing structure and nature of medicines distribution: implications for stakeholders

Access and availability of medicines

Nowhere else has the changing nature of distribution and the advent of the agency and the reduced wholesaler models, had a significant impact than the UK and, to a certain extent, the Netherlands. In principle, changes in the distribution model should make the process of delivering medicines from factory gates to the patient bed-side leaner (more efficient) and cost-effective. Yet, there seem to be some concerns about the availability of medicines; it could be the case that manufacturers' activities in streamlining supplies and managing stock coupled with the ever fragmented nature of distribution, can lead to shortages in some markets.

In a survey of 220 pharmacists conducted in August 2010 and published in the *Chemist & Druggist*, extensive reference is made to medicine shortages, attributable to changes in the UK pharmaceutical distribution model. According to the survey, as a result of shortages patient anxiety levels have increased significantly, particularly in the case of severe conditions such as cancer and Parkinson's disease (two diseases with medicines difficult to source). Almost all pharmacists have experienced turning clients away more than once (93% of pharmacists surveyed). Pharmacists are concerned of the effect on patients (70%) and many spend significant periods of time sourcing medicines (80%). Almost 70% of pharmacists have to wait 3 to 5 days for manufacturers to make emergency deliveries, while 80% report wholesalers being out of stock for 5 to 50 medicines (an increase from 2009). Branded medicines appear particularly difficult to find, and manufacturers with bespoke supply deals seem more susceptible to stock shortages. Almost all pharmacists (93%) have had to ask a GP to change a prescription due to supply issues, while 86% have rated industry and government efforts to solve supply shortages as poor. As a result, almost two-thirds believe that shortages will be worse during the next year and only one-third of those surveyed believe the situation will stay the same.

Implications for manufacturers

In principle, manufacturers have an obvious financial and non-financial incentive to promote the agency model or distribute their products via the reduced wholesaler model; this incentive lies in at least three fronts: first, by selecting either of the above arrangements they can largely control where the stock actually goes, and this has direct implications for parallel trade (especially parallel exports), in the sense that conducting parallel trade activities may prove more difficult with the new distribution arrangements; second, subject to negotiation with the preferred agent or wholesaler(s) of choice, there is always an opportunity to retain part of the wholesaler's margin, although this will need to

be balanced against the requirement to invest into a distribution model in the short-term. And, third, manufacturers see the new distribution model as a possibility to improve medicine supply to patients and, indirectly, get closer to patients, via pharmacies. This last point is more strategic in nature and seems to underpin a significant part of the rationale towards agency or reduced wholesaler distribution. By directly serving specific communities, pharmacies have access to and directly store information about the needs of these communities.

One leading manufacturer stressed at interview that getting closest to patients was the primary consideration for changing the distribution model arrangements and that they “work closely with pharmacists to ensure that the latter can obtain the company’s medicines and there is continuity of supply for UK patients”. Further details on how precisely continuity of supply is guaranteed are lacking, although pharmacists experiencing difficulties are instructed to contact individual manufacturers’ customer contact centres. From a manufacturer’s perspective, shortages are not justified.

Implications for pharmacy

Pharmacists are primarily concerned about three issues: the first relates to having to manage with a more complex distribution model and the second deals with medicine shortages; to an extent, these two issues seem to be interlinked. Finally, the third issue is falling profitability across a number of products.

The first issue arises from an increasingly fragmented structure in distribution. Pharmacists are having to source product from a variety of sources, instead of simply placing an order with a full-line wholesaler. If the product in question is subject to an agency agreement, they will need to order directly from manufacturers, whereas if it is subject to a reduced wholesaler agreement, it could lead to extra time to secure a delivery if one or more of the preferred wholesalers do not have the product in stock and to further delays if none of them do. In the UK, pharmacists (individually) and the PSNC have complained that they had to wait three days or more for emergency stock to be delivered from a manufacturer (Chemist & Druggist 2010 survey). About 80 per cent of pharmacists said it was harder to source products from pharmaceutical firms running distribution schemes, the Chemist & Druggist Stock Survey 2010 found and only 6 per cent said supply deals had improved access to medicines. It is recognised that pharmacists are spending precious time each day trying to source medicines – an activity which, in principle, takes them away from direct patient contact. The Royal Pharmaceutical Society of Great Britain (RPSGB) has highlighted that while the effect on patients is being mitigated by the tremendous efforts of pharmacists, the additional workload to source medicines is putting huge pressure on frontline staff. Whether this is sustainable over the longer term is unknown, but interviewees who contributed to this section highlighted this as an issue of significant concern for the profession.

The reasons for stock shortages are diverse, ranging from (a) raw material shortages to (b) parallel trade and (c) manufacturer distribution systems. It is likely that the combination of parallel export potential due to lower prices coupled with changes in the distribution system have contributed to a surge in shortages reported in countries such as the UK during 2009-2010. Indeed, in the UK, the PSNC reports that 13 of the 19 manufacturers whose products either appear on shortages lists or are most frequently linked to shortages operate a supply model. Parallel trade (parallel exports in particular) seems to be one contributing factor to this problem, although, according to estimates, less than one in ten pharmacies parallel trade. Rigorously enforced quotas seem to be in operation and pharmacists have complained that with the new distribution arrangements, getting hold of just a couple of extra packs of medicine can turn into a lengthy and humiliating interrogation highlighting issues of trust between manufacturers and pharmacists.

Agency models, where they apply, essentially mean that wholesalers do not own the stock and simply deliver to pharmacy without the ability of passing a discount on to pharmacy. If pharmacies rely on discount income for their overall income – as is the case in countries such as the UK and the Netherlands - and if manufacturers do not offer a discount, then the agency model may well result in brand profitability for pharmacies. In the UK, the recent advent of Direct-To-Pharmacy (DTP) distribution by a number of manufacturers since 2007 has meant that many pharmacies now dispense branded medication at a loss, due to the lack of wholesaler discount on these lines. Interviews with independent community pharmacists have highlighted this problem.

'Pharmacists switched off about 15 years ago when the PSNC was allowed to take control of negotiating, and took a back seat. My clawback⁴ is about 9.8-10.5% but this depends on the nature of dispensing the pharmacy does. When I dispense a GSK product that is not a zero discount (ZD)⁵ line, I accrue an immediate 2-4% loss. The retained margin via the clawback is definitely not a true reflection of what the new pharmacy contract asks for, and the new contract is definitely more expensive to service'.⁶

'The new pharmacy contract is definitely more expensive to service than the old one. The costs of DTP were never included into the new contract, and so a loss arises. Pharmacies who entered under relaxed entry laws took money out of the global sum, so there was less of the retained margin to compete for. There are still drugs that I dispense at DTP which are not on the ZD list, such as Viagra; but there are many others, so yes, I dispense branded medicine at a loss. Operating costs have increased in recent years, with energy and fuel costs rising, and wholesalers imposing a fuel surcharge.'⁷

⁴ A policy, whereby the government retains part of the discount achieved by pharmacies.

⁵ Refers to a number of products which carry nil discount from wholesalers.

⁶ Interview with an independent community pharmacist.

⁷ Interview with an independent community pharmacist.

Meetings and interviews with stakeholders in the UK and, to a lesser degree, the Netherlands have highlighted that the combined effect of changes in the distribution chain leads to pharmacies having to spend more time sourcing products and that this can be at the expense of frontline services towards patients, whilst at the same time making a range of products, particularly those subjected to DTP arrangements, significantly less profitable. This affects equally community pharmacies as well as chain pharmacies, as the latter are not immune to changes in the distribution system and are often subjected to similar searches for products on behalf of patients. It is, however, likely that the impact in terms of search costs is lower in chain pharmacies than it is in community pharmacies. Overall, pharmacies and their representative bodies are totally opposed to this type of development as it increases their operating cost and can have adverse impact on the quality of contracted services.

Implications for wholesaling

In Directive 2001/83/EC, the public service obligation was defined as “..the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.” Extensive use of a reduced wholesaler model in principle satisfies the public service obligation, but, as discussed previously, it does mean that the concept of full-line wholesalers effectively becomes redundant. The interpretation of the public service obligation varies in different Member States and this sometimes means that a public service obligation does not exist.

Agency or Direct-To-Pharmacy (DTP) distribution arrangements imply the involvement of one wholesaler only to distribute branded products to pharmacy. The wholesalers never own the medicine, and only act as couriers or logistics providers, who are in no position to offer any discount on the products they distribute. The argument is that, where an agency model exists, it effectively gives manufacturers outright control on pricing and discounting of their medicines.

Wholesalers argue that recent developments in wholesale distribution are an inefficient way of distributing medicines to pharmacies and then on to patients. According to one source, the agency or the reduced wholesaler model “have added significantly higher numbers of vehicles on the road from multiple agents doing precisely the same as prior to the advent of this new reality; this cannot but be an inefficient outcome, as, among other things, it increases the environmental footprint of distribution altogether.”

Meetings with wholesalers (Phoenix, AH), who continue to be bound by the public service obligation, suggest they have been worried about the supply chain for a while, as well as concerned about the effects the changes in distribution – particularly shortages - are having on patients, in terms of public health impact and safety. It is also suggested that regulators and competent authorities have little power to change the system unless health outcomes

are shown to be affected due to shortages. In addition, it is believed that passing the sourcing burden onto pharmacists complicates a previously simple process, and they try to ensure that their distribution is 'fair across distribution channels'. Wholesalers also contend that availability will continue to be a problem whilst insufficient supply struggles to meet demand.

It is likely that, based on the above changes in the distribution system, a wave of consolidation among wholesalers may take place, and some may altogether be driven out of the market.

Implications for patients

Patients are very concerned about medicine shortages, particularly in rural areas and across illnesses that require timely access to needed medicines, as, in the opposite case, care and outcomes can be negatively affected. Negative effects on patient health are not unusual with stock shortages, in addition to the added anxiety it may bring on fragile health states. Increased stress due to lack of medicine can have significant negative effects on top of the stress of chronic illnesses. Not only is this the case for branded but also for generic versions as well at times, in addition to doctors' having to change their care plans due to stock shortages.

There is some evidence that the changing nature of supply in the distribution chain may be impacting access to and availability of medicines, although the evidence base is hitherto weak and relies on one survey. The results of Chemists and Druggists' Stock Survey⁸ in the UK, explicitly referred to several pharmacist-reported cases of patients' health suffering because they simply could not get hold of prescribed medications, ranging from geriatric patients forced to catch three separate buses to track down their medicine to fits in epilepsy sufferers leading to hospital admissions.

Ensuring availability: the payer view

Payers find little reason to intervene unless patient access to medicines is significantly affected or shortages are shown to be having an impact on care and outcomes. At the same time, it looks as though breaches from the public service obligation do not necessarily occur in situations where a reduced wholesaler model operates.

Nevertheless, in the UK, recent concerns about product shortages have led to some action by the competent authorities. The Medicines and Healthcare products Regulatory Agency (MHRA) has agreed to carry out a targeted programme of inspections, and if manufacturers or wholesalers are found to be in breach of legal duties to maintain an adequate supply of medicines they risk prosecution and losing their licences. Similarly, pharmacists and

⁸ <http://www.chemistanddruggist.co.uk/stocksurvey2010>.

doctors will be held to account by their professional bodies for failing in their ethical obligation to put patients first. The UK government has also promised to raise the standards required for wholesaler dealers' licences, including inspection, sunset clauses and re-licensing, and other measures include the development and maintenance of a list of drugs that are endangered, "so that no-one has the excuse that they were not aware of supply difficulties", as the Department of Health explained, as well as the prioritisation of products on that list for further investigation to find possible resolutions to the worst supply issues. In addition, best practice guidance for dispensing doctors, pharmacy, wholesalers and manufacturers is intended to take place in order to help them better manage supply problems. Finally, and managing within the current environment of distribution model changes, it is explored how manufacturers and wholesalers could be assigned a "more explicit duty" to ensure that stocks do not run dry, as well as the feasibility of establishing buffer stocks to be held by wholesalers, to help give the supply chain greater flexibility.

7.3. Policies on distribution margins and their implications

7.3.1. Key issues

The information on wholesale and pharmacy margins, collected from various sources, including the PPRI reports and updated and confirmed by own inquiries, the PGEU and GIRP, found startling differences between countries in the methodologies they apply and the actual margins themselves. The creation of regressive margins may have as little as 2 categories (e.g. Spain) or more than 10 (e.g. Austria). Depending on the Member State, the final margin category may be set at more than €600 or less than €20. Private negotiations can be found in wholesale margins and pharmacies typically receive discounts from wholesalers or benefit financially from other arrangements e.g. for timely settlement of invoices, bulk purchasing, etc. Many Member States have created fixed maximum margins above a certain threshold which may be less than €10 or more than 50€ of the ex-factory or the wholesale price.

These patterns divulge the diversity of distribution remuneration throughout the EU, as well as their application in different drug classes or differently priced drugs (e.g. expensive versus low-priced medicines). The application of these margins across the seven molecules, reflects this diversity in margins in the large price gaps found between Member States. Although the price gap is largest for low-priced medicines, particularly generics, it is also found in mid-priced and expensive medicines.

The price gap between Member States is more apparent for generic medicines than branded medicines. In a number of cases, the EFP portion for the generic medicine was less than 10% of the gross PRP and in many cases less than 50%. In those countries, the examination of the branded counterpart also found low relative EFP but not near to the same extent as the generic version.

Overall, it appears that for most countries and most medicine types (price and branded/generic), the EFP determines to some extent the final gross PRP. There are, however, some exceptions to this rule where countries can swing wildly between beginning with a low EFP and ending up middle to high range, and vice versa.

These patterns suggest major differences between Member States in their distribution costs as well as large differences in their applications to branded versus generic medicines.

7.3.2. Stakeholder perspectives

Manufacturers

Manufacturers recognize the importance and contribution of the distribution sector to ensuring access and availability of medicines to patients. Yet, it is often argued that the cost of distribution is in many cases disproportionate to the value it offers to the general public and, as such, should be reconsidered and become more in-line with the contribution that the pharmaceutical sector makes in terms of bringing new therapeutic alternatives to market. Equally, it has been argued that where brands and generics co-exist, the structure of margins and markups in many cases favour generic medicines, thus creating an unequal playing field among equivalent therapeutic options. This is exacerbated in situations where therapeutic reference pricing exists and where branded, in-patent products are included in therapeutic clusters.

Partly as a result of the above, it is not uncommon for manufacturers to consider more direct options to distribute their products and reach pharmacies. Although this implies considerable initial investment, it is often considered worthwhile. Other stakeholders in the distribution chain contend that these movements by manufacturers automatically result in wholesale (and, potentially, retail) margins and other income being curtailed as manufacturers can re-define the terms of engagement by wholesalers.

Wholesalers

Wholesalers operate on the basis of large volume and small margin. They feel squeezed by the nature of competition and the requirements of public service obligation and frequent distribution to retail outlets, the net result being a very low net margin on wholesale distribution of medicines. They also perceive recent changes in the distribution model in a number of Member States, particularly relating to higher cost medicines, as partial and creaming off a significant source of revenue for their operations. Where already experienced, the direct involvement of manufacturers in distribution has changed the way the sector operates and the ability of wholesalers to compete and offer value deals to their customers.

It is likely that if these trends become more generalised in the years to come, the wholesale sector will experience further consolidation. Already, as pointed out at interview, a number

of wholesalers have gone out of business or have merged with others, as a direct impact of the above trends.

Pharmacies

Pharmacists often feel they are asked to do more for less, that there is reluctance by payers to remunerate them for additional services rendered and that, as a result, other segments within pharmacy is cross-subsidising the POM segment. Importantly, the changing role of pharmacy in the community does not necessarily seem to be reflected by actions at policy level. In addition, their ability to negotiate terms with wholesalers is beginning to change in environments where products are delivered directly by manufacturers and where pharmacy is incurring a significantly higher cost in search of product.

Patients

Patients are largely unaware of the costs of distribution and their primary consideration is the availability and affordability of medicines. Distribution remuneration, particularly at retail level, should capture some of the gaps in availability, particularly in remote or rural areas where such problems seem to be more acute. Patients in some cases argue that the pursuit of profit across pharmacy chains is responsible for problems in the geographical allocation of pharmacies and that this ought to be addressed.

Insurers and payers

Insurers face a significant cost of distribution and taxation. Significant changes have taken place over the past decade in the majority of Member States in an attempt to reduce the impact of distribution (but not taxation) and calibrate remuneration structures, often resulting in a reduction of wholesaler and – in some cases – retail margins.

In some cases, health insurers have experimented with “novel” initiatives for the retail market, such as tendering and rebate policies. Apart from the unintended consequences that such schemes may have⁹, these initiatives have revealed, among other things, the reservation price of mature (off-patent) medicines and the cost payers should be paying without it being inflated by discounts.

In some Member States the cost of taxation is set at disproportionate levels. While a majority of Member States have set reduced (or zero) VAT rates for prescription medicines, in some (e.g. Austria, Denmark and Germany) normal rate VAT levels reflect the perception of prescription medicines as normal consumption goods. While there is little in terms of a theoretical or empirical justification for imposing VAT on prescription medicines, its use reflects a reverse tax by national Treasuries on health care resources. Yet, it appears that

⁹ These have also explored in a previous EMINet report (2009) on preference-based policies and rebate policies and relate to the impact on pharmacy operations, among others.

there is little Ministries of Health or sickness funds can do to mitigate this, as it relates to national (taxation) policy priorities, where decisions are taken by Finance Ministries.

7.4. Impact of Distribution Margins and Markups on Retail Prices

7.4.1. Key trends

From the pricing analysis of the seven molecules, a number of patterns emerge, which also carry important messages for decision-makers and other stakeholders.

First, ***there seems to be significant price variation across products and across countries.*** It appears there continue to be significant variations in prices between Member States (a) during all stages of the price building exercise, from the initial EFP to the final gross PRP, and (b) among originator brands and generics. Of course, this is the effect of regulation and the way it applies across brands and generics. Price variations amongst brands were greatest among older medicines and narrower among newer medicines. Comparing a sample of seven medicines and the portions making up the final gross PRP, the smallest price gap (between lowest and highest) in branded prices amongst Member States was 79% for branded HP-A PPP and the largest range was 2206% for branded LP-GERD EFP. Among generic medicines, the smallest price gap found was 243% for generic MP-CVD net PRP pharmacy margin/markup and largest price gap found was 9177% for generic LP-HC PPP. The majority of the large differences between Member States were reported for wholesale and pharmacy margin/markups, both in branded and generic versions.

Second, ***margins/markups have on certain occasions significant impact on retail prices.*** Certain countries appear to have consistently high or consistently low prices, with not much movement with the application of margins/markups. Germany, for example, has consistently high EFP and PRP in general. Other countries have low EFPs, but distribution margins have a significant impact and elevate their retail prices towards the higher end of the EU-27 distribution (e.g. Italy, Greece). These effects can be seen in Figures 7.1 – 7.5. Finally, some countries seem to have very high generic prices (e.g. Greece, Figure 7.5) irrespective of the impact distribution margins have on EFP.

Third, ***the difference between branded and generic versions of gross PRP of the same medicine varies between and within Member States.*** Ex-factory price as a proportion of gross PRP between Member States is far greater for generic versus branded medicines, particularly for low priced medicines. This extends to within Member States, where certain members such as Belgium, Czech Republic, Denmark, Finland, France, Germany, Luxembourg, Netherlands, Poland, Sweden and UK, show different distribution between branded and generic versions within the country.

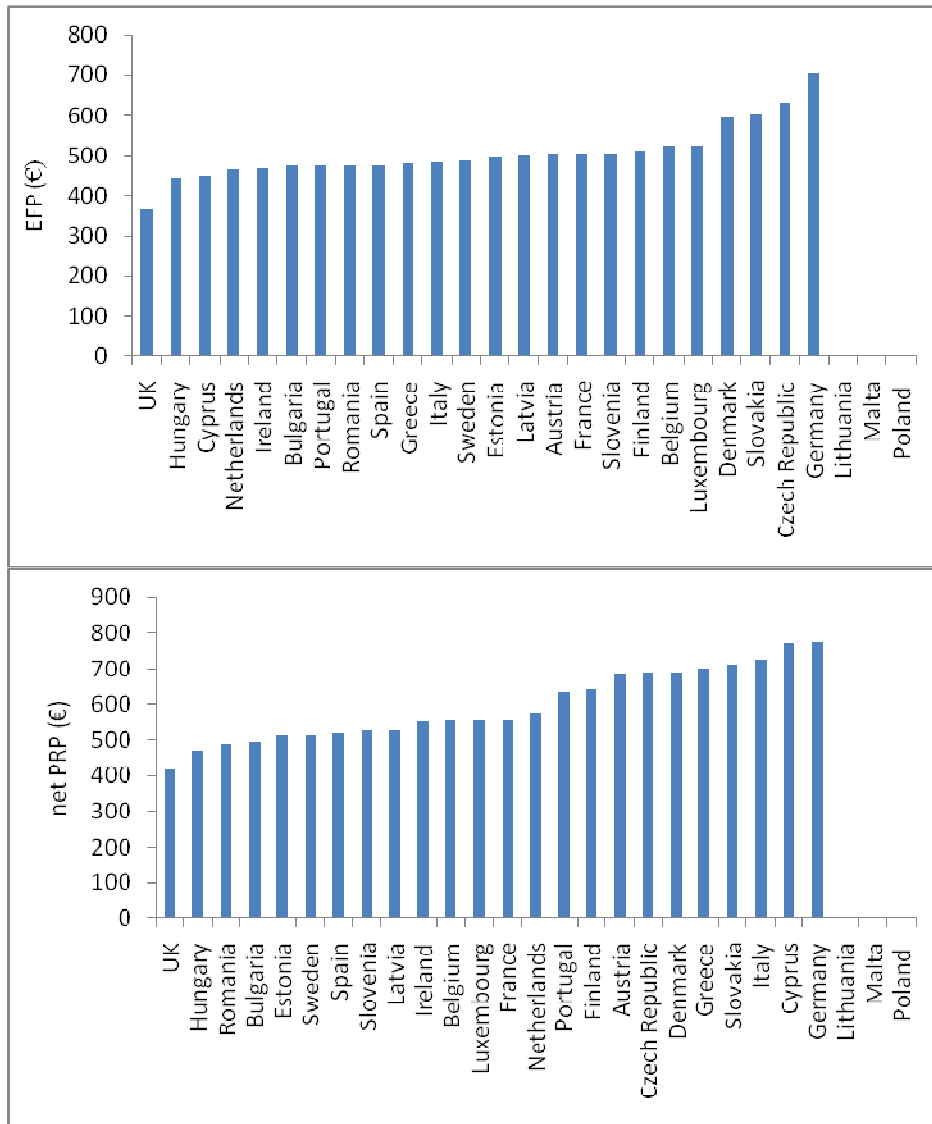
Fourth, ***differences in wholesale and pharmacy retail margin/markups affect expensive, mid- and low-priced medicines differently.*** Specifically, the absolute EFP price

gap between Member States is smaller for expensive and mid-priced medicines (price gap range 104-353%) than low-price medicines (364-8610%) both generic and branded, and continued with gross PRP. Examinations of the proportions of the gross PRP found larger differences between Member States for generic medicines only. Generic EFP as percent gross PRP found low-priced medicines had a larger price gap (range 86-89% than mid-priced generics (range 44-97%), while proportional pharmacy margin/markups also displayed larger price gap for low-priced generics (price gap range 88-95%) than mid-priced generic medicines (24.8-37.8%).

Fifth, there appears to be ***a greater effect of margin/markups on lower-priced drugs, particularly generics, than expensive drugs.*** Examination of the following rankings (Figures A2.1 – A2.11) using the Netherlands as an example, finds that the most dramatic movements in placement take place for generic LP-HC than any other medicine. In the case of the Netherlands this is due to the relatively high (in comparison with other countries) flat dispensing fee on a low-priced generic product. Similar trends hold for Greece and Ireland.

Figure 7.1

HP-A ex-factory price (EFP) (upper panel) and net pharmacy retail price (PRP) (lower panel) (including dispensing fees but no VAT) ranking across the EU27 Member States, as of 15 June 2009.

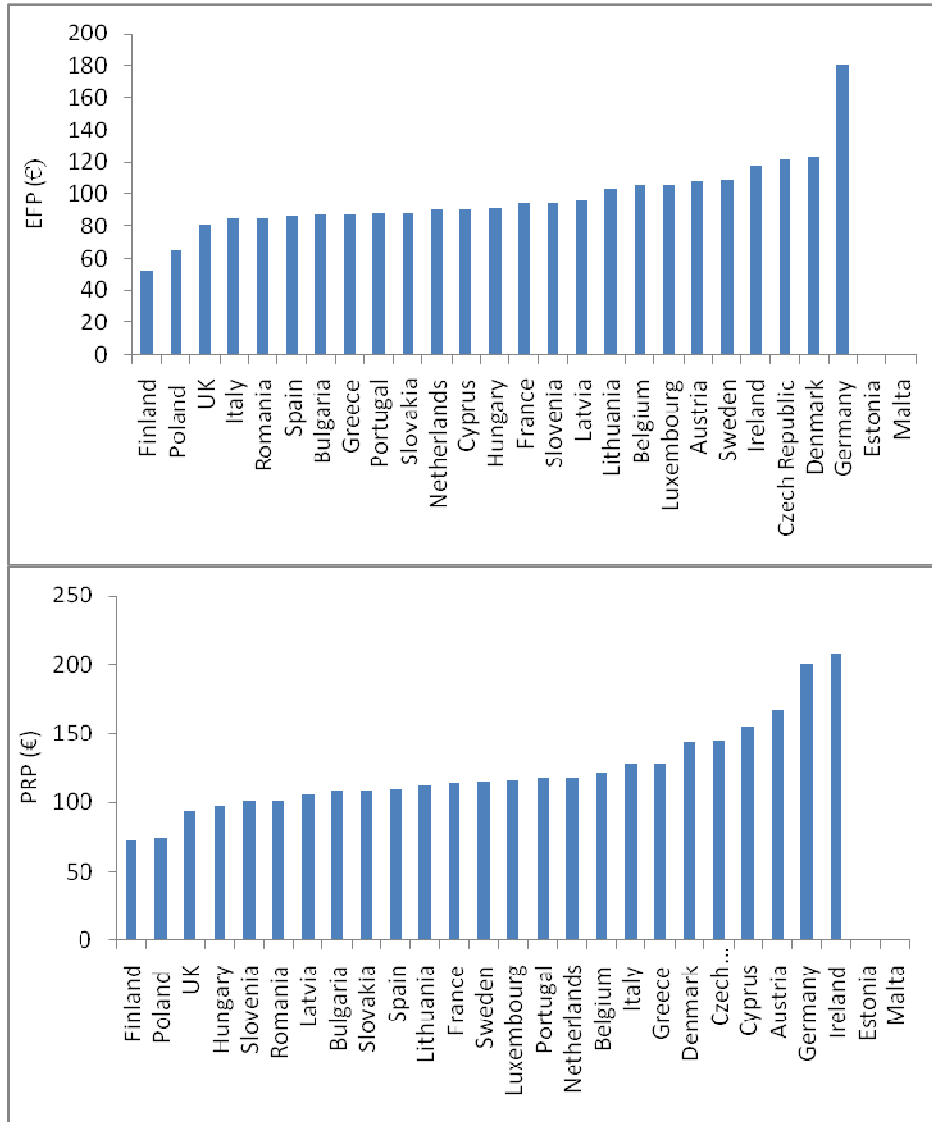


Note: Data for Malta, Lithuania and Poland, not available.

Source: Authors' calculations from pricing data received from Member States.

Figure 7.2

Branded MP-S ex-factory price (EFP) (upper panel) and net pharmacy retail price (PRP) (lower panel) (including dispensing fees but no VAT) ranking across the EU27 Member States, as of 15 June 2009.

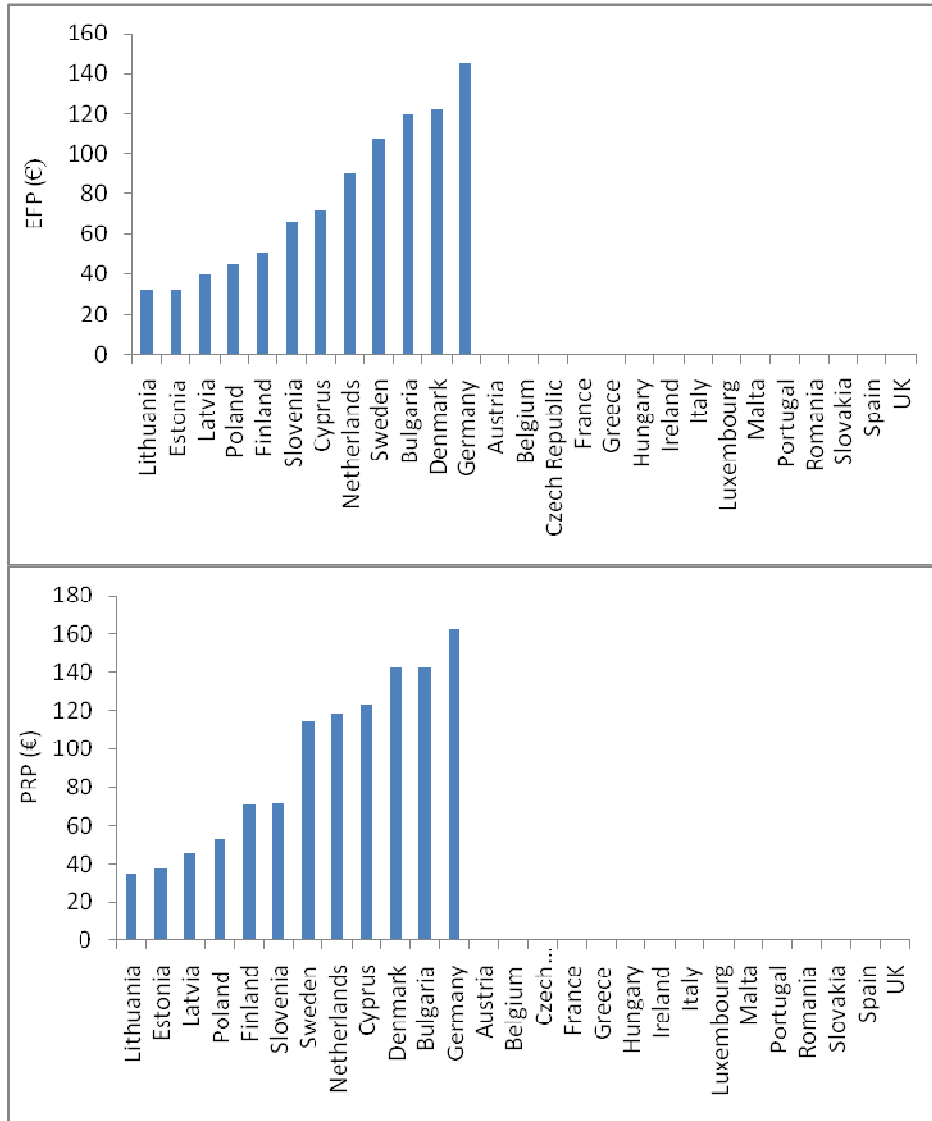


Note: Data for Malta and Estonia not available.

Source: Authors' calculations from pricing data received from Member States.

Figure 7.3

Generic MP-S ex-factory price (EFP) (upper panel) and net pharmacy retail price (PRP) (lower panel) (including dispensing fees but no VAT) ranking across the EU27 Member States, as of 15 June 2009

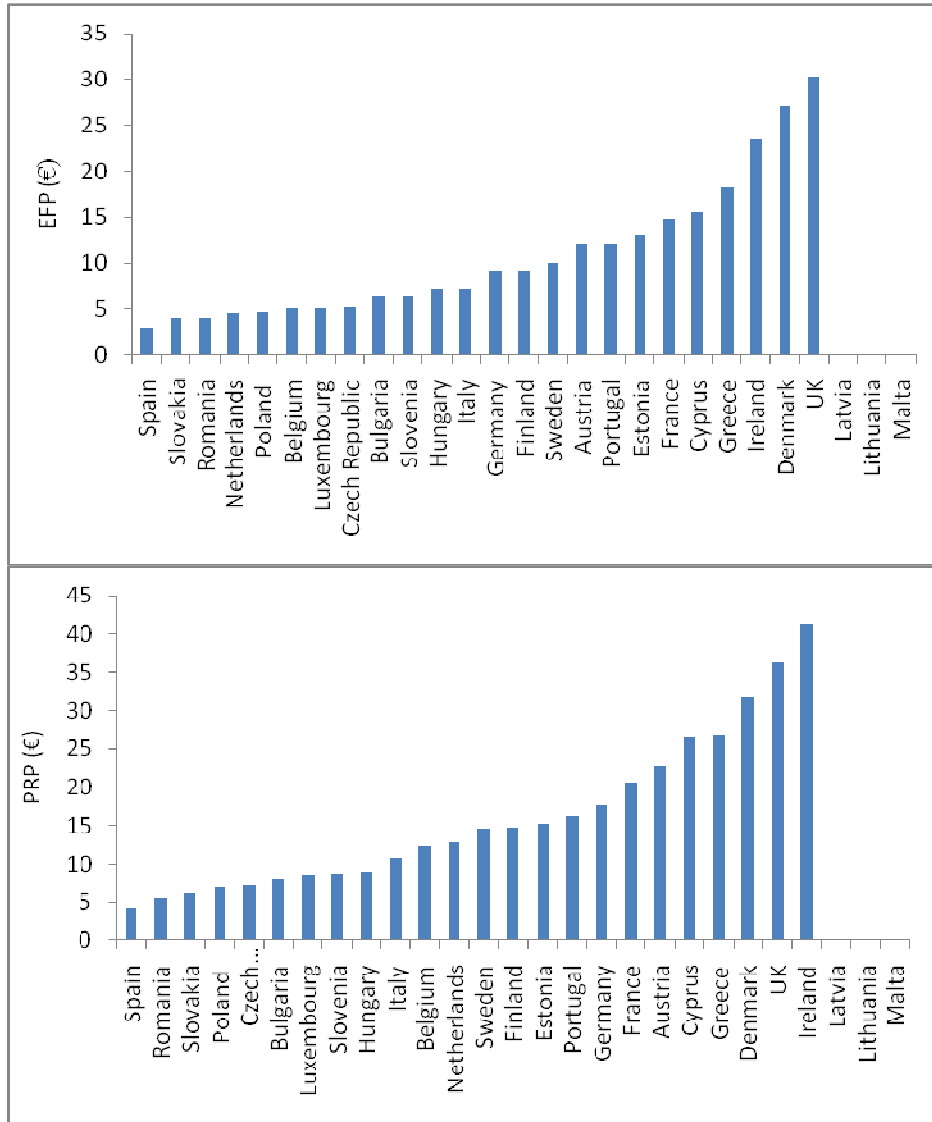


Note: Data for several Member States not available.

Source: Authors' calculations from pricing data received from Member States.

Figure 7.4

Branded LP-HC ex-factory price (EFP) (upper panel) and net pharmacy retail price (PRP) (lower panel) (including dispensing fees but no VAT) ranking across the EU27 Member States, as of 15 June 2009

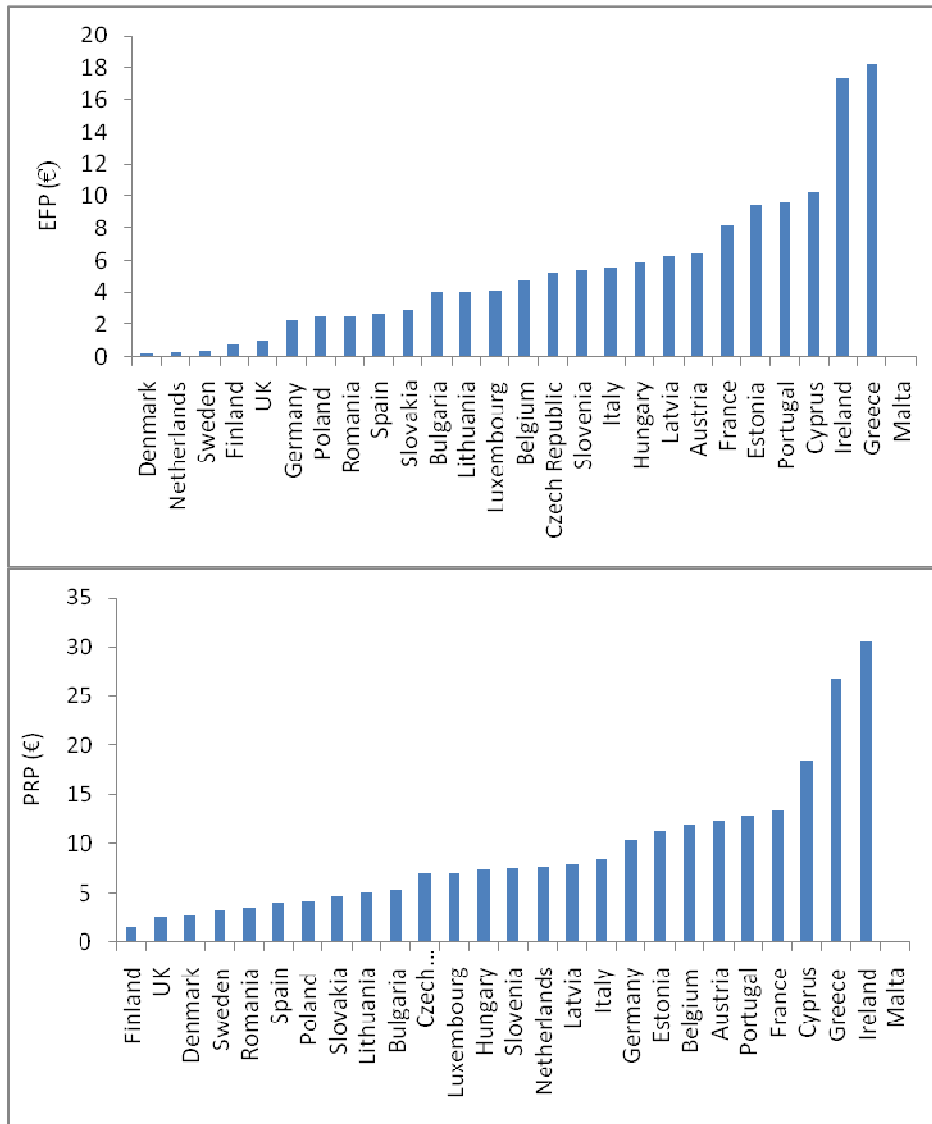


Note: Data for Malta, Lithuania and Latvia not available.

Source: Authors' calculations from pricing data received from Member States.

Figure 7.5

Generic LP-HC ex-factory price (EFP) (upper panel) and net pharmacy retail price (PRP) (lower panel) (including dispensing fees but no VAT) ranking across the EU27 Member States, as of 15 June 2009



Note: Data for Malta not available.

Source: Authors' calculations from pricing data received from Member States.

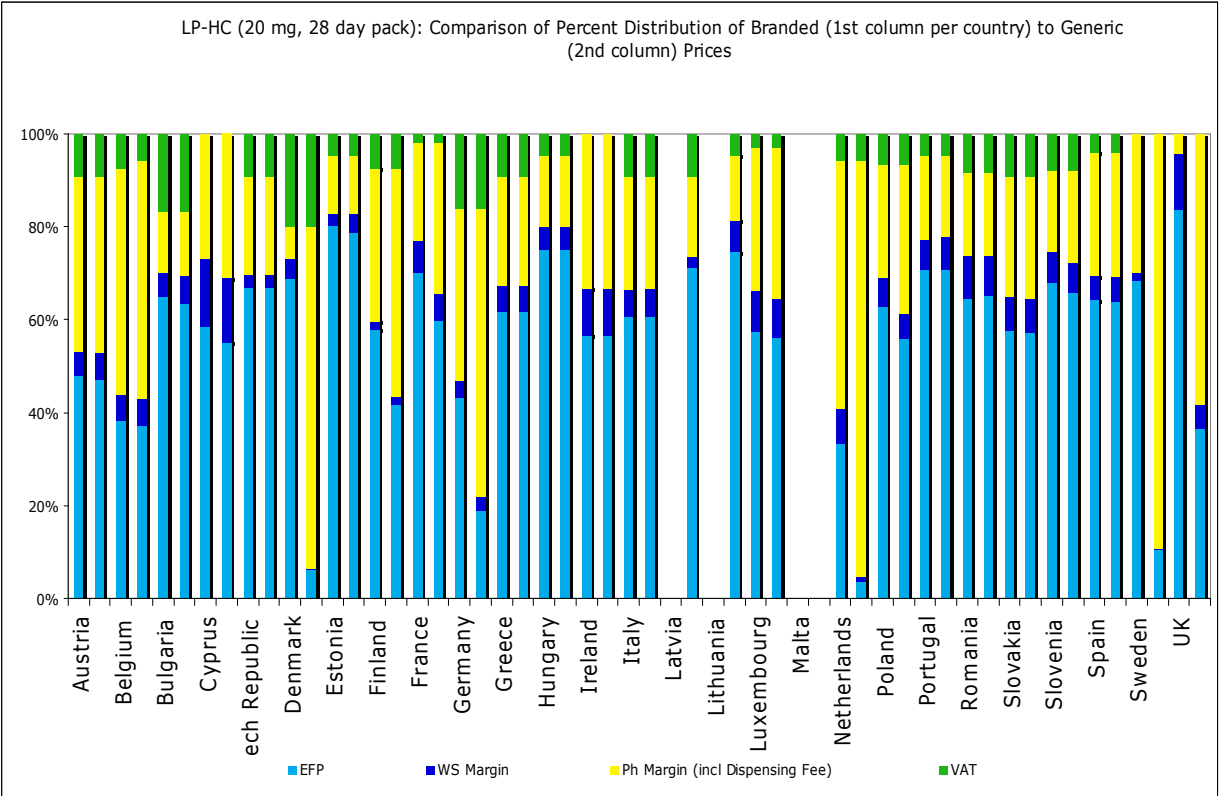
7.5. Distribution margins: brands versus generics

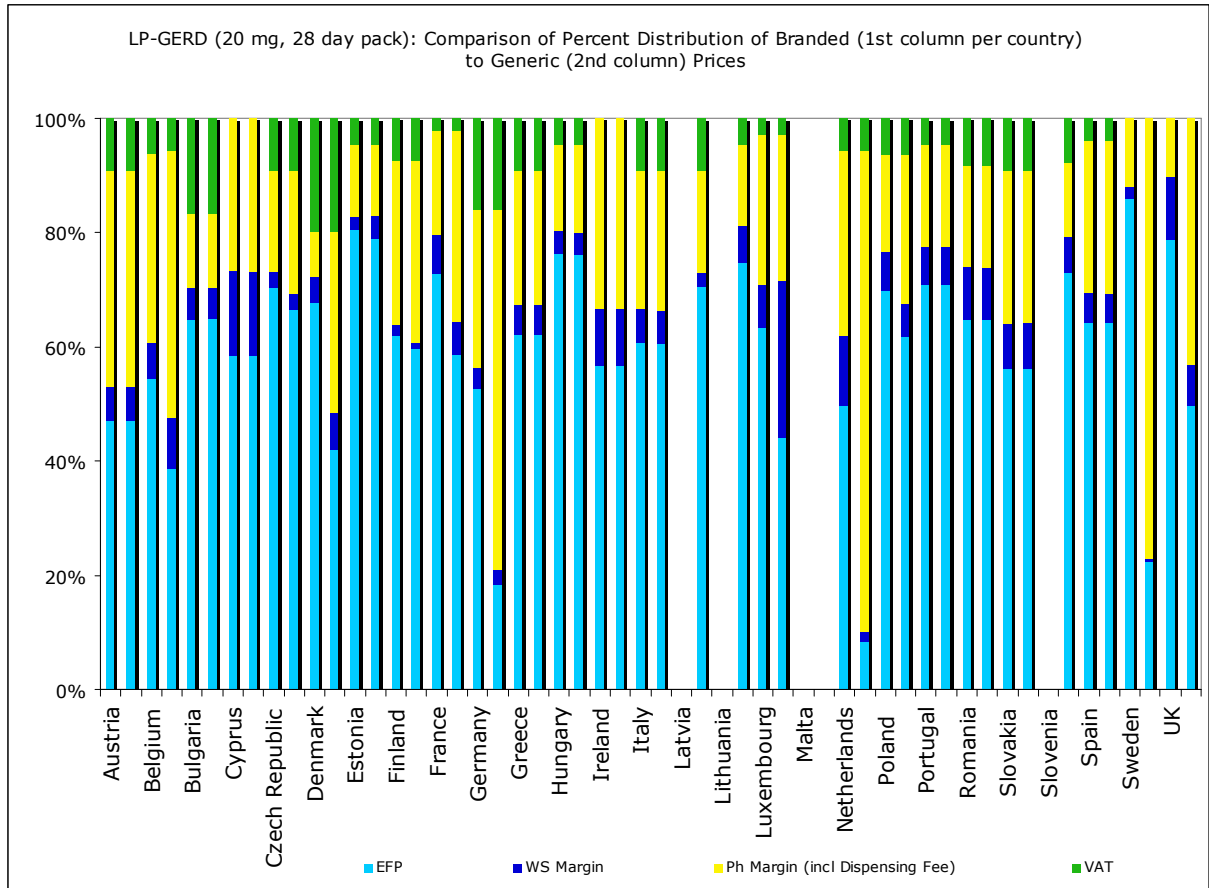
Comparisons of branded medicines with their generic versions were made to determine the impact of wholesale and pharmacy margins on final prices in EU27 and to identify similarities or differences across Member States. First, the extent of price gaps between highest and lowest countries for EFP, PPP and PRP were identified for generic and branded

medicines. Second, the relative impact of wholesale and pharmacy margins on PRP was compared for branded and generic medicines, across Member States.

Two widely used products, where this occurs are LP-GERD and LP-HC and the distribution costs as a proportion of retail price are outlined in Figure 7.6. Distribution costs for generics are highest in Denmark, Germany, The Netherlands and Sweden.

Figure 7.6: LP-HC and LP-GERD as percent of gross PRP, branded (1st column per country) and generic (2nd column per country) versions presented side-by-side, as of 15 June 2009





Note: Data for some Member States not available.

Source: Authors' calculations from pricing data received from the Member States.

8. Overall Conclusions

8.1. Summary of Key Findings

- There are variations between Member States in the degree and content of regulations of distribution margins as well as the overall operating framework concerning wholesaling and retailing.
- There are large variations between Member States in the degree of vertical and horizontal integration.
- “New” distribution models seem to be emerging in many Member States, although their uptake is subject to market conditions or may be constrained by the regulatory arrangements regarding wholesaling and retail operations; Direct to Pharmacy (DTP) is one of these and DTP arrangements can be found in many Member States; although its application is restricted to the UK currently; Reduced Wholesaler Arrangements (RWA) or sole wholesaler arrangements, however, are beginning to have considerable impact on overall distribution. In some cases, wholesalers are used as agents to distribute products as logistics providers.
- Numerous developments in the type, breadth and depth of additional services offered by both wholesalers and pharmacies, also highlighting pressures in the existing distribution model.
- Variations exist *between* Member States in the type and application of wholesale and pharmacy margins
- Distribution obviously has an impact on the prices that payers pay, but this varies by Member State (as a result of different policies being implemented) and by the general (EFP) price level
- Taxation of prescription medicines, by means of variable VAT rates, continues to be an issue in most Member States and in a few the normal VAT rate applies.

8.2. Findings by category

8.2.1. Market structure of pharmaceutical wholesaling and retailing in the EU

There is a diversity and fragmentation of wholesaling and retailing entities at EU level, as reflected by the market structure of both wholesaling, but, more importantly, retailing entities. Significant variation continues to exist in the density of wholesale and retail outlets in the EU, propagated by national regulation and historical patterns.

There exist different densities in terms of number of wholesalers and number of pharmacies in the population in the member states, as well as different regulatory policies setting the operating framework for distribution (both wholesale and retail) outlets.

Some consolidation in activities has been observed over time, particularly in pharmacies, as experienced by horizontal integration through pharmacy chains.

Vertical integration has been on the ascendancy particularly with wholesaler groups taking over pharmacies or pharmacy chains, although the opposite is also possible.

The frequency and influence of schemes such as DTP and RWM has risen substantially in the past 5 years; this trend can alter the rules of the game, particularly where the public service obligation is not present. Through a variety of schemes manufacturers are in a position to bypass wholesalers and sell directly to pharmacies.

Elements of diversification (expansion of services) by both wholesalers and pharmacies, particularly where there is a squeeze on margins have been shown to exist as a response to some of the pressures on margins and the emergence of new distribution models.

8.2.2. Distribution Margins

The majority of Member States have regulated markup/margin schemes to both wholesale and retail segments, at least for reimbursable medicines.

There are different markup/margin schemes for reimbursable and non-reimbursable medicines in a few countries, specific schemes for other retailers of prescription medicines in the very few countries where such other retailers operate and a specific incentive for dispensing generics in one country (France).

Regressive markup/margins are very common, but some countries also apply linear markups/margins. For pharmacies, dispensing fees are used in a few countries, and in one country (Slovenia) pharmacies are funded on a fee-for-service remuneration. Average wholesale margins range from 2-24% of PRP (low in Sweden, high in the Netherlands, both unregulated private negotiations), with the majority ranging between 4-8% of PRP.

Considerably less information is available regarding the average pharmacy margin in a country; however, for the 15 countries for which average pharmacy margins could be surveyed, the range is 12-50% of PRP (low in Romania, high in Luxembourg).

Discounts and rebates play an important role defining the precise amount of the wholesale and pharmacy remuneration. On the one hand, in several countries commercial discounts (offered by manufacturers to wholesalers, by wholesalers to pharmacies, by manufacturers to pharmacies, and in some cases by pharmacies to patients) are granted, in a few cases limited by regulation. The exact level of these discounts and rebates is confidential. On the

other hand, wholesalers and, in particular, pharmacies are obliged to grant discounts and rebates to the public payers in nine countries (known as “clawback” or “solidarity contribution”).

8.2.3. Impact of Wholesale and Retail Margins on the Prices of Prescription Medicines

It looks as though that there is a tremendous range in prices at each stage of the exercise from EFP to gross PRP between EU27 Member States. This price spread between lowest and highest is significantly more apparent in generic medicines than it is in branded, and far more apparent in less expensive medicines than more expensive medicines.

Although EFP appears to some extent to predict approximately the final gross PRP to the payer, this is not always the case. Countries such as Greece, Italy and Luxembourg for branded medicines, and the Netherlands for generic medicines saw dramatic changes in their ranking with the addition of wholesale and pharmacy margins. This highlights the fact that the impact of distribution is different in different Member States.

It appears that the application of distribution margins may be different between branded and generic medicines, in some countries in particular. Countries with consistently low EFP, in some cases less than 5 percent of the final gross PRP, were Belgium, Denmark, Germany, Netherlands, Sweden – of interest these countries also had low relative EFP for their branded counterparts.

The structure of wholesale and retail margins does mean that in certain, but *extreme*, cases the impact of distribution costs and taxation exceeds 90% of the total cost to health systems and the average seems to be higher than in the case of branded medicines.

8.2.4. The changing market structure - impact on stakeholders

Manufacturers

Manufacturers would in principle be interested in a supply chain that guarantees the efficient distribution of their products for the intended markets and at reasonable cost. Access to patient information at the micro level (i.e. in individual communities) would be key and an area worth investing in. In an era of logistics and stock management being driven remotely by advances in information and communication technology (ICT), the value-added of certain components of the distribution chain have often been questioned in relation to the services provided and the overall cost of these services.¹⁰ As a result, it is not surprising that manufacturers explore alternative (wholesale) distribution arrangements.

¹⁰ Interviews with 4 leading manufacturers.

Wholesalers

Wholesalers feel squeezed by current practices as well as some recent developments. Current practices in wholesaling suggest that wholesalers typically offer a proportion (in some cases significant) of their allowable margin as a discount to pharmacy. Interviews with wholesaler stakeholders alluded to actual margins ranging between 1.5 – 3.5%. Pharmacy chains may have greater negotiating power and can, as a result, benefit from a higher discount from wholesaling, although the extent to which this is true at aggregate level is unclear and can be the subject of further scrutiny.

Competition among wholesalers for the retail business has intensified in recent years by developments in IT and logistics, as well as the entry of manufacturers who are increasingly interested in establishing direct vertical links with the retail business. In some cases, this is resulting in the map of players on the market being re-drawn with consolidation of existing entities and entry of others or a re-definition of activities by existing players.

These dynamic developments can have a significant impact on wholesaling and the competitive advantages it has in the distribution of medicines. Interviews with wholesalers and other stakeholders indicate that the traditional full-line wholesaling model (stocking the widest possible gamut of pharmaceutical products, easy access to stock by and timely & frequent delivery to retailers) is under dispute – indirectly - in a number of Member States, particularly those where the environment is more flexible regarding ownership and integration. As a result, if wholesaling is to survive it will probably need to develop further competences and links downstream strengthening existing advantages.

Pharmacy

Retail market structure remains diverse across EU Member States, as does the regulatory environment relating to ownership, procurement and ability to integrate both horizontally and vertically.

Greater efficiencies can be achieved by joint procurement and this can materialize through a horizontally or a vertically integrated structure or a cooperative. Countries where horizontal or vertical integration are limited by current legislation are taking advantage of the “cooperative solution”, e.g. Spain, France and Greece.

Redefining the role of pharmacy is a great pursuit, particularly in what concerns health promotion, prevention, aspects of disease management and monitoring. There may be considerable benefits to society and the health care system from this development in terms of quality, access and cost. Pharmacy chains are likely to benefit more from this development in terms of volume, facilities within pharmacy and network or population coverage. Yet, the willingness of health authorities to pursue this remains sluggish.

An important competitive advantage of pharmacy, making it an attractive target to pursue further consolidation in the field is its direct relationship with the patient population and

the use by the latter as a source of information and advice. This is already driving developments in some Member States and further developments are still to come.

Where access to pharmacy problems exist, particularly in rural or/and remote areas, alternative solutions may exist, e.g. via dispensaries or dispensing physicians.

Patients

Patients are in principle neutral to consolidation in the distribution sector, so long as access and availability of medicines are not compromised and the range of available services increases at no additional cost to them. Increasing services at pharmacy level could prove beneficial particularly if they are offered in a timely fashion and avoiding waiting times. In some instances, patients have raised questions about access to services and the length of time it takes for them to access a pharmacy. This is particularly important for elderly and vulnerable patients in rural areas. Where these phenomena exist action could be taken by the competent authorities to ensure that access remains at acceptable levels. Where pharmacies occupy a significant proportion of retail distribution access problems in rural areas could be addressed by operating outlets or other dispensaries in such areas.

Insurance and Payers

From a payer perspective, greater consolidation could mean lower distribution costs because of economies of scale in procurement and distribution, taking advantage of common networks and more efficient operations. In theory, consolidation would imply lower fixed costs, but it is questionable whether compressing these can be achieved *ad infinitum*. It may even be doubtful whether cost reductions can be achieved in the first place given the changing patterns in the distribution of medicines and the increasing proliferation of agency and reduced wholesaler models.

But even if these models are not taken into account for a moment, it is likely that the environment in the distribution chain is becoming more competitive with payers demanding greater generic dispensing (and, therefore, at a lower overall margin) and driving the market for generic products, as it has recently been seen with outpatient tendering in some countries (the Netherlands, Germany, and Hungary, among others). Such developments are unlikely to enable further sustainable reductions in margins without having an impact on market structure of distribution.

Additional services that can be provided by retail pharmacies could go some way to maintain existing structures, yet, it is not always clear what additional value these services create and what an adequate remuneration is as a result. For instance, health promotion campaigns, monitoring, audit, or clinical governance could be undertaken by pharmacies, yet, a number of stakeholders at national and regional level have suggested that they cannot support financially these services.

In an environment characterized by consolidation, payers need to be mindful that access to pharmacies is maintained overall, particularly in rural areas, which are, in principle, under-provided. In areas where there seems to be a problem, rural pharmacies can be offered financial incentives to continue operating for the benefit of the wider community they serve.

8.2.5. Changes to the prevailing distribution model

Access and availability

The changing nature of distribution and the advent of the agency and the reduced wholesaler models, is beginning to have a significant impact in some countries. In principle, changes in the distribution model should make the process of delivering medicines from factory gates to the patient bed-side more efficient and cost-effective. Yet, there seem to be some concerns about the availability of medicines; it could be the case that manufacturers' activities in streamlining supplies and managing stock coupled with the ever fragmented nature of distribution, can lead to shortages in some markets.

Clearly, there are all kinds of incentives and disincentives from different stakeholders' perspective (manufacturers, wholesalers, retailers) in this process, but these do not seem to be aligned at all times. Payers, on the other hand, find little reason to intervene unless patient access to medicines is significantly affected or shortages are shown to be having an impact on care and outcomes. At the same time, it looks as though breaches from the public service obligation do not necessarily occur in situations where a reduced wholesaler model operates. This may be the subject of a wider further discussion on the subject. Competent authorities, where appropriate have intervened to provide some clarity on some of the newly emerging rules of the game.

8.2.6. Policies on distribution margins and their implications

The stakeholder perspectives in this part of the analysis revealed significant rifts in the perceptions of stakeholders about their respective contributions.

Manufacturers

Manufacturers recognize the importance and contribution of the distribution sector to ensuring access and availability of medicines to patients. Yet, it is often argued that the cost of distribution is in many cases disproportionate to the value it offers to the general public and, as such, should be reconsidered and become more in-line with the contribution that the pharmaceutical sector makes in terms of bringing new therapeutic alternatives to market. Equally, it has been argued that where brands and generics co-exist, the structure of margins and markups in many cases favour lower priced medicines, in fact generics in most cases, thus creating an unequal playing field among equivalent therapeutic options.

This is exacerbated in situations where therapeutic reference pricing exists and where branded, in-patent products are included in therapeutic clusters.

Partly as a result of the above, it is not uncommon for manufacturers to consider more direct options to distribute their products and reach pharmacies. Although this implies considerable initial investment, it is often considered worthwhile. Other stakeholders in the distribution chain contend that these movements by manufacturers automatically result in wholesale (and, potentially, retail) margins and other income being curtailed as manufacturers can re-define the terms of wholesaler engagement.

Wholesalers

Wholesalers operate on the basis of large volume and small margin. They feel squeezed by the nature of competition and the requirements of public service obligation and frequent distribution to retail outlets, the net result being a very low net margin on wholesale distribution of medicines. They also perceive recent changes in the distribution model in a number of Member States, particularly relating to higher cost medicines, as partial and creaming off a significant source of revenue for their operations. Where already experienced, the direct involvement of manufacturers in distribution has changed the way the sector operates and the ability of wholesalers to compete and offer value deals to their customers.

It is likely that if these trends become more generalised in the years to come, the wholesale sector will experience further consolidation. Already, as pointed out at interview, a number of wholesalers have gone out of business or have merged with others, as a direct impact of the above trends.

Pharmacies

Pharmacists often feel they are asked to do more for less, that there is reluctance by payers to remunerate them for additional services rendered and that, as a result, other segments within pharmacy is cross-subsidising the reimbursement segment. Importantly, the changing role of pharmacy in the community does not necessarily seem to be reflected by actions at policy level. In addition, their ability to negotiate terms with wholesalers is beginning to change in environments where products are delivered directly by manufacturers and where pharmacy is incurring a significantly higher cost in search of product.

Patients

Patients are largely unaware of the costs of distribution and their primary consideration is the availability and affordability of medicines. Distribution remuneration, particularly at retail level, should capture some of the gaps in availability, particularly in remote or rural areas where such problems seem to be more acute. Patients in some cases argue that the pursuit of profit across pharmacy chains is responsible for problems in the geographical allocation of pharmacies and that this ought to be addressed.

Insurers and payers

Insurers face a significant cost of distribution and taxation. Significant changes have taken place over the past decade in the majority of Member States in an attempt to reduce the impact of distribution (but not taxation) and calibrate remuneration structures, often resulting in a reduction of wholesale and retail margins.

In some cases, health insurers have experimented with “novel” initiatives for the retail market, such as tendering and rebate policies. Apart from the unintended consequences that such schemes may have, these initiatives have revealed, among other things, the reservation price of mature (off-patent) medicines and the cost payers should be paying without it being inflated by discounts.

In some Member States the cost of taxation is set at disproportionate levels. While a majority of Member States have set reduced (or zero) VAT rates for prescription medicines, in some (e.g. Denmark and Germany) normal rate VAT levels reflect the perception of prescription medicines as normal consumption goods. While there is little in terms of a theoretical or empirical justification for imposing VAT on prescription medicines, its use reflects a reverse tax by national Treasuries on health care resources. Yet, it appears that there is little Ministries of Health or sickness funds can do to mitigate this, as it relates to national (taxation) policy priorities, where decisions are taken by Finance Ministries.

Appendix 1: Data Requests and Open-Ended Interviews with GIRP and PGEU

GIRP

1. How many wholesalers are full line / short line?
2. How many wholesalers are national / regional?
3. What is the frequency of delivery from wholesalers to pharmacies? Regulated frequency?
4. How many wholesalers are involved in parallel imports? What are the regulations surrounding parallel imports?
5. Do any wholesalers also supply to other EU countries? Which countries?
6. Is integration between wholesaler and manufacturer allowed? If yes, how many are involved? What percent of market share do they have? What regulations surround integration between wholesaler and manufacturer?
7. Can manufacturers deliver directly to pharmacies? If yes, how many do? What percent of market share do they have? What regulations surround manufacturer direct delivery?
8. Can wholesalers integrate with pharmacies? If yes, how many do? What percent of market share do they have? Do any produce their own brands of medicines? What regulations surround integration between wholesaler and pharmacy? Are any integrated wholesalers-pharmacies part of a chain?
9. What is the average wholesale margins for reimbursed medicines?
10. Are there any mandatory rebates/clawbacks/discounts for wholesale margins? If yes, describe?
11. What is the future of wholesaling in the EU?
12. What are the issues surrounding wholesaling in EU countries? What is the impact of recent changes in wholesale distribution?

PGEU

1. How many pharmacies dispensing medicines to outpatients? What locations do they operate from?
2. What fees are involved in repeat prescriptions?
3. Are pharmacists involved in provision of health services, such as blood pressure monitoring, further diagnostics or counseling? If yes, what regulations surround this practice? Any additional fees?
4. Are pharmacy chains allowed? If yes, what percent market share do they have? What regulations surround chains? Do any chains operate in other countries?
5. Can manufacturers deliver directly to pharmacies? If yes, how many do? What percent of market share do they have? What regulations surround manufacturer direct delivery?
6. Can wholesalers integrate with pharmacies? If yes, how many do? What percent of market share do they have? Do any produce their own brands of medicines? What regulations surround integration between wholesaler and pharmacy? Are any integrated wholesalers-pharmacies part of a chain?

7. What is the status of online pharmacies in the EU? If these exist, where and how many? What percent market share do they have? What regulations surround their existence? Are they part of a 'bricks and mortar' pharmacy?
8. What is the average pharmacy margin for reimbursed medicines?
9. Are there any mandatory rebates/claw backs/discounts for pharmacy margins? If yes, describe?
10. What are the key issues facing pharmacy in the EU?
11. What is the future of pharmacy in the EU and what is the impact of current changes in the distribution model in many EU countries?

Appendix 2: Wholesale and Retail Margins in EU-27

This Appendix presents the current margin policies in EU-27, validated as of October 2010. Data is supplied separately in Excel.

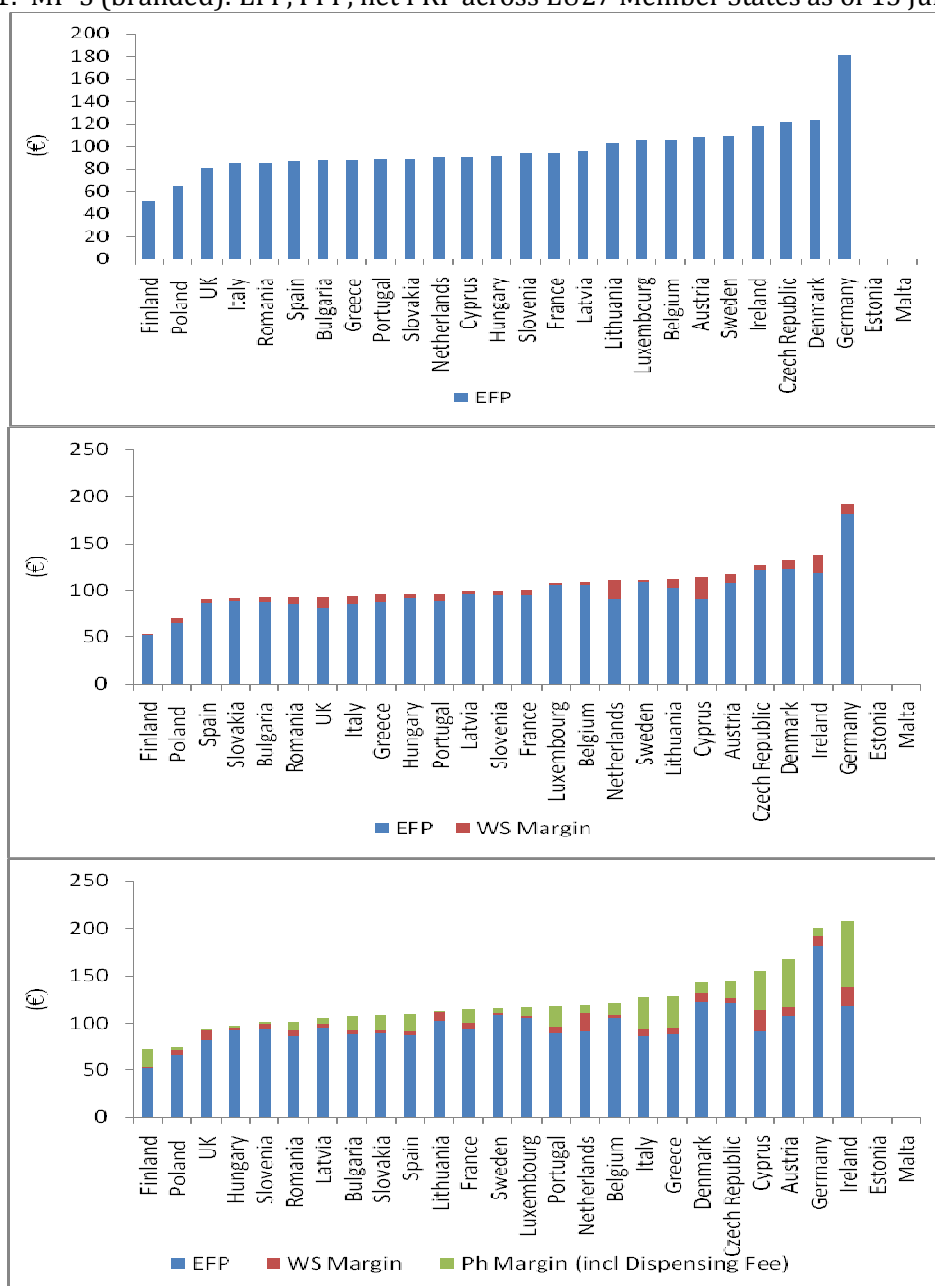
Appendix 3: Pricing Information Incremental Graphing

This Appendix contains a set of graphs that build up incrementally on selected medicines from the ex-factory price (EFP) to pharmacy purchase price (PPP) to net pharmacy retail price (net PRP). At each step the countries are ranked from lowest to highest prices.

The following caveats need to be considered when analyzing the pricing data provided by Member States:

- Selected medicines were not available in all Member States.
- The selected price types could not be delivered by all Member States.
- Not all pack sizes were the same across countries, so the most common pack size was chosen and in some cases data were adjusted upwards or downwards as needed using unit (pill or capsule) price.
- Prices were analyzed on unit basis.
- PRP net are partly those paid by private customers (excluding VAT and other taxes), whereas in other countries those paid by the public payer were given by the Member States.
- In some countries (e.g. the Netherlands) service charges are not included in the displayed prices.
- Claw backs, public rebates or commercial discounts on either distribution levels as well as any non-product based discounts (e.g. price-volume agreements are not considered / deducted).
- Reimbursement status and rates vary among the selected medicines and the Member States.
- So called generic prices given concern the lowest priced product comparable to the originator available at the time of the survey. In some cases (e.g. Figure A3.2) the lowest priced product was a parallel import rather than a generic.
- Biosimilars were also considered as “followers” and are labeled as generic.

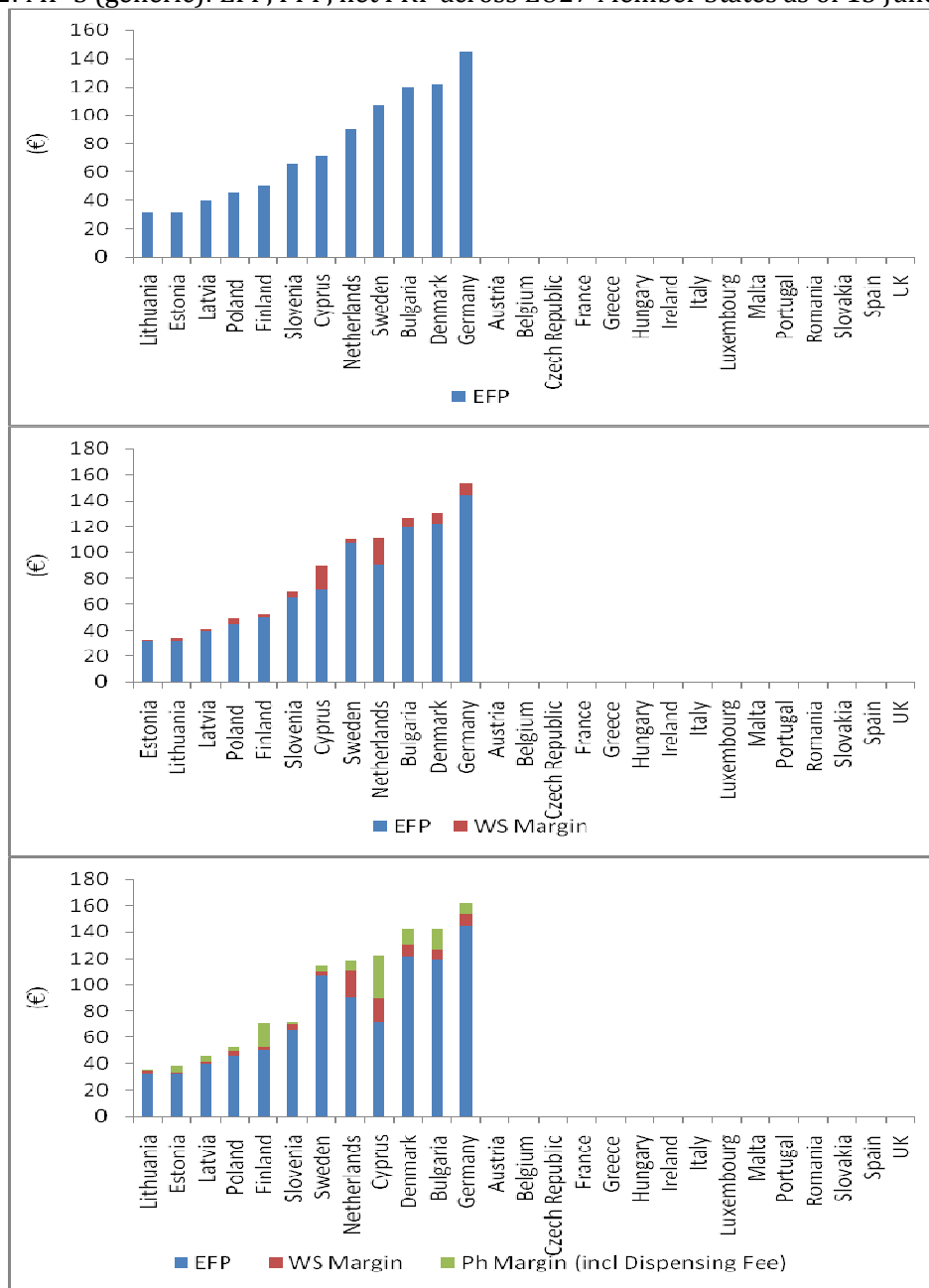
Figure A3.1: MP-S (branded): EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for Malta and Estonia not available.

Source: Pricing data received from the Member States.

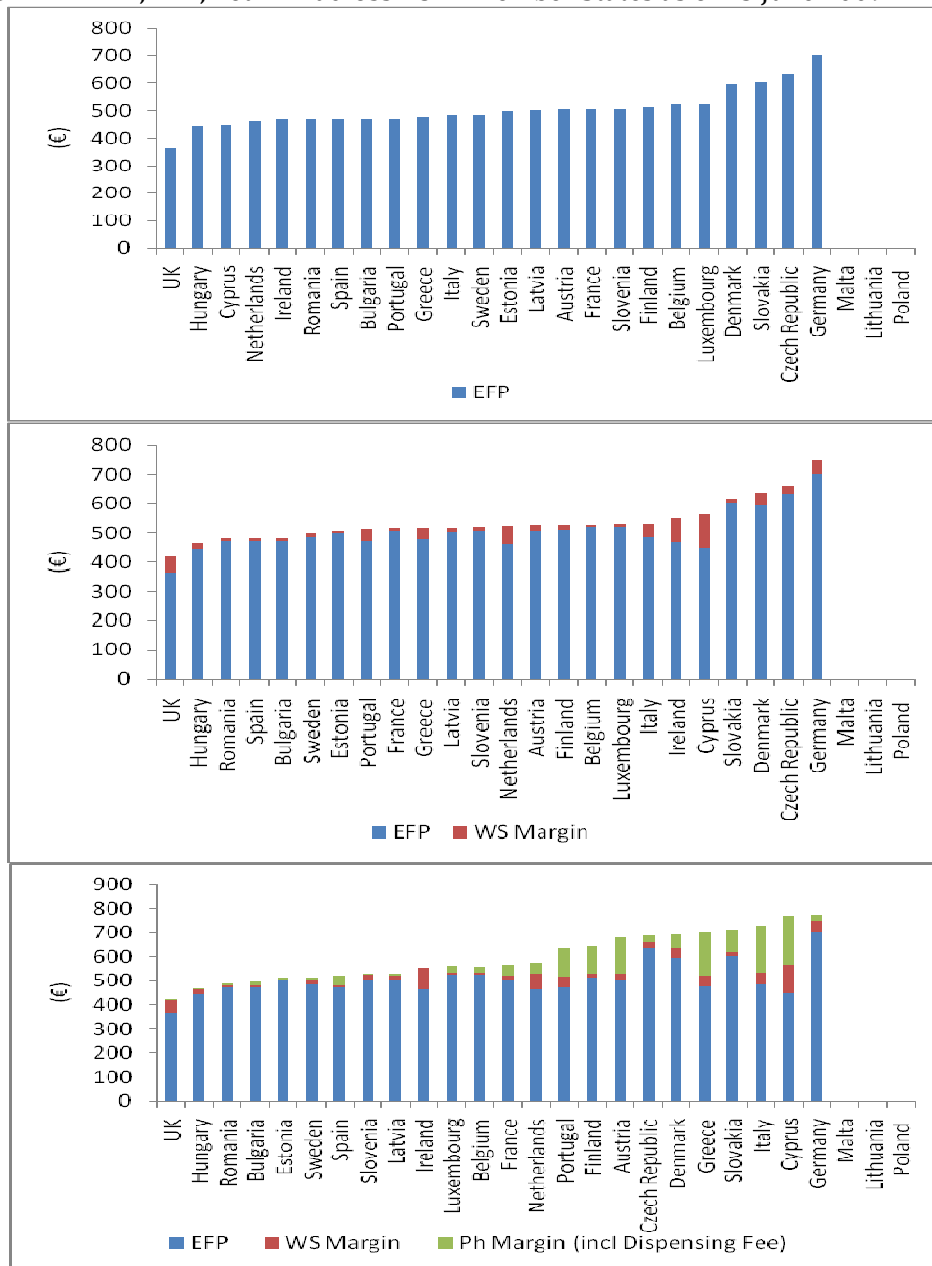
Figure A3.2: MP-S (generic): EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for several Member States not available.

Source: Pricing data received from the Member States.

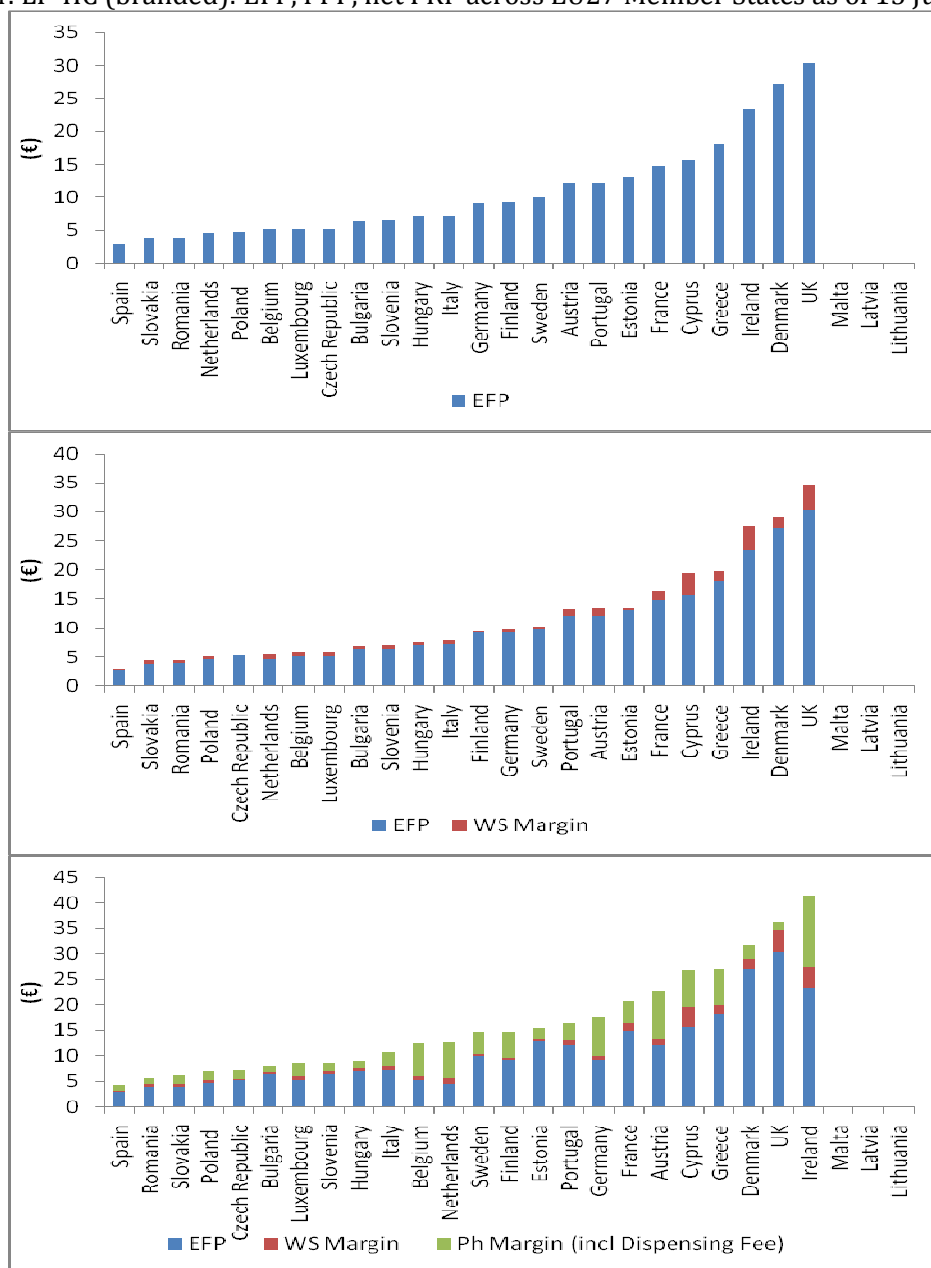
Figure A3.3 HP-A: EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for Malta, Lithuania and Poland not available.

Source: Pricing data received from the Member States.

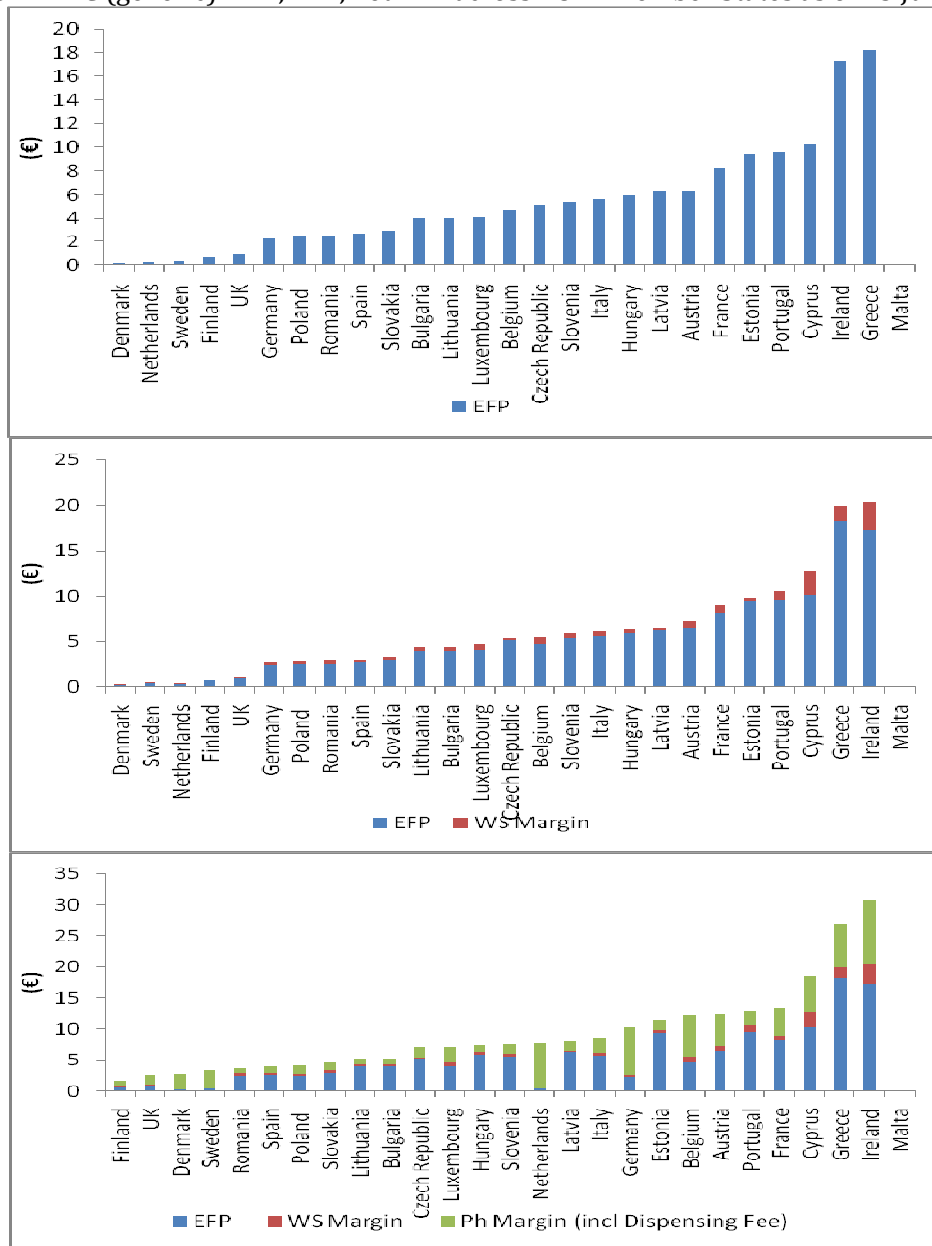
Figure A3.4: LP-HC (branded): EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for Malta, Latvia and Lithuania not available.

Source: Pricing data received from the Member States.

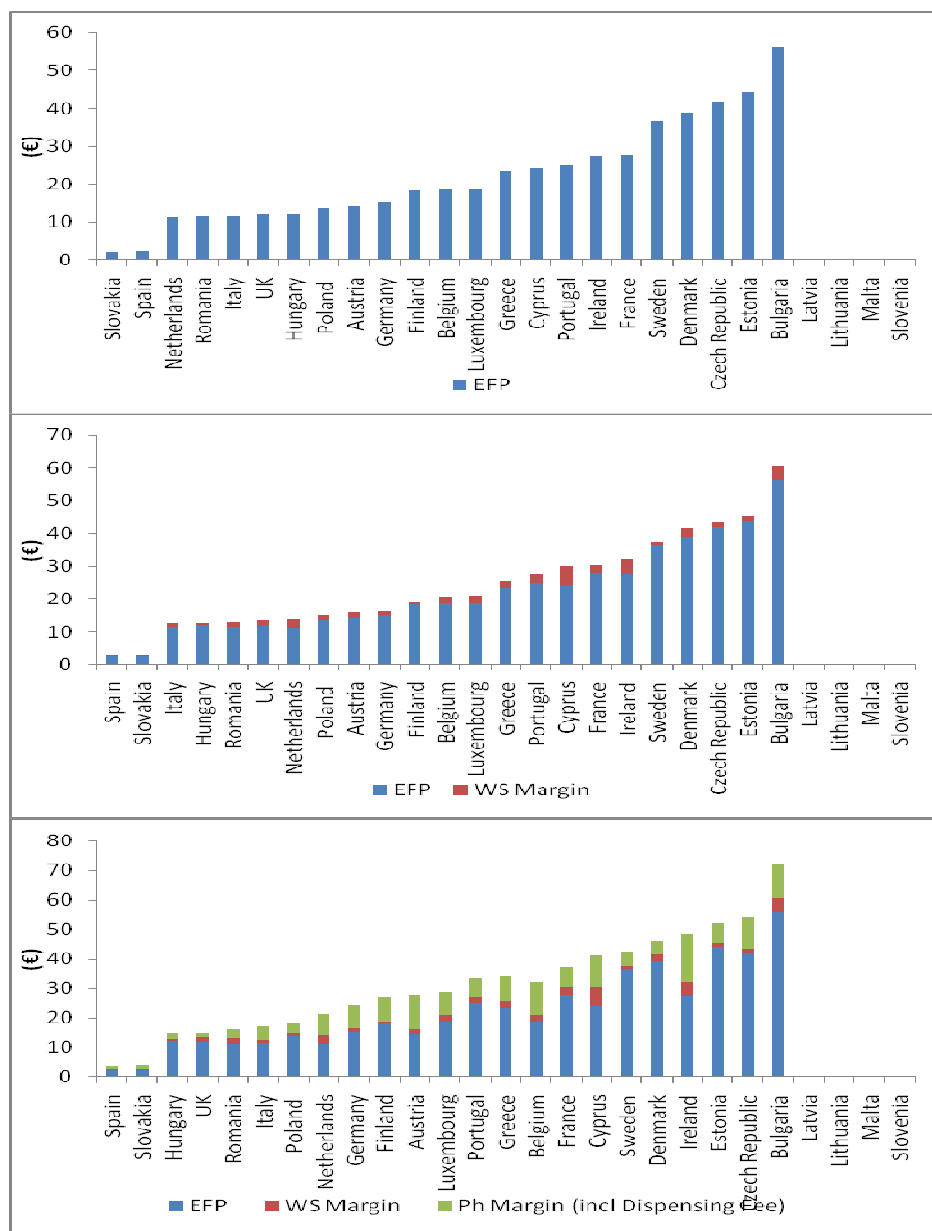
Figure A3.5: LP-HC (generic): EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for Malta not available.

Source: Pricing data received from the Member States.

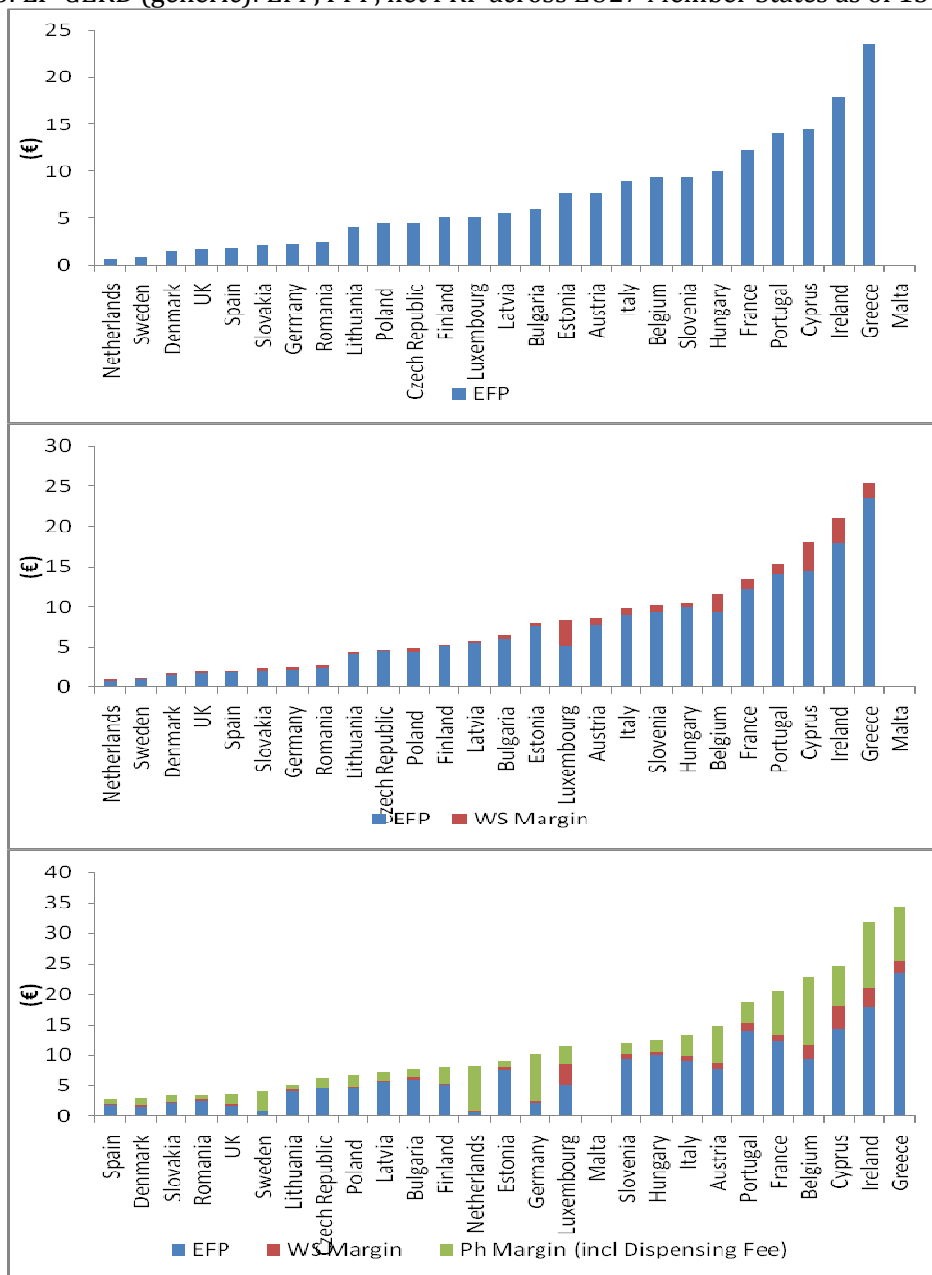
Figure A3.6: LP-GERD (branded): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for Malta, Latvia, Lithuania and Slovenia not available.

Source: Pricing data received from the Member States.

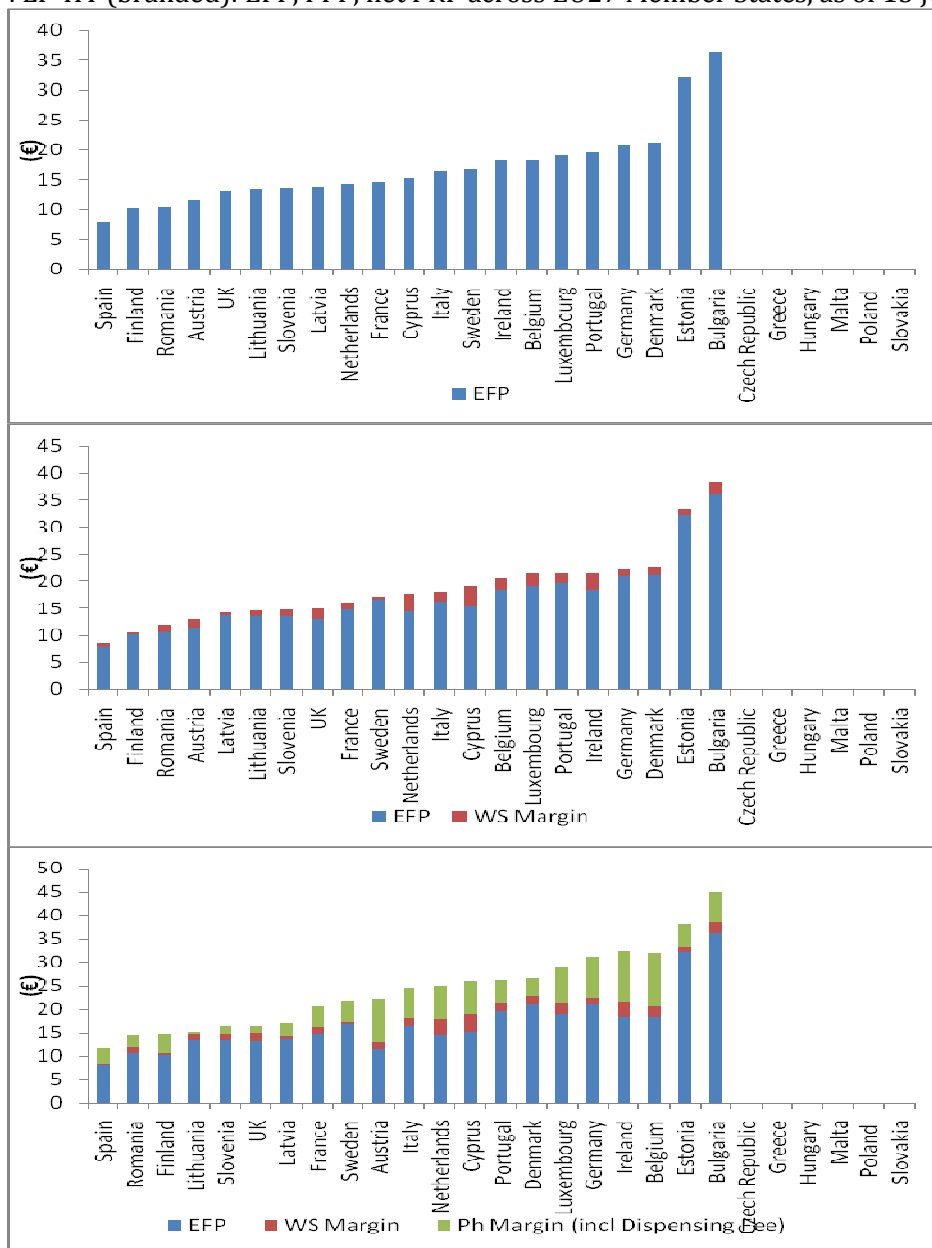
Figure A3.6: LP-GERD (generic): EFP, PPP, net PRP across EU27 Member States as of 15 June 2009.



Note: Data for Malta not available.

Source: Pricing data received from the Member States.

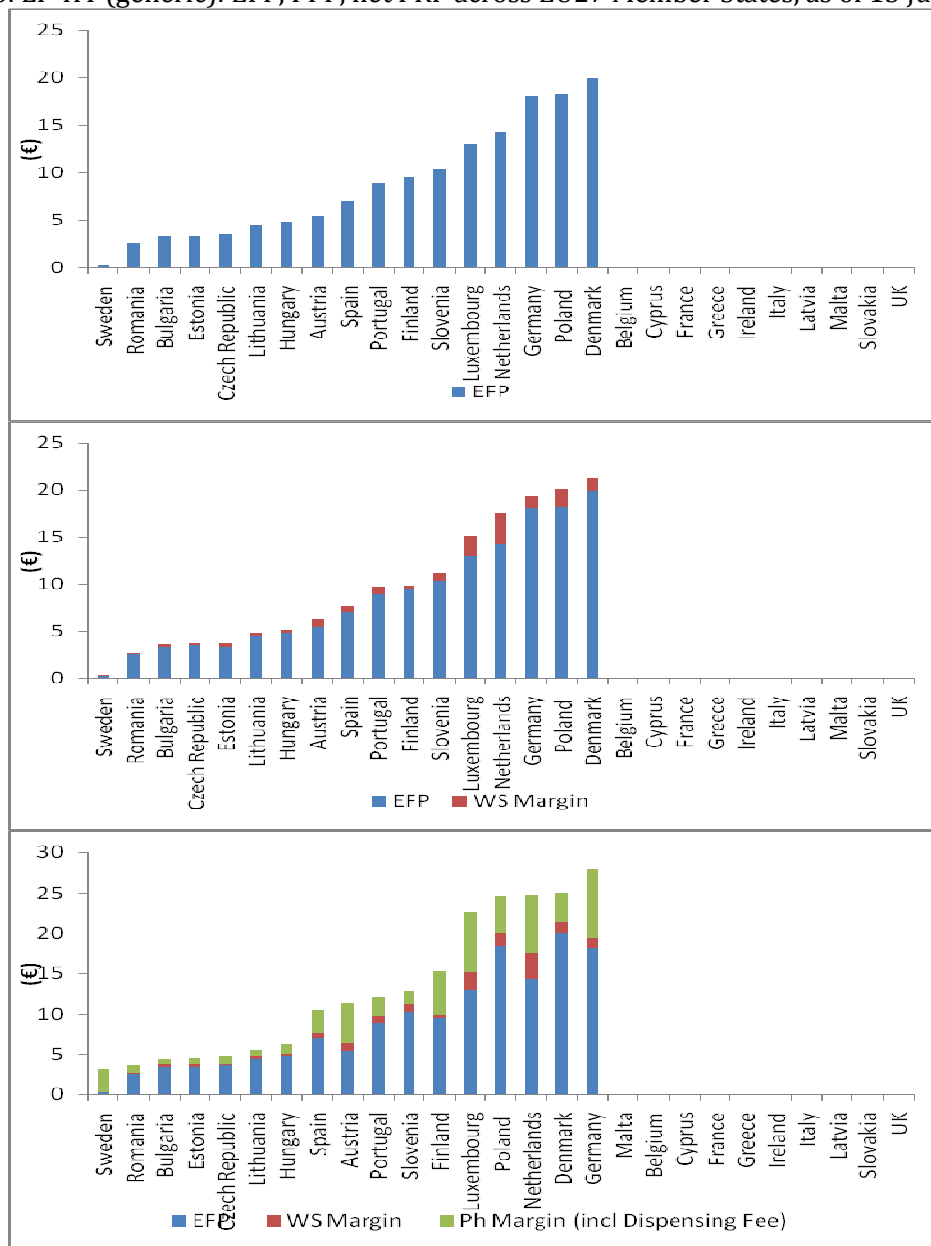
Figure A3.7: LP-HT (branded): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for several Member States not available.

Source: Pricing data received from the Member States.

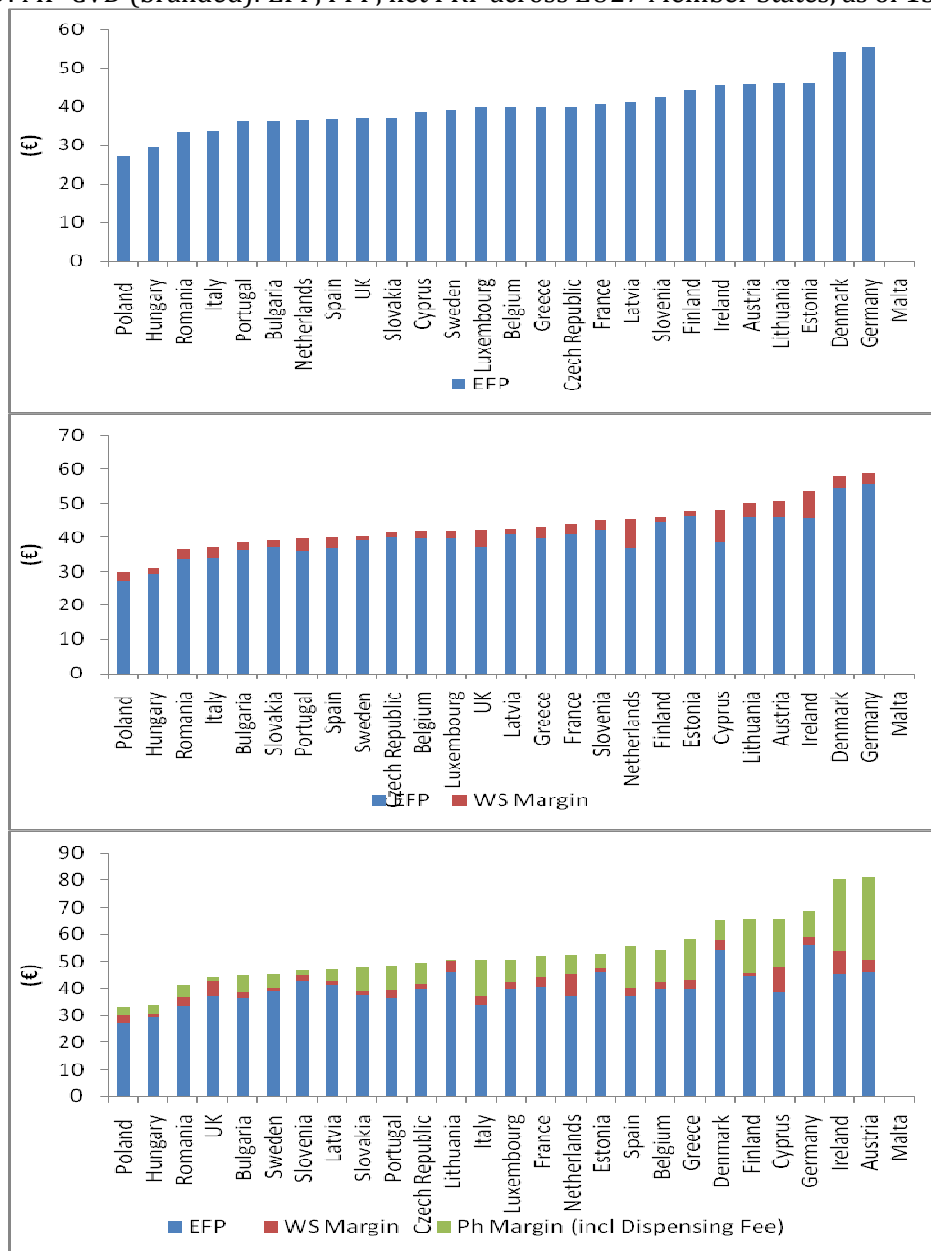
Figure A3.8: LP-HT (generic): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for several Member States not available.

Source: Pricing data received from the Member States.

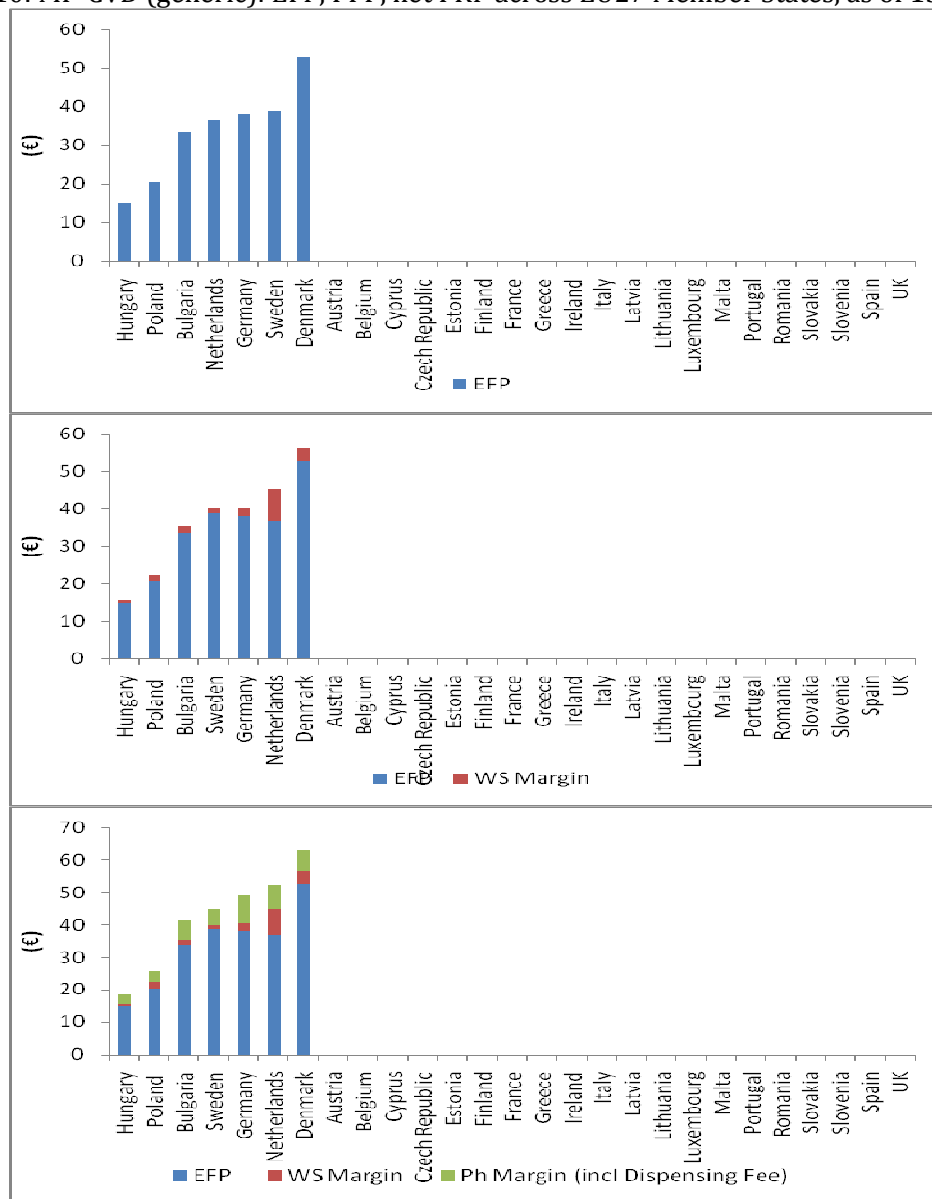
Figure A3.9: MP-CVD (branded): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for Malta not available.

Source: Pricing data received from the Member States.

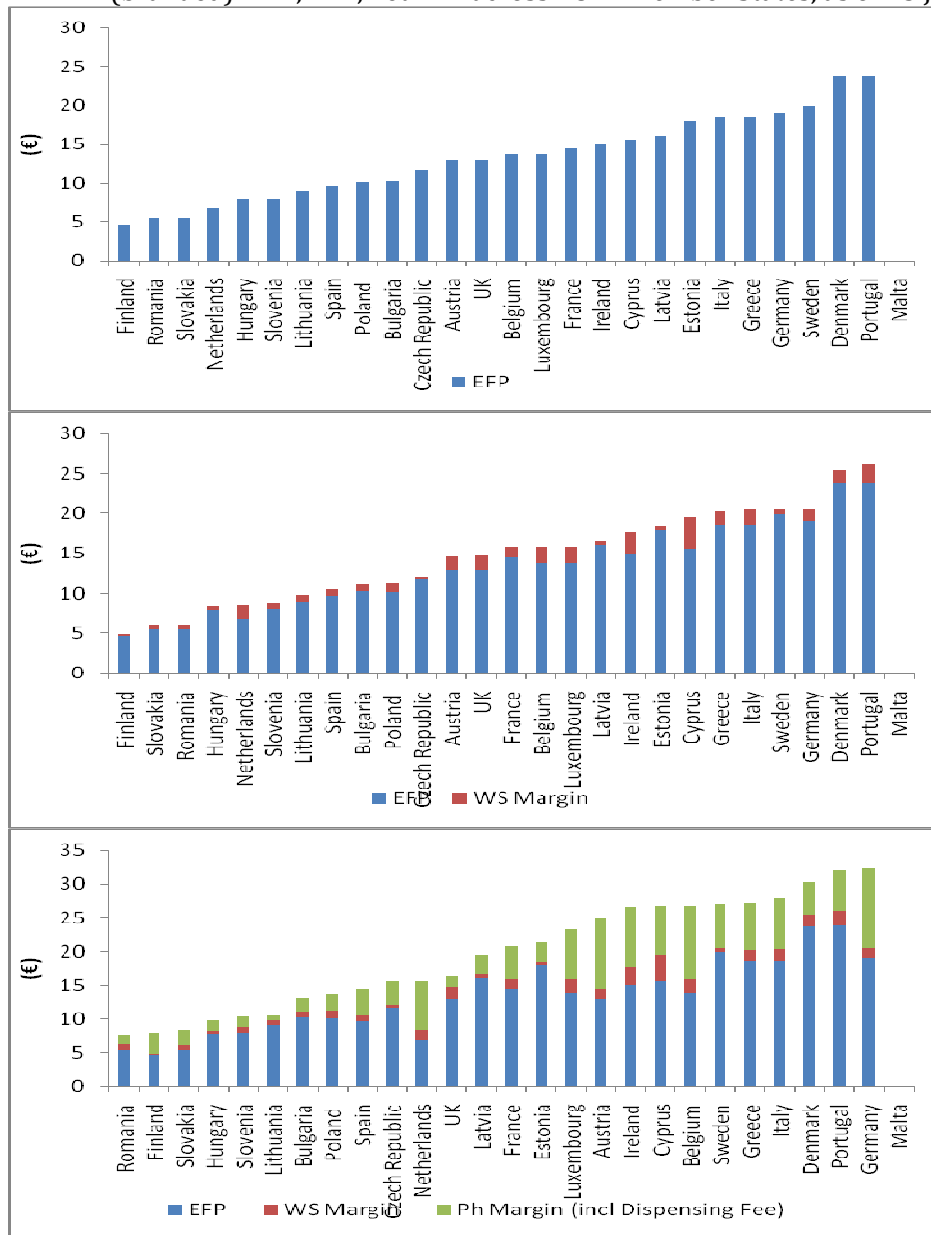
Figure A3.10: MP-CVD (generic): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for several Member States not available.

Source: Pricing data received from the Member States.

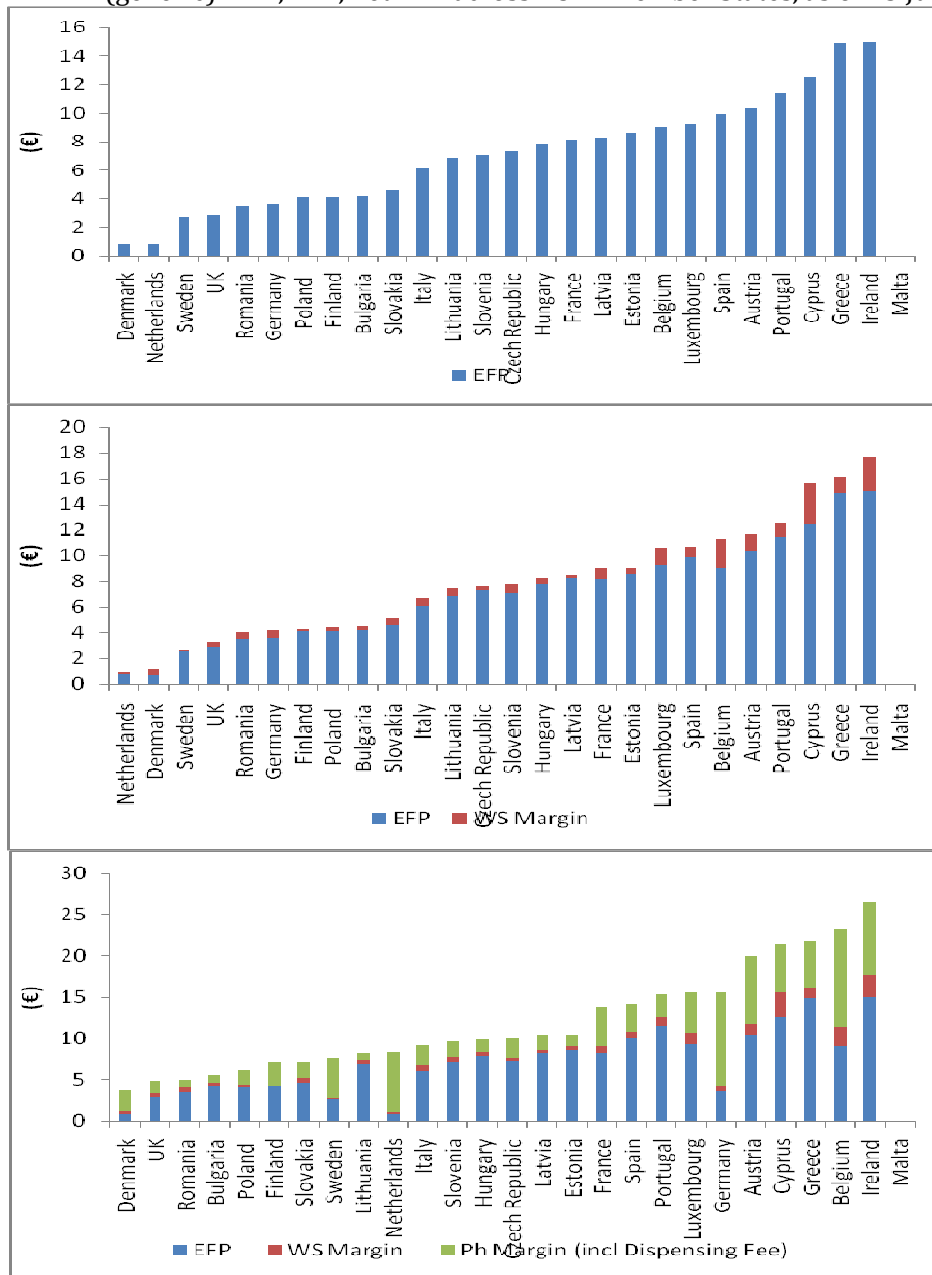
Figure A3.11: LP-D (branded): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for Malta not available.

Source: Pricing data received from the Member States.

Figure A3.12: LP-D (generic): EFP, PPP, net PRP across EU27 Member States, as of 15 June 2009.



Note: Data for Malta not available.

Source: Pricing data received from the Member States.

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