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Political Regulation of Wholesalers' and Pharmacists' Margins for Prescription-Only-Medicines in Europe: An analysis of different markup schemes and their potential rationale.

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List of Abbreviations

DTP	Direct-To-Pharmacy
EFP	Ex-Factory Price
EU	European Union
GKV-SV	GKV-Spitzenverband
HSE	Health Service Executive
Na	Not available
OFT	Office of Fair Trading
OTC(s)	Over-The-Counter Medicines(s)
POM(s)	Prescription-Only-Medicine(s)
PPP	Pharmacy Purchase Price
PPRS	Pharmaceutical Price Regulation Scheme
PRP	Pharmacy Retail Price
PSP	Pharmacy Selling Price
RWA	Reduced Wholesaler Agreement
RWM	Reduced Wholesaler Model
VAT	Value Added Tax
WHsM	Wholesalers' Margin(s)
WS(s)	Wholesaler(s)

Introduction

“If pharmaceutical manufacturers were to sell products at the marginal cost of production and distribution, they would be unable to recoup the cost of R&D and would thus have no incentive to develop new innovative products that would potentially benefit public health. In the absence of patent protection legislation which allows firms to recoup the large fixed costs of R&D, output would be lower than the socially optimal level due to the possibility of free riding behaviour on the part of competitors.” (Gorecki et al., 2012, p.11)

High return of investment is the fuel for innovation. Technical and technological development motivation based on a purely social benefit (foregoing gains), without seeking proper compensation for the input invested, is more than utopian; economic forces drive current markets and shape the way economies strive forward. And one of the fastest growing segments of innovation – as controversial as it may be – is the pharmaceutical industry. Many features make this segment of particular interest: classic supply-and-demand curves do not apply as with other non-vital marketable products, all the while pharmaceutical makers have to deal with critical decision making that seek to balance the ethical obligation to supply medicines that can knowingly save lives (or at least maximize its quality) while still complying with profitability principles that can keep the innovation motor running (complying on economic grounds with investors and other stakeholders).

Diverse elements are taken into account when establishing prices for medicines in different countries; for Germany are of prime importance the health technology assessment outcome of a given product, the relative prices of comparable drugs and the international reference price (GKV-Spitzenverband, 2015). The external price referencing process, on layman’s terms, is the price comparison of a medicine in a given set of countries to level out outliers on the international price horizon and reach a benchmark price to apply on the price decision-making process of the country where the medicine is to be launched (to achieve harmony with the countries that it is compared to) (Vogler et al., 2015, p.5). A significant amount of specifications surrounds this price comparison: while some countries have rudimentary comparison mechanisms (list price of other countries vs target price in launch country), many have devised very complex structures that build up this price. For the German setting, it consists broadly of a predetermined set

of countries for comparison, followed by weighing of prices for the medicine (list price and actual selling price) in accordance to countries economic performance, number of inhabitants, potential markets for the given drugs, special handling of outliers, etc. The last bracketed information, as innocuous as it may seem, entails such a significant value for the price-setting procedure in Germany that it justifies the foundations for this paper.

Prevalent distribution schemes consist of a pharmaceutical company selling their products to a wholesaler who in turn sells the medicines to pharmacies; these fulfil the public obligation of delivering the products in a timely and appropriate manner to end user. Lastly, through a set reimbursement framework, pharmacies collect the billed products and services from a system payer. This leaves a significant number of *possible price levels* to be studied: the ex-factory price, the wholesalers' buying price (which does not have to necessarily match with the latter), the ex-wholesalers' price (or wholesalers' selling price), and again the same for pharmacies and payers; buying and selling price of each distribution player differ in the margin each one adds in return for their services. Adding the possibility of a wide range of discounts/rebates that are customarily offered – or obliged or even desired – and given the financial necessity for all stakeholders in the distribution pathway to remain profitable, many net margins¹ and deductions are to be expected all throughout the supply chain, from pharmaceutical company to end user.

As many countries do not publicize all price levels for all medicines in their respective official market information sources, many times *approximations* have to be made – some are relatively easy to calculate as distribution margins are regulated (and known) and thus prices can be deducted upstream (from one distribution player to the previous). But other countries have more intricate regulation frameworks or private negotiation schemes that are not readily available to the public eye, hindering the international reference pricing procedure and, more importantly, casting a shadow on the knowledge stand of economical sciences within and across the European Union. Given prevailing financial difficulties, a deeper understanding of public and private negotiations of margins is needed to progress financial efficiency in the EU.

It is therefore of prime importance to know regulation schemes within distribution pathways and elucidate those distribution margins that escape the public eye, at least in a responsible approximated manner. Many authors have made small advances in the topic: Kanavos, Schurer and Vogler (2011, pp. 42-43, 47-49) deliver two interesting tables

¹ The terms “margin(s)” and “mark-up(s)” are henceforth used indifferently.

where distribution margins can be derived from. This source is the main reference for Carone, Schwierz and Xavier (2012, p.44), a known source to refer to when talking distribution margins in the EU. A more recent attempt, Vogler et al. (2015, p.5) (coauthor of the first publication in this sense) portrays her own interpretation of (this time only) wholesalers' margins upon which the modelling structure presented by her study is based.²

A seemingly sufficient³ amount of known authors in the broad pharmaceutical spending setting in the EU have delivered their renderings (all very similar) of a topic that seems clear enough not to require further scientific audit; this more than suffices eminence-based science criteria. A deeper scrutiny, nonetheless, reveals that the current state-of-the-art on the topic fails to withstand one of the main pillars of the scientific method: reproducibility. The findings by the aforementioned authors are through and through inconsistent on many levels with one another (even though very similar in appearance), thus their scientific accuracy is in need of a review.⁴ A major problem lies in a factor named by Kanavos, Schurer and Vogler (2011) and Carone, Schwierz and Xavier (2012) but omitted by Vogler et al. (2015) and that is the fact that regulations have *regressive categories* and as such should not be interpreted as absolute figures. Even in the two prior articles where it is mentioned, it is not explained in detail, which is a methodological error.

The opening reference by Gorecki et al. (2012) not only mentions the conventional incentive-innovation paradigm in products/services markets, but goes further beyond to explore the significance of patent protection of medicines within the framework of pharmaceutical companies' competitiveness. While the importance of patent legislation itself is beyond the scope of this paper, the importance of a market differentiation between distribution of patented medicines versus generics is of prime importance given the implications on the actual distribution margins and is an additional drive to pursuing the paper's thematic. The supply of products with relatively narrow demand elasticity (rather insensible to price changes) such as most of the medicinal products, dictates a dire need to clearly cut limits between the those that can be offered at such low prices that only a high turnover can render them profitable from those high(er) priced products that need to

² An exhaustive comparison of the references as a theoretical foundation is to be found in chapter „Theoretical Background“, section „State-of-the-art“.

³ To be handled with care. Literature is in fact *insufficient*, but the few publications to be found on the matter appear to coincide on general terms and the topic does not seem to provide obvious knowledge obstacles, leaving scholars with a strange feeling of scientific scrutiny criteria fulfillment.

⁴ A more detailed criticism of the mentioned references is to be found in the chapter „Discussion of the database“.

be distribution-margin adjusted downwards as to offer appropriate return of investment for stakeholders without giving away unnecessary budget (think opportunity costs for payers).

The current state of the art on distribution of POMs is but a plethora of regulation and handling strategies specific to the politic milieu of the EU member states. Recent adjustments to the prevailing distribution models pose a challenge for policymakers thus incentivizing change; some countries operate regular direct distribution to pharmacies (known as Direct-To-Pharmacy) models, whereas others involve conventional wholesalers in the distribution pathways. With the subsequent regulation of distribution comes the regulation of wholesalers' and pharmacists' margins in the countries to be studied⁵. Some regulations are operationalized in a transparent and binding manner, whilst others are negotiated behind closed doors between the interested parties (stakeholders). The lengths to which regulations can modulate privacy (and thus transparency) result in three main schemes in which most EU countries (of interest) can be placed. These schematic frameworks compare and contrast structures between countries and hope to derive conclusions as to similarities of healthcare policymaking between countries within one scheme, as well as contrasts between the groups. Such a schematic approach is currently unavailable in scientific literature.

The problem is then clear: scientific discourse has not yet deepened the problematic of wholesalers' and pharmacies' regulations in the context of interest, for as many variable influencing factors impede this topic from being generalized in an effective manner – quite the contrary, for the understanding of the functional roles of legislations in the matter, each country's regulation has to be first broken down into its constitutional pieces in order to be able to properly deduce the logic that hides behind it and give value to the idiosyncrasies of governments. Scientific construction is thus vital.

⁵ The particularities of the countries' selection will be dealt with in chapter „Results“.

Objectives

The **general objective** of this paper is to appraise in a qualitative manner through literature research the regulations of wholesalers' and pharmacies' margins in the European Union Member States (as of the EU15 German Basket⁶).

This paper aims to fill a literature gap in the knowledge of distribution margins of medicines, as previous literature expresses this thematic in a general, non-individualized manner which takes away importance from particular factors for singular countries. In order to achieve this, the author sets off to assess the regulations and the ceilings for wholesalers' and pharmacies' margins within derived comparable structures and embed these within the objectives framework for healthcare policies.

The current paper is intended to further discuss the notion that regulations of distribution pathways and margins of wholesalers and pharmacists pursue, in the given member nations of the EU, political regulatory and system-inherent goals.⁷

The **specific objectives** offer a responsible operationalization:

- To identify, summarize and portray regulation statutes in their qualitative and quantitative aspects
- To identify comparable regulation structures among the countries and define overarching regulatory schemes
- To elucidate the relationship between the schemes and the countries-specific health policymaking goals

⁶ As listed in Attachment 2 of the „Rahmenvereinbarung nach § 130b Abs. 9 SGB V“; even though the theoretical background applies to general EU regulation schemes, for the special case of the German context price handling in the so-called AMNOG process is sensible to EU prices of products which could be well elucidated by addressing the margins issue for the appointed EU15 Basket. Germany will be dealt further on as a reference point – for the other countries and for the actual literature stand on the matter. This paper is written in the German context and as such is delimited to the actual scientific information necessities of the local setting.

⁷ A historical depiction of margins is not within the scope of this paper, will be nonetheless carried out for UK and Ireland, as it is of uttermost relevance.

Materials and methods

Given the inherently political cut of the topic, a systematic review was quite hard to propose in a prospective manner at the beginning of the literature research, for as no rigorous gold standard for systematic grey literature research was found. As country-specific regulations are part of the vast grey literature⁸ database to be found on- and offline, a (broad) semi-systematic grey literature research strategy was set upon, which broadly included (but was not limited to) the following items:

1. Consultation with content experts
2. Google searches
3. Targeted websites (mainly governmental)

The consultation with content experts led to the gross direction in which regulations could be found for the countries studied, as well as governmental and non-governmental organizations that could provide additional information on the subject. From the consultation, search terms and boundaries were defined⁹. Then Google searches on the topic were cross-checked with the results from the prior consultation to land on the (mainly) governmental websites where the legislation information was found. Since abstracts are rarely found in such literature, executive summaries and table of contents were screened (when available), then full-text screening followed.

The use of PRISMA for this research would not depict useful information. Since grey literature is hardly indexed. The use of “Web of Science” and other references’ follow-up tools render unuseful.

There were a variety of, once again, rather vague inclusion and exclusion criteria, which contained (but were not limited to):

⁸ This is understood as, but not limited to, reports of all kinds, working papers, government documents, white papers, evaluations and the such.

⁹ These are not portrayed in the body of this paper because the search continuum proved all terms to be fluent and easily re-interpretable; the acquisition and revision of new references quite often led to redefinition of terms and boundaries.

Inclusion criteria	Exclusion criterion ¹⁰
<ul style="list-style-type: none"> ▪ Published by government or non-governmental expert institutions ▪ Dealing with distribution margins (at wholesaler level and pharmacy levels) ▪ Most current version of the document 	<ul style="list-style-type: none"> ▪ Regards to countries outside the EU15 Basket for Germany

The method that proved most efficient for literature procurement was however the snowball method: parting from the three main literature references aforementioned, following a backwards-tracing fashion, most of the literature – or at least the governmental organizations that produced them – was identified and withdrawn. Forward tracing of references proved too difficult to pursue.

¹⁰ Notably absent in this category is the search language. More on this in the section „Discussion of own method“.

Theoretical Background

Distribution pathways

The distribution pathway schemata set the stepping stone upon which a responsible research on margins can be constructed, as regulations on the latter eventually channel the margins (or distributions thereof) in practice. The variety of distribution models of POMs begins with the model that prevailed until the beginning of the millennium:



Figure 1: Distribution model, prevailing pattern

in which the pharmaceutical company sells the products¹¹ to a WS that in turn completes the distribution cycle by again selling the products to pharmacies¹². However, ever growing horizontal competition and strengthening of market and distribution regulations has led all players in the equation to come up with novelty arrangements to counteract eventual diminishing profits. Two main emerging models are of importance: the reduced-wholesaler-model (-agreement) (RWM/RWA) and the direct-to-pharmacy model (DTP), also known as agency models (Kanavos, Schurer and Vogler, 2011, pp.23ff). RWM/RWA functions as follows



Figure 2: Reduced-Wholesaler-Model/Reduced-Wholesaler-Agreement

in which the pharmaceutical company arranges for a *limited* number of wholesalers to distribute a certain product or product line (RWMs for complete portfolios are rare if existent). Wholesalers buy the products and as owners can offer rebates to pharmacies. RWMs give wholesalers a privileged position in the distribution chain, as downstream (and presumably upstream) bargaining power is substantially increased.

DTP models (or agency models) function as follows:

¹¹ Medicines and products to be understood indifferently.

¹² All end-user considerations will be foregone as they are beyond the scope of this paper.

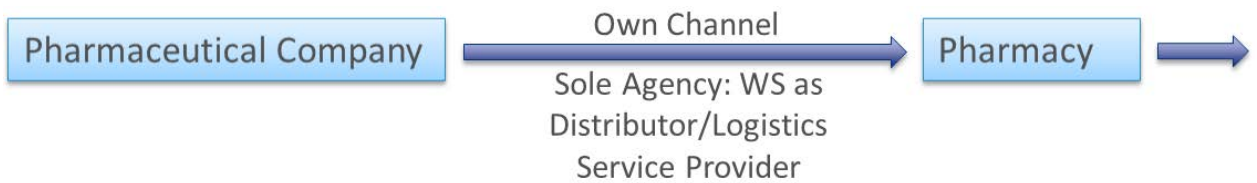


Figure 3: Direct-To-Pharmacy Model

in which pharmaceutical companies do not actually sell the products to the wholesalers, but only use them for logistic and distribution purposes. The wholesaler never owns the products and as such cannot offer rebates, thus acting as a sole agent in the distribution chain. Some pharmaceutical companies have even gone further as to bring into existence own distribution channels (or contract non-wholesaler logistic service providers), usually for high-priced drugs with low rotation – as logic would dictate. Given that wholesalers act as a means of transport and temporary storage, they no longer compete to supply pharmacies, but rather to become a pharmaceutical company service. The power acquired through a RWM diminishes, while they forego risks that come up with acquiring and owning the products as well as liability issues that could arise. In this model, the main client for WSs swaps thus from pharmacies to pharmaceutical companies (Gorecki et al., 2012, pp.85ff.).

The significance of these emerging structures that are set to function as a parallel to previously prevalent distribution models is a response to the inaccurate WSs' margins regulations in some countries that lead to assigning a net cut in the distribution chain that is inappropriate for the expected profit (revenue considerations in terms of low fixed plus variable costs) for the WSs to be profitable while maintaining a sustainable distribution chain total cost without a reduction in quality. As a response to these emerging models, policymakers in some countries have already adapted regulations, bringing into life "clawback" mechanisms¹³ and percentually regressive margins' models that counteract the unproportioned assignation. Simply put, emerging models are (were?) *reactive* to insufficient/improper wholesalers' regulations, which in turn have caused further action from the policymaking side.

A higher competition ground for all distribution stakeholders could eventually prove beneficial for the payers, given integration of services as well as implementation of new distribution schemes that allow for parties to profit from economies of scale. The considerations here are countless, e.g. diminishing the per-unit fixed costs when handling bulk acquisitions as well as efficiencies in operation and of course synergic workflows.

¹³ 'The recouping of already reimbursed money.

State-of-the-art

As mentioned in the introduction, there are three main literature references known to the general public where distribution margins are mentioned in some detail. These papers constitute the most up-to-date references when talking scientific discourse about margins regulations in the selected countries.

The actual margins to be found in these publications (for objective reference purposes) are found in the table on the following page. On the next page are some annotations referring to the three information sources.

At this point, only a data table with the actual figures presented by the sources will be offered along with operational annotations. In the “Discussion” chapter, these findings will be further discussed – in light of the results of this paper.

Country	Kanavos, Schurer and Vogler, 2011			Carone, Schwierz and Xavier, 2012				Vogler et al., 2015
	Average WS Margin (% PPP)	Linear Mark-up (WS)	Average Pharmacy Margin (%PRP)	Avg. wholesaler margin (%PPP)	Type of wholesaler markup	Avg. pharmacy markup (%PRP)	Type of pharmacy markup	Approx. WS mark-up
Austria	6.5-13.4%	X	19.16%	10.0%	Regressive	19.2%	Regressive + dispensing fee	9.10%
Belgium	8.45%	X	Na	8.5%	Regressive	Na	Regressive + dispensing fee	8.50%
Czech Republic	4.3%	X	Na	4.3%	Regressive	Na	Regressive	4.10%
Denmark	6-7%		19.3%	6.5%	Negotiations with manufacturers	19.30%	Linear + dispensing fees	6.30%
Finland	3.0%		23.6%	3.0%	Negotiations with manufacturers	24%	Regressive + dispensing fee	3.00%
France	6.2%	X	Na	6.2%	Regressive	Na	Regressive + dispensing fee	4.30%
Germany	4-6.1%	X	24%	5.0%	Regressive	24%	Linear	5.90%
Greece	4%		Na	4.0%	Regressive	Na	Regressive	4.20%
Ireland	Na		Na	Na	Na	Na	Dispensing fee	8.00%
Italy	3%		Na	3.0%	Na	Na	Linear	9.10%
Netherlands	13-24%		Na	18.0%	Negotiations with manufacturers	Na	Dispensing fee	10.60%
Portugal	6.87%		18.25%	6.9%	Regressive	18%	Regressive	9.30%
Slovakia	n.appl.	X	21%	Na	Regressive	21%	Regressive + dispensing fee	13.00%
Spain	3.5%	X	Na	3.5%	Regressive	Na	Regressive	5.26%
Sweden	2-3%		21.3%	2.5%	Negotiations with manufacturers	21%	Regressive	3.60%
UK	12.5%		Na	12.5%	Negotiations with manufacturers	Na	Linear + dispensing fee	12.50%

Notes: PPP: Pharmacy Purchase Price, WS: Wholesaler, PRP: Pharmacy Retail Price, Na: Not available
All categories to be found under the reference names are portrayed verbatim from the original source.

Kanavos, Schurer and Vogler, 2011

Average WSSs:

- All margins are linked with the following annotation: “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.”
- Austria, Italy, Portugal and UK: not the total market
- All countries where a margin for is shown are followed by a year, presumably reference date (this information is not further detailed so a reference check is not possible)

Average Pharmacies:

- All margins are linked with the following annotation: 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.”
- %PRP is nowhere defined, assumed by the author as “Pharmacy Retail Price”
- All countries where a margin for is shown are followed by a year, presumably reference date (this information is not further detailed so a reference check is not possible)

Carone, Schwierz and Xavier, 2012

Average WSSs:

- All margins are linked with the following annotation: “Average, when range of margins was provided by Kanavos et al. (2011a).”

Vogler et al., 2015

Average WSSs:

- Mention of a price level for the wholesalers’ margins is not fully clear.
- Sole information source for this reference is “Vogler S and Schneider P [9]”, as stated underneath the table. Reference [9] in the “Annex 17: References of the Annex” is cited as follows: “Vogler S, Schneider P. Vergütung der Arzneimitteldistribution in den europäischen Ländern. Vienna: Gesundheit Österreich Forschung und Planung GmbH (GÖ FP), 2015 (unpublished).” As an unpublished paper, it is not possible to cross check.

Results

Wholesaler and Pharmacies Margin Schemes

A quick review of distribution margins' regimes for the countries of interest in the European Union immediately reveals common political structures that can be compared within country groups and contrasted against the others. These structures are portrayed in the image below:

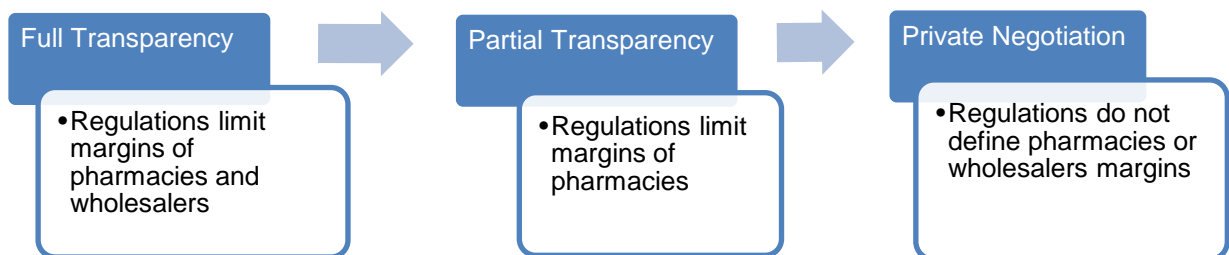


Figure 4: Common regulations schemes

The schemes are of a logical nature: either both distribution players (wholesalers and pharmacies) are regulated in terms of margins, or just one is fixed – for all cases pharmacies, while wholesalers undergo private negotiations with pharmaceutical companies – or no clear regulation is existent (only regulations on pharmacy net selling price cap¹⁴).

Given the aforementioned structures, countries can be aggregated as follows:

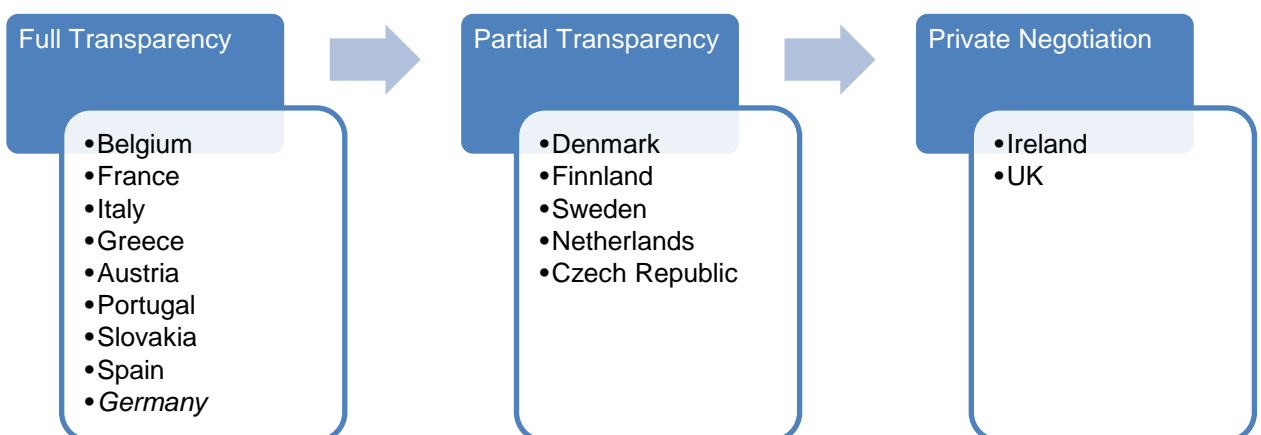


Figure 5: Common regulations schemes, countries aggregated

¹⁴For this last scenario, margins for pharmacies could be regulated but *not* in terms of individual product selling price, but in pharmacies' overall economic performance, meaning there is indeed some form of regulation; see annotations on Ireland and UK. Geographical location can also play a role; see annotations on Italy.

Full transparency – a deep look

When talking wholesalers' and pharmacies margins, there is one annotation that deserves care: different countries, and thus different social health care systems, account for different understandings of the term “reimbursable”, and hence have to be interpreted with due care. This is especially important when reviewing Belgium and Austria, as both these countries have differentiated margins' regulations for distribution players in terms of the reimbursement status of the medicines at hand.

Absolute and relative margins' graphs will be portrayed in a single range of Ex-Factory Prices set at 1€ - 1.400€¹⁵ on the horizontal scale; this was decided on a writer's discretion basis, but is not at all random because a top-down retrospective analysis of the raw data showed only marginal changes in the relative margins (in the first to second after-comma position) from this point on – this suffices to pursue a highlighting of market segment segregation between generics and in-patent POMs¹⁶. The vertical axis was adjusted for every graph to better depict the corresponding scale starting from zero all the way to the highest value to be shown. Unless otherwise noted, the margins shown are portrayed for in-patent POMs.

The cut point set for comparing wholesalers' margins in the different countries was set – at the writer's discretion – at 2%, as it retrospectively showed to differentiate and thus contrast countries in an appropriate manner. However, a general comparison with continuous values will be set forth in the discussion with a proper graph. For pharmacies such a depiction is impossible given the variety of price levels upon which regulations are based plus non item-dependent costs/fees that make it impossible for a single medicine item price to be confidently differentiated.

For all countries¹⁷ within the “Full Transparency” group, the regulators devised margin mechanisms based on categories – the exact regulations are found on Annex A for all countries.

Following will be shown *relative* and *absolute* margins for wholesalers and pharmacies in graphical depiction – that is, margins expressed in percent (%) or amount in euros (€)

¹⁵ Where not otherwise noted. Special attention to the labels of the graphs is to be paid.

¹⁶ Generics vs. in-patent POMs are not *per se* fixed to determined price ranges. It is however axiomatic that generics have far lower prices than the originator, in-patent counterparts.

¹⁷ Italy is the exception. This exceptional status will be further noted in the section pertaining this country.

(respectively) assigned from the labeled Ex-Factory Price¹⁸ expressed in euros (€), portrayed as a continuous line on the Cartesian coordinate system.¹⁹ For countries where particularities are found, these will be described accompanying the graphs.

A “category” means, from this point on, a price range for which a specific markup regulation applies, several categories mean that distribution players do not accrue the same (fixed or proportional) for all products, but that the cut accrued changes with ever-increasing EFPs (or any other price level of reference, for that matter).

The broad international comparison will be carried out in the chapter “Discussion”, where an appraisal of the results is to be set forth.

¹⁸ Refer to footnote 14.

¹⁹ The tabular absolute margins can be found in the Annex A to this paper.

Belgium

Belgium is regulated both at the wholesaler and the pharmacy level. For the margins perceived by the two distribution players, the policymaker devised two different schemes: one for reimbursable medicines and one for non-reimbursable medicines.

In Belgium, margins for reimbursable medicines are based upon the EFP, while margins for non-reimbursable medicines are based upon PSP²⁰. This difference does not allow for both wholesalers' and pharmacies' margins to be portrayed on one summarized graph.²¹

For wholesalers, 3 categories are devised for reimbursable medicines and 2 categories for non-reimbursable medicines. Following are the graphic representation for relative and absolute margins for Belgium at wholesalers' level (Economie Belgium, 2013a):

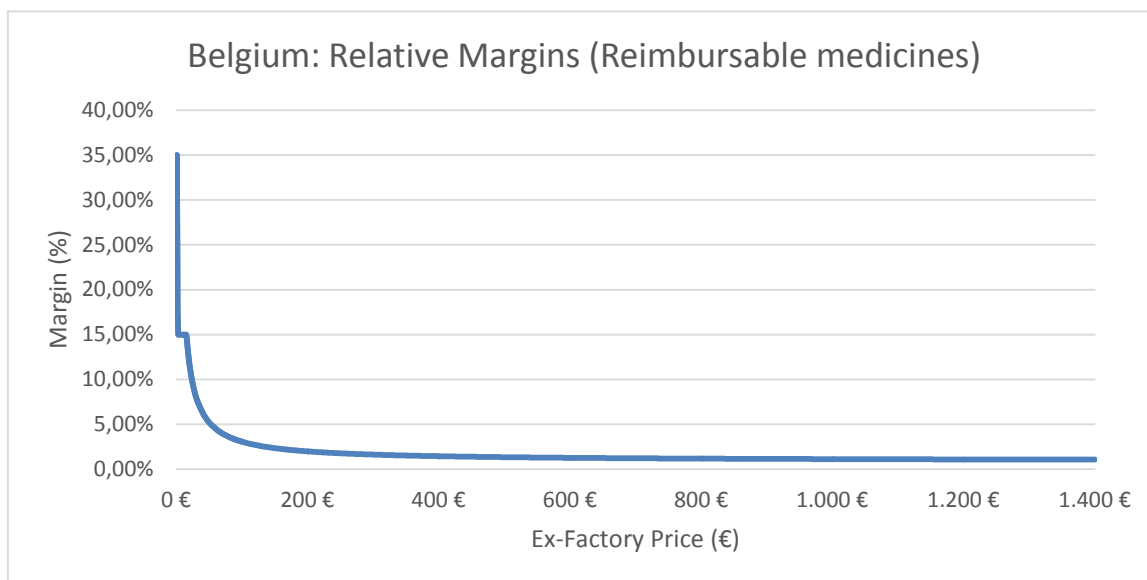


Figure 6: Belgium, wholesalers, relative margins for reimbursable medicines

²⁰ Pharmacy Selling Price, unless otherwise noted, is interpreted as without Value Added Tax.

²¹ Given that not all countries base their margins on EFP, for consistency purposes wholesalers' and pharmacies' margins will be portrayed for each country in separate graphs.

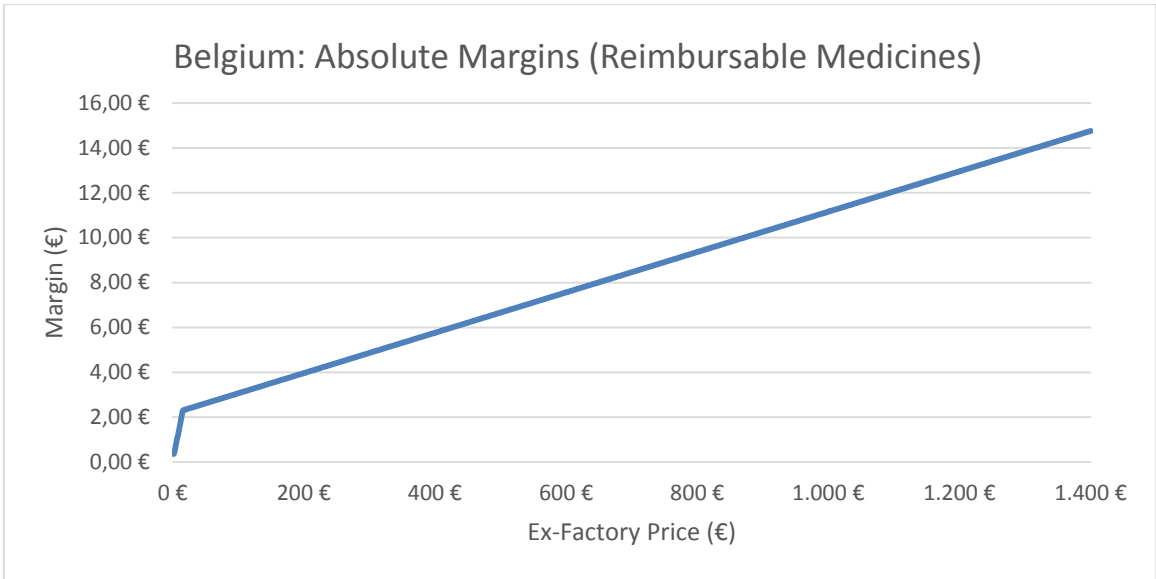


Figure 7: Belgium, wholesalers, absolute margins for reimbursable medicines

For Belgium, reimbursable medicines up an EFP of 197€ signify less than 2% margin for the wholesaler.

The panorama for non-reimbursable medicines is as depicted (Economie Belgium, 2013b), for wholesalers, as follows:

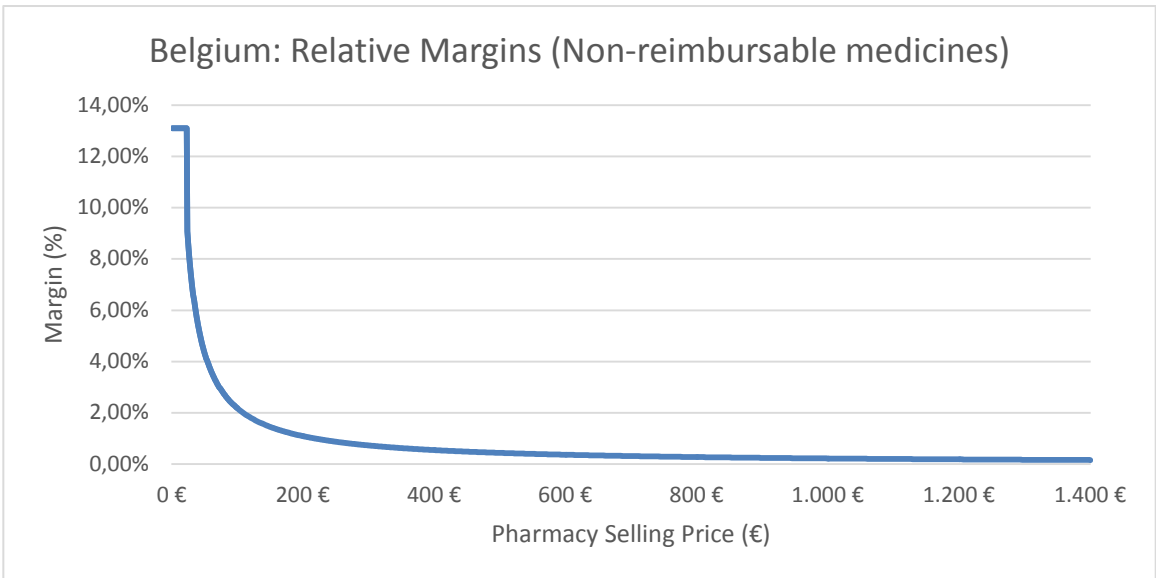


Figure 8: Belgium, wholesalers, relative margins for non-reimbursable medicines

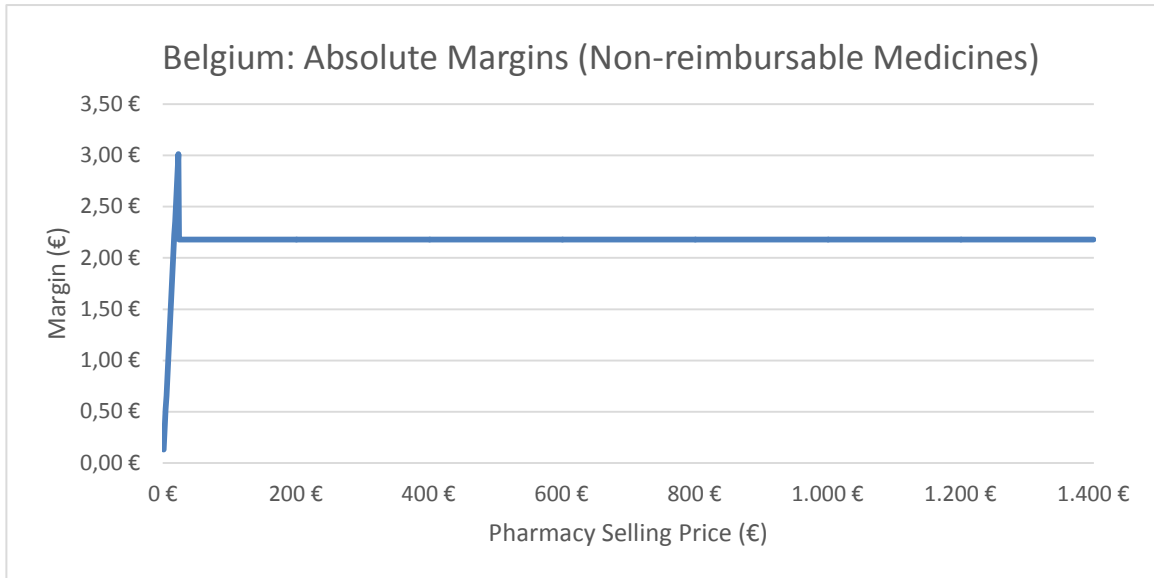


Figure 9: Belgium, wholesalers, absolute margins for non-reimbursable medicines

As for pharmacies (2 categories), the panorama is as follows for reimbursable medicines (Economie Belgium, 2013a):

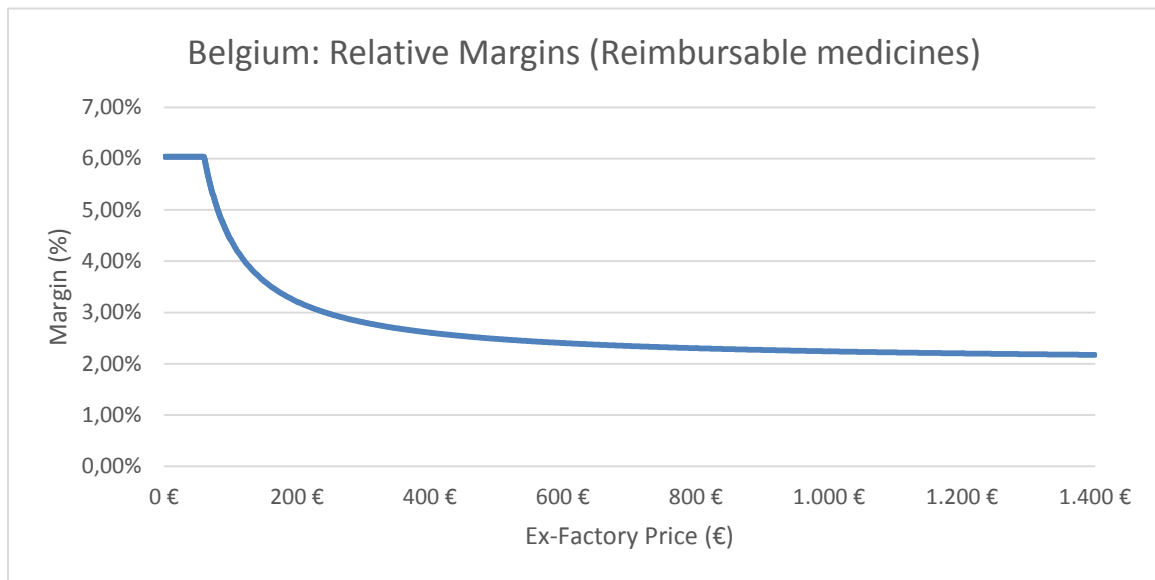


Figure 10: Belgium, pharmacies, relative margins for reimbursable medicines

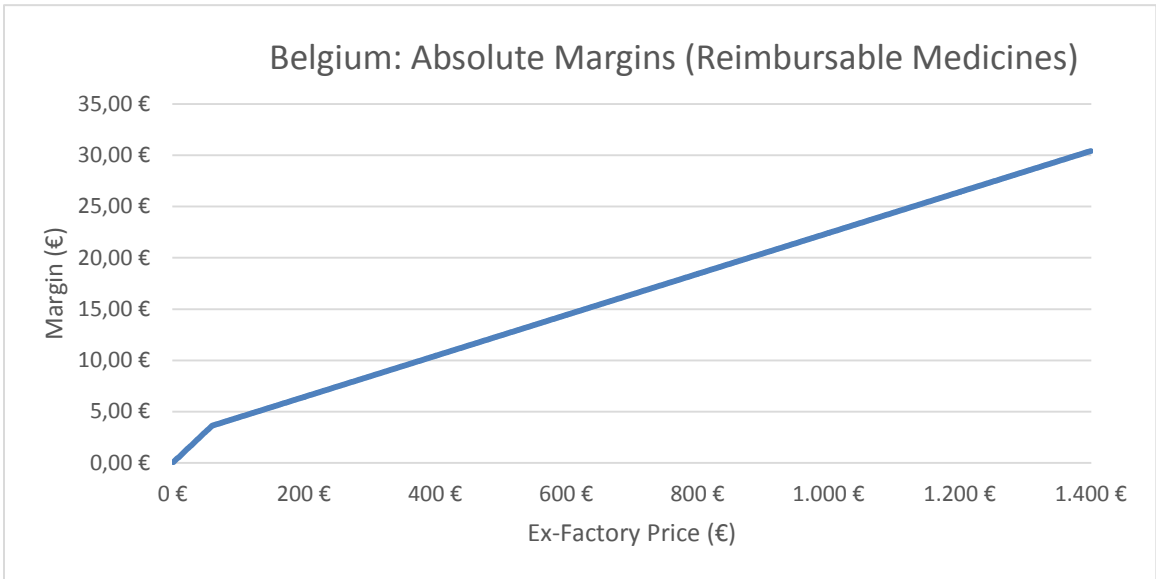


Figure 11: Belgium, pharmacies, absolute margins for reimbursable medicines

And for pharmacies selling non-reimbursable medicines (Economie Belgium, 2013b):

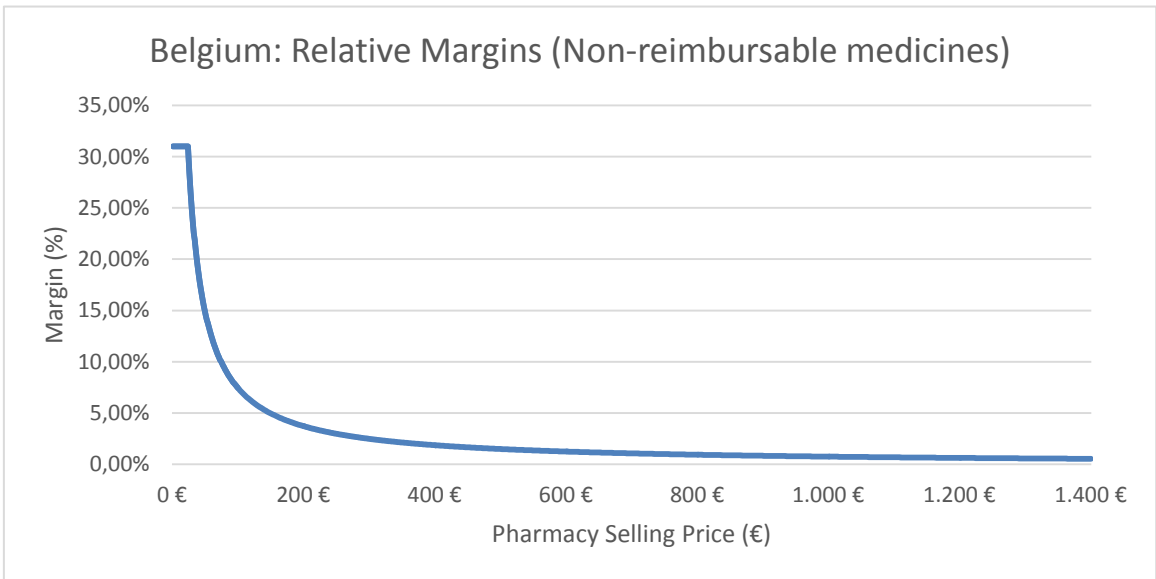


Figure 12: Belgium, pharmacies, relative margins for non-reimbursable medicines

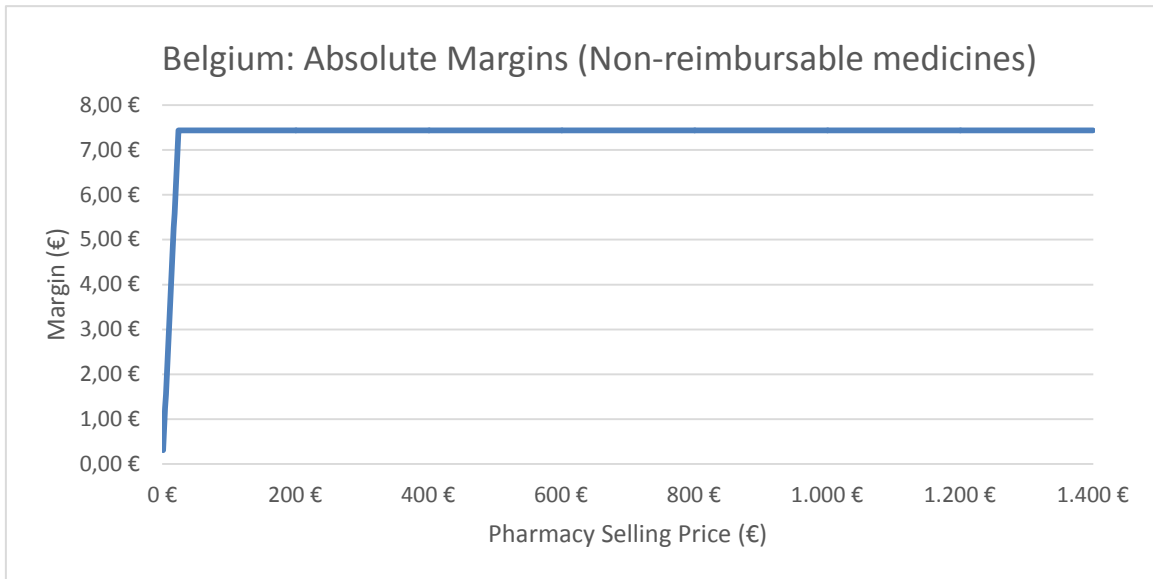


Figure 13: Belgium, pharmacies, absolute margins for non-reimbursable medicines

(Note that wholesalers' and pharmacies' margins for non-reimbursable medicines are based upon PSP and not EFP.)

The 4,16€ fee-for-service for Belgian pharmacies (Institut national d'assurance maladie-invalidité, 2014) was not depicted, as it is not clear whether the fee is assigned per item dispensed or per order dispensed (regardless of items number).

All in all, this means that all reimbursable medicines, regardless their patent status, of around 200€ EFP and up signify less than 2% wholesalers' margin. This to note the importance of depicting price ranges/references to be able to confidently renounce to averages altogether, as they are irresponsible in portraying the detailed, complex wholesalers' margins landscape –not to mention pharmacies per-case fees that are beyond the scope of a simplistic per-unit regulation, or the geographical and profit based considerations taken upon by some countries for the latter (to follow).

France

To further exemplify this, the case of France. The French government also regulates both levels in distribution for in-patent medicines: for wholesalers 3 categories are outlined, for pharmacies 5 categories (Legifrance, 2015). This results in the following:

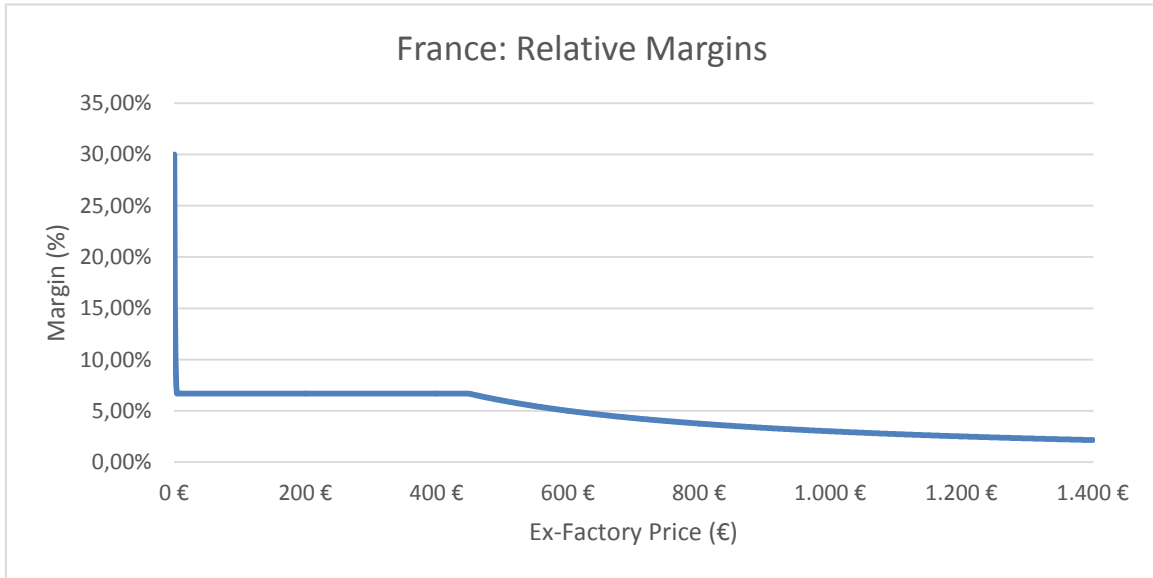


Figure 14: France, wholesalers, relative margins

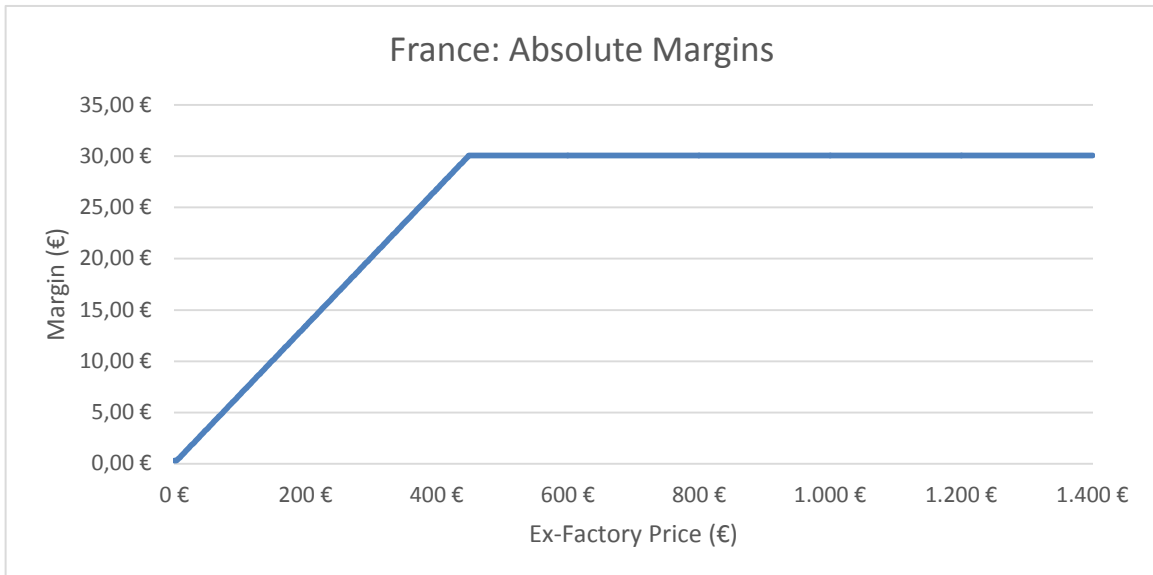


Figure 15: France, wholesalers, absolute margins

For France, in-patent POMs up an EFP of 1504€ signify less than 2% margin for the wholesaler.

For pharmacies results the following (5 categories):

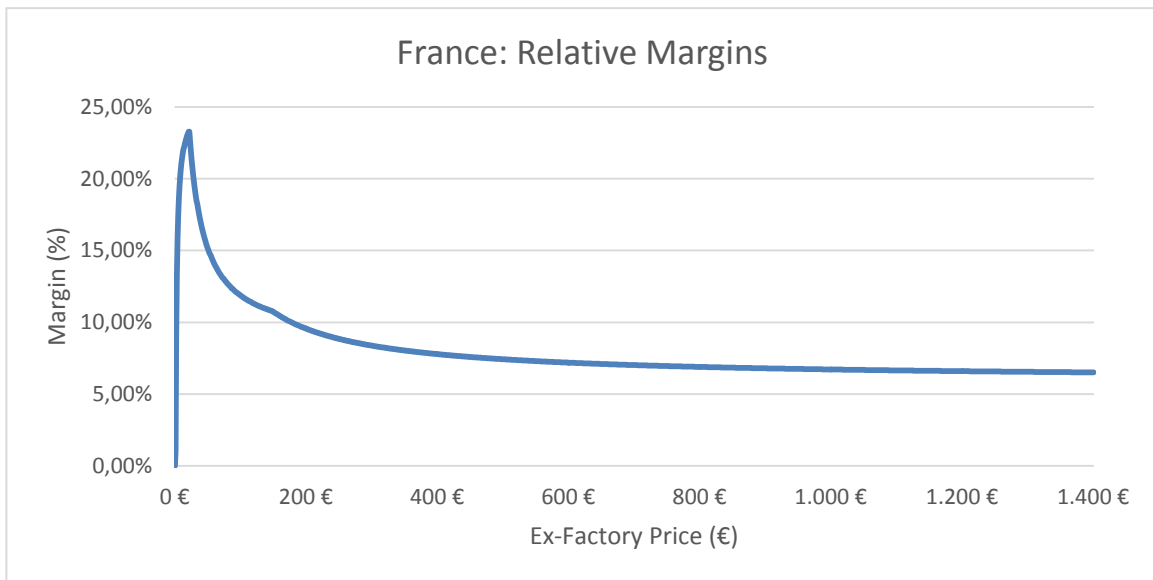


Figure 16: France, pharmacies, relative margins

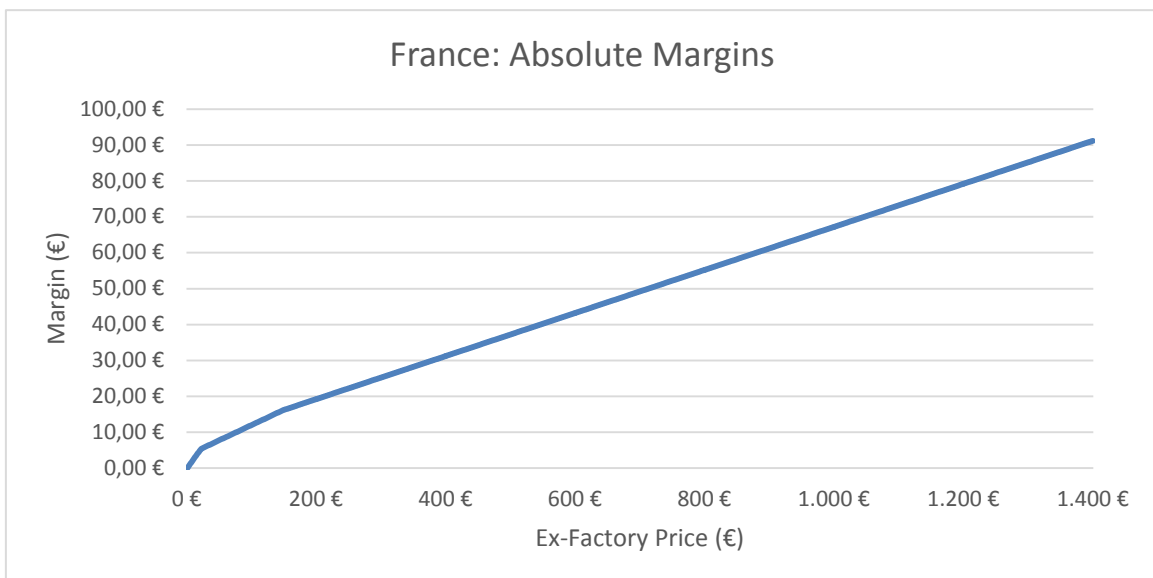


Figure 17: France, pharmacies, absolute margins

A dispensing fee for French pharmacies was not found.

Italy

In Italy, WSS' and pharmacies' are regulated by law. The exact regulation is to be found in Annex A – Italy. This regulation, however, deserves a bit of attention as to its interpretation.

By law, WSS are to be accrued 3% and pharmacies 30,35% (Gazzetta Ufficiale Della Repubblica Italiana, 2010); the policymaker, however, is not very clear about the price level to be referred to. The “Camera Dei Deputati” (roughly translated as “House of Representatives”) provides a meaningful explanation, in which these two margins are to be calculated from the resulting “public selling price” and not added upon the EFP (Camera Dei Deputati, 2010).

For consistency purposes, this paper aims to only portray margins calculated upon a price level which are to be added to that price level – the author refers to this as “forward calculation” – e.g.:

For any given margin regulated at x percent of EFP,
Resulting price at the posterior level is equal to EFP + margin (on top)

However, Italy regulation presents a margin percentage which is to be calculated upon the resulting price level when the given margins are already added – the author refers to this as “backward calculation” – e.g.:

For any given margin regulated at y percent of PSP,
Resulting price at the anterior level is equal to PSP – margin (deducted)

To aid the consistency goal, this “backward calculation” can be converted to a “forward calculation” as follows:

	Total of PSP (= 100,00%)
+ WS Margin of	+ 3,00%
+ Pharmacy Margin of	+ 30,35%
= EFP of	$(100,00\% - 3,00\% - 30,35\%) = 66,65\%$

This illustrates that, for the given margins for WSS and pharmacies calculated backwards from the total PPP, the EFP would signify 66,65% on a comparable level. If, however, this

EFP is normalized at 100,00% and WSs and pharmacies calculated against EFP (and not PSP), this results in the following:

	Total of PPP (= 100,00%)	Total of EFP (=100,00%)
+ WS Margin of	+ 3,00%	$(3,00/66,65)*100= 4,50\%$
+ Pharmacy Margin of	+ 30,35%	$(30,35/66,65)*100= 45,54\%$
= EFP of	66,65%	100%

Using simple algebraic cross-multiplication, WSs and pharmacies margins are calculated as 4,50% for WSs and 45,54% for pharmacies based on EFP (as margins on top). This results in a PSP of 150,04% of EFP.

As this conversion was somewhat cumbersome, the author set forth a confirmation to sustain the interpretation. This validation was rapidly achieved with the help of the pharmacist information website Codifa.it (Codifa L'Informatore Farmaceutico, 2016)²² applying a simple empirical brute force method: For a set of 5 publicly available medicines in Italy the prices were located within the webpage and, starting from a EFP ("Prezzo Ex-Factory") of x, the PSP was forward calculated as $EFP * 1,5004 * 1,1$ (given a VAT in Italy of 10% on top). In all cases, the calculation resulted in the publicly available PSP including VAT ("Prezzo").

Once this conversion was confirmed for accuracy, the following graphs representing WSs margins were elaborated:

²² This webpage shows publicly available medicines' prices information, presenting two price levels: EFP and PSP including VAT.

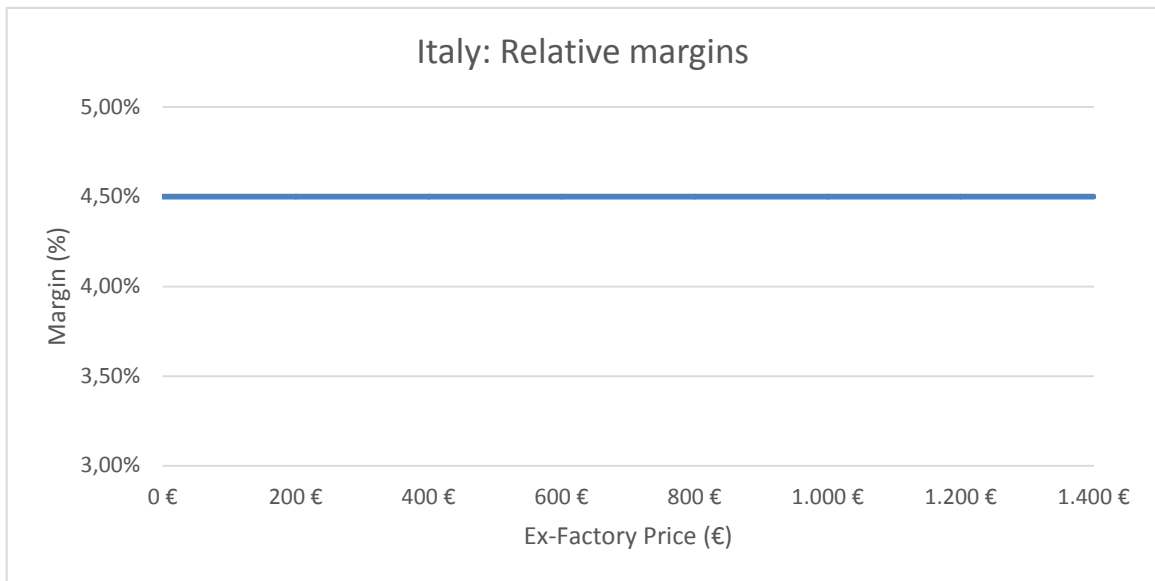


Figure 18: Italy, wholesalers, relative margins

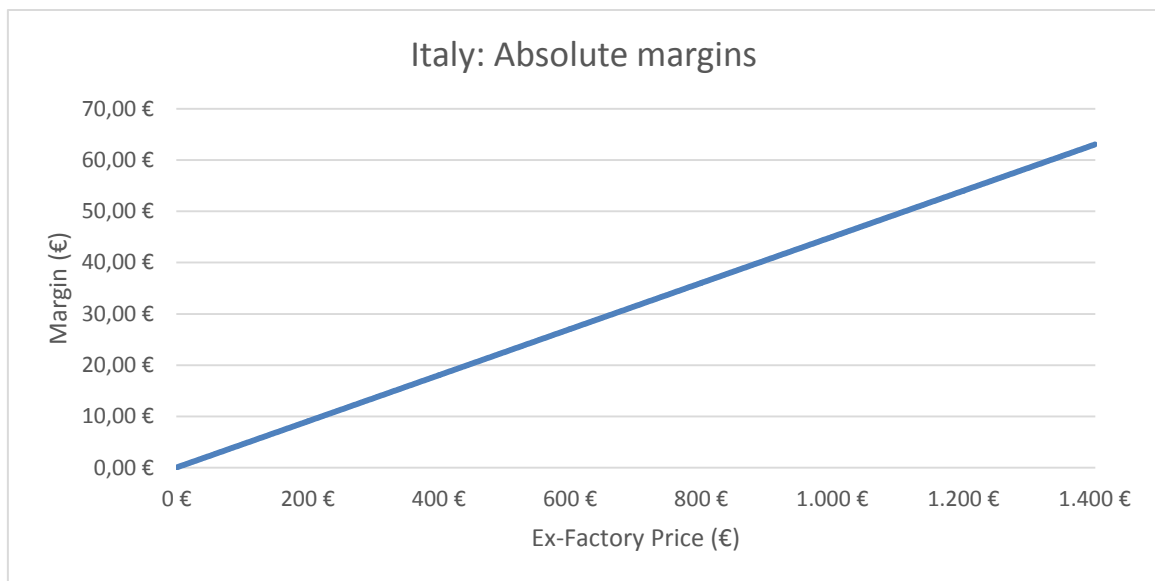


Figure 19: Italy, wholesalers, absolute margins

Italy deserves a further comment: within a fairly regulated mark-ups' mechanism for both distribution levels, pharmacies are further deducted discounts in terms of their geographical location (urban versus rural setting) and the yearly turnover, regardless of the nature of medicines sold. The idea is to incentivize the setting of rural pharmacies – these enjoy subventions and fewer deductions – as to secure a better access to pharmaceuticals (Camara Dei Deputati, 2010).

This means, in practice, that pharmacies' margins for medicines sold under the Italian general distribution margin regulation are lower than the percentual constant pharmacy margin set at 45,54%. It falls under the transparency framework because every step of the distribution chain is intervened and can be calculated, when given the geographical location of a pharmacy and their yearly financial turnover.

This is the only country, however, to be found in the full transparency scheme that regulates pharmacies' margins based on pharmacies economic performance (and geographic situation); all other countries regulate margins for wholesalers and pharmacies in terms of individual (single item-dependent) ex-factory prices and successions of it down the distribution line (pharmacy purchase or selling price, the latter with or without VAT).

This does not allow for a clean comparison of margins across countries for pharmacies; the present paper focuses on in-patent POMs, but cross-country comparison necessitates for *only one possible distribution margin* on each price level base to allow for a plausible comparison. Given that one medicine with the same reimbursement and patent status characteristic can mean different discounts – and thus different prices – in Italian pharmacies, in terms of geographical location and economic performance, Italian pharmacies' graphical depiction is discarded altogether.

Greece

For Greece, both wholesalers and pharmacies' markups are regulated by law. 2 categories are set for WSs and 20 for pharmacists (Government Gazette of the Greek Republic, 2014). The margins for wholesalers are depicted as follows:



Figure 20: Greece, wholesalers, relative margin

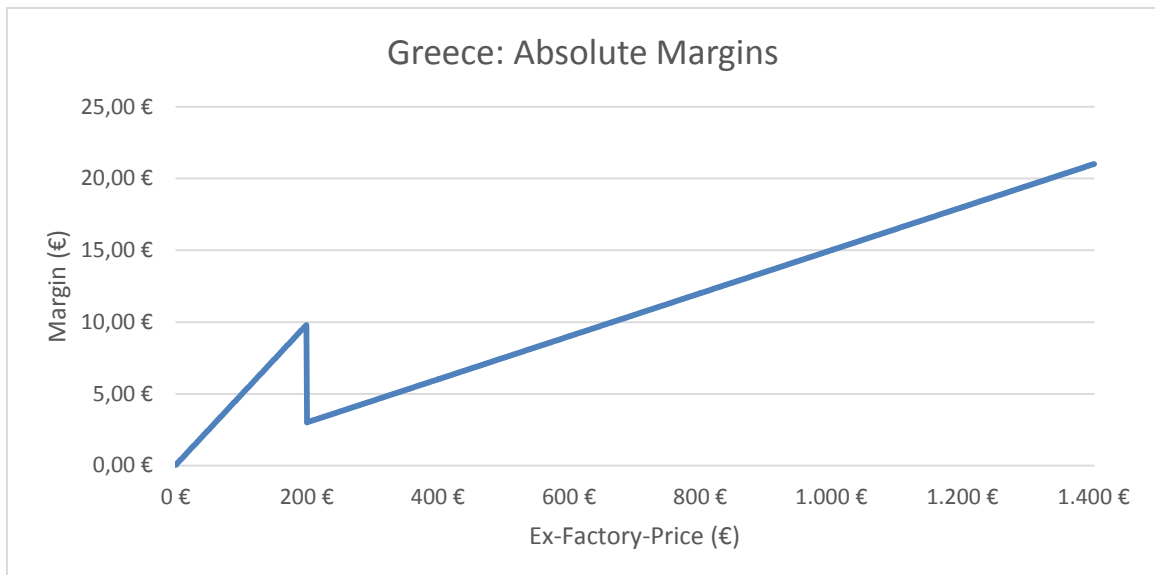


Figure 21: Greece, wholesalers, absolute margins

For Greece, all medicines up an EFP of 200€ signify exactly 1,5% margin for the wholesaler.

For pharmacies, the margins are portrayed as follows:

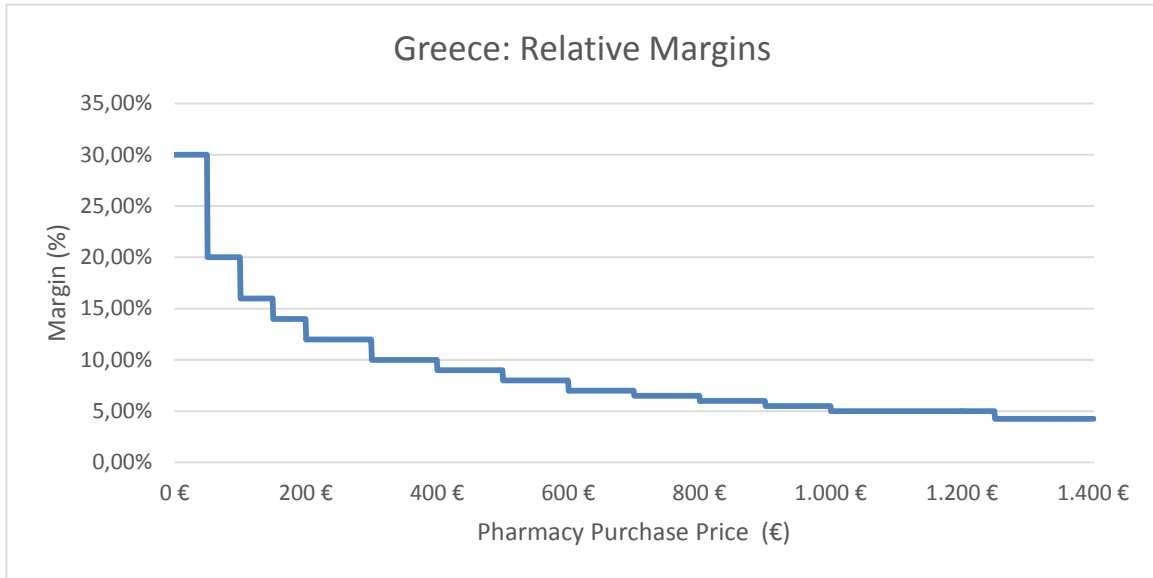


Figure 22: Greece, pharmacies, relative margins



Figure 23: Greece, pharmacies, absolute margins

It caught the author's attention that margins for pharmacies are regulated in a seemingly unclean manner, as for cut points between ranges are included in both the lower and the upper range, and there is no provision for medicines with an EFP above 3.000,00€.

Austria

Austria regulates both wholesalers' and pharmacies' margins. For both distributors, two models are in place: one for reimbursable medicines and one for non-reimbursable medicines. Both models offer a perceptible degree of complexity, setting up price ranges where the margin is percentual constant, and within-the-latter price ranges where the margin is set as an absolute cap for EFP/PPP and the margin on top (for wholesalers/pharmacists, respectively). For wholesalers and reimbursable medicines (10 categories), the latter results in the following graphical depiction (Bundesministerium für Gesundheit und Frauen, 2016):

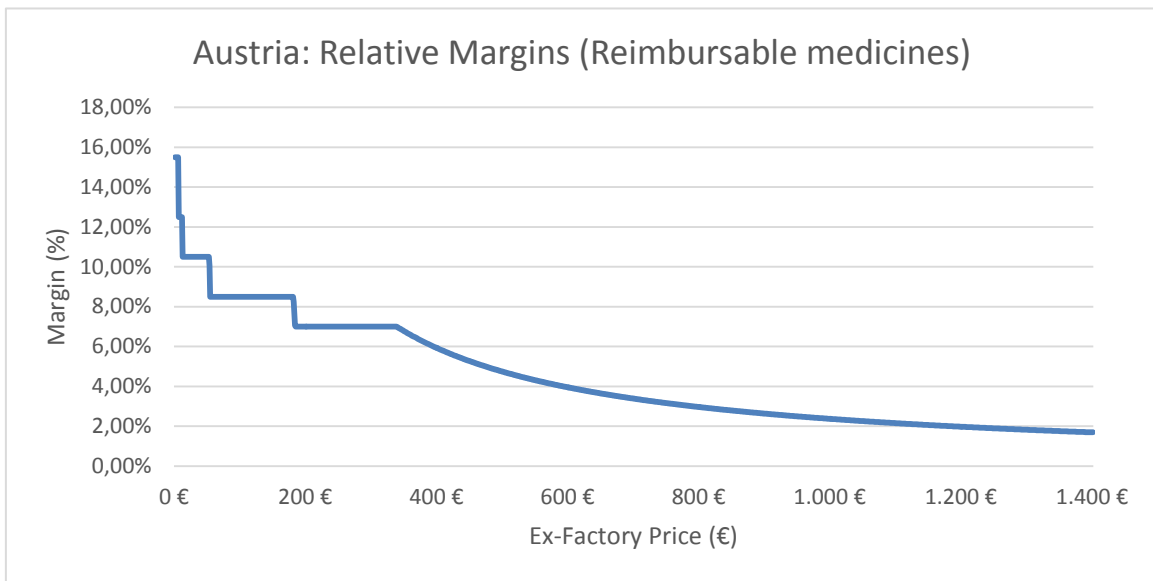


Figure 24: Austria, wholesalers, relative margins for reimbursable medicines

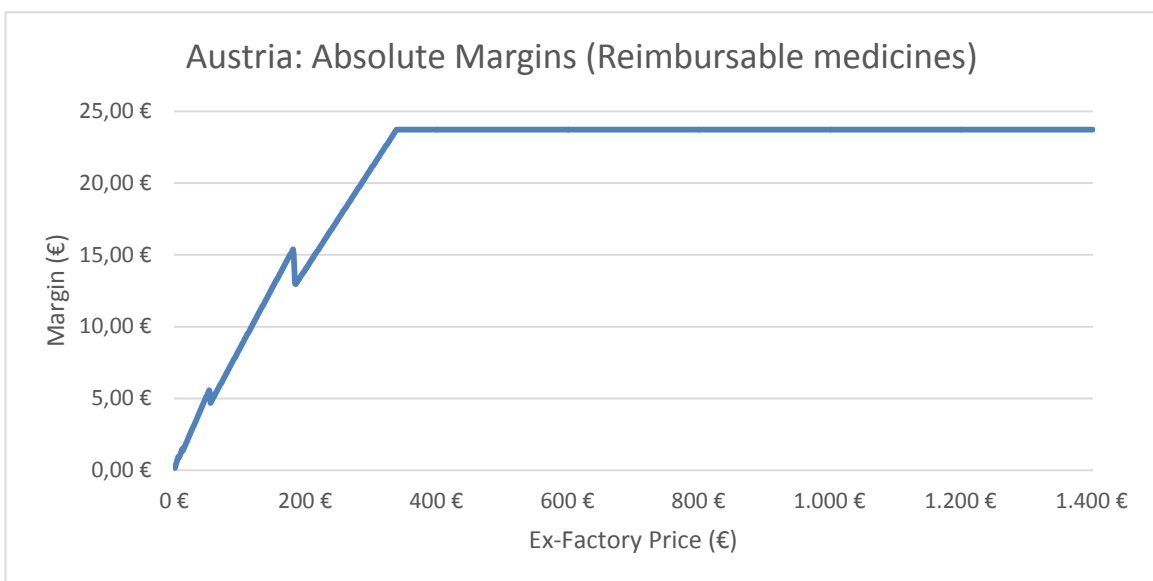


Figure 25: Austria, wholesalers, absolute margins for reimbursable medicines

For Austria, all reimbursable medicines up an EFP of 1188€ signify less than a 2% margin for the wholesaler.

For non-reimbursable medicines, the margins for wholesalers are a tad higher (also within 10 categories), as follows:

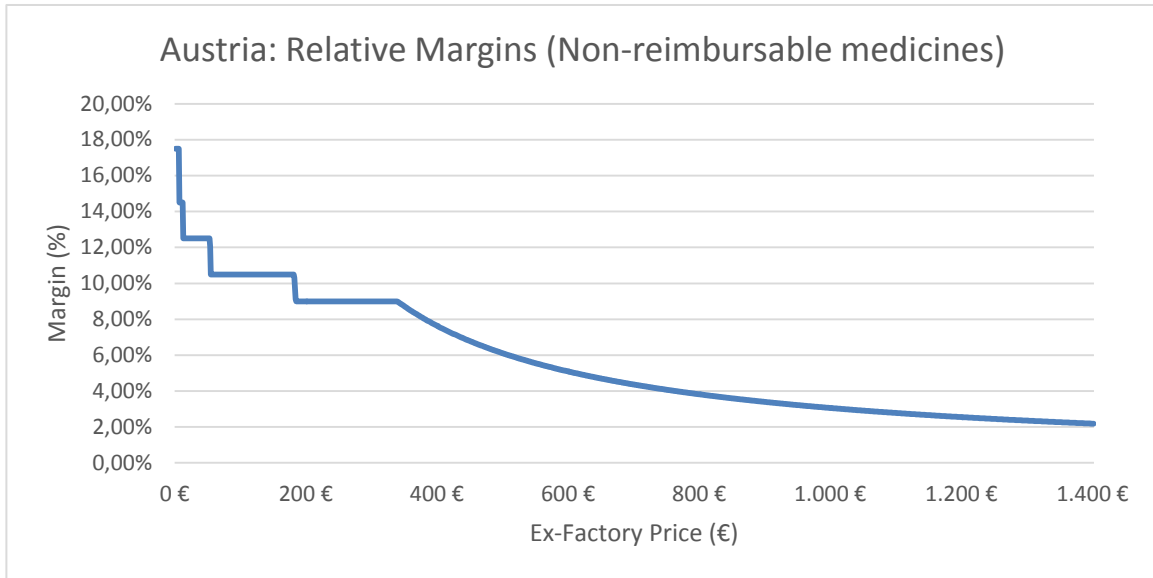


Figure 26: Austria, wholesalers, relative margins for non-reimbursable medicines

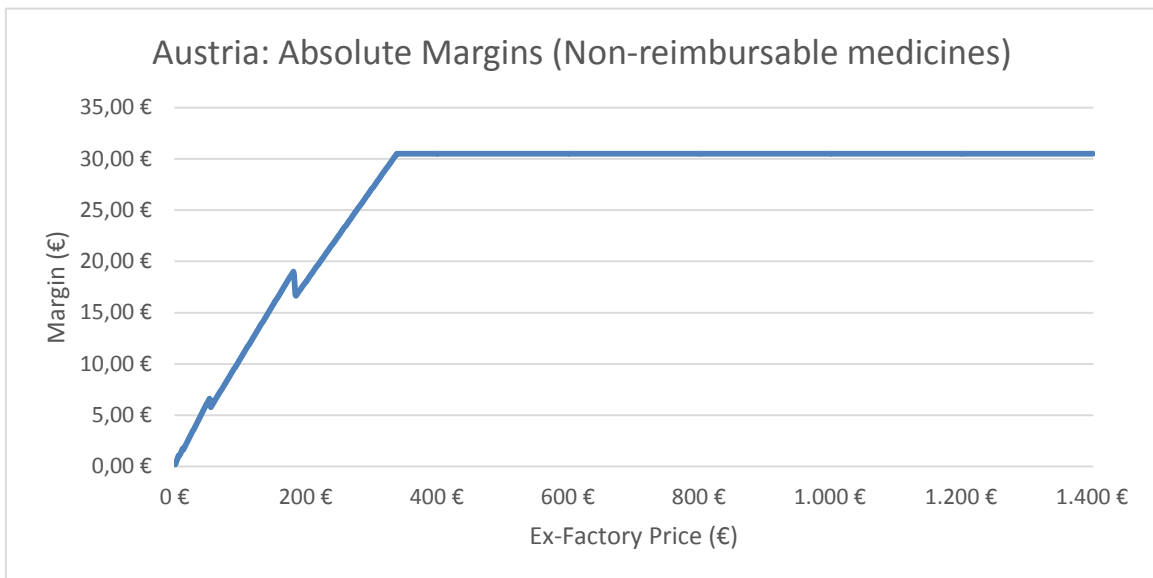


Figure 27: Austria, wholesalers, absolute margins for non-reimbursable medicines

For Austria, all non-reimbursable medicines up an EFP of 1527€ signify less than a 2% margin for the wholesaler.

In the case of pharmacies, from the regulation following graphs are derived of the 19 categories present (Bundeskanzleramt Rechtsinformation, 2016) for reimbursable medicines:

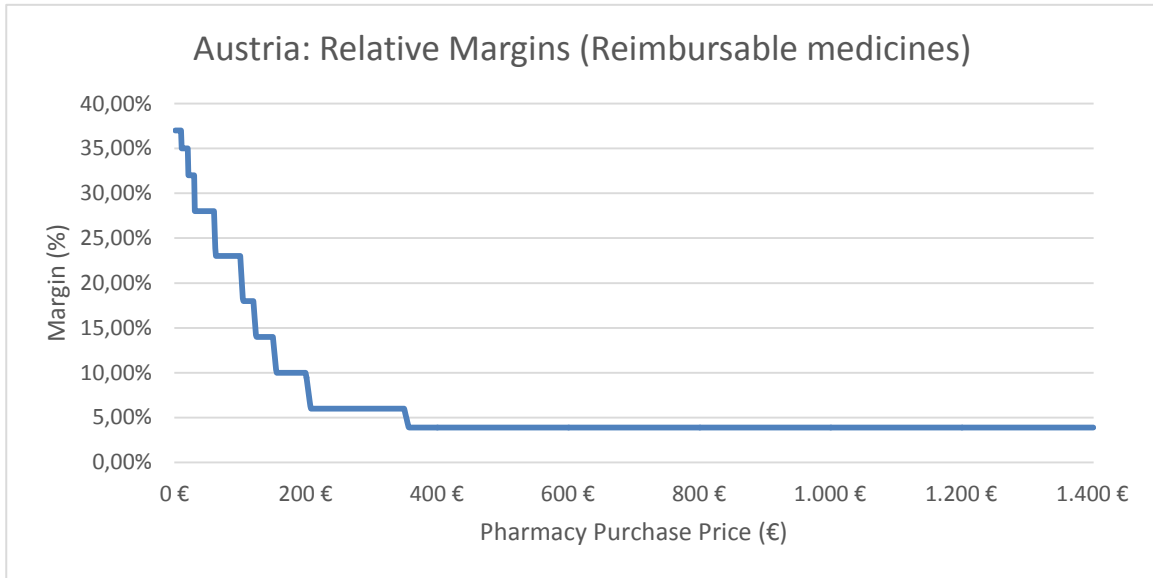


Figure 28: Austria, pharmacies, relative margins for reimbursable medicines

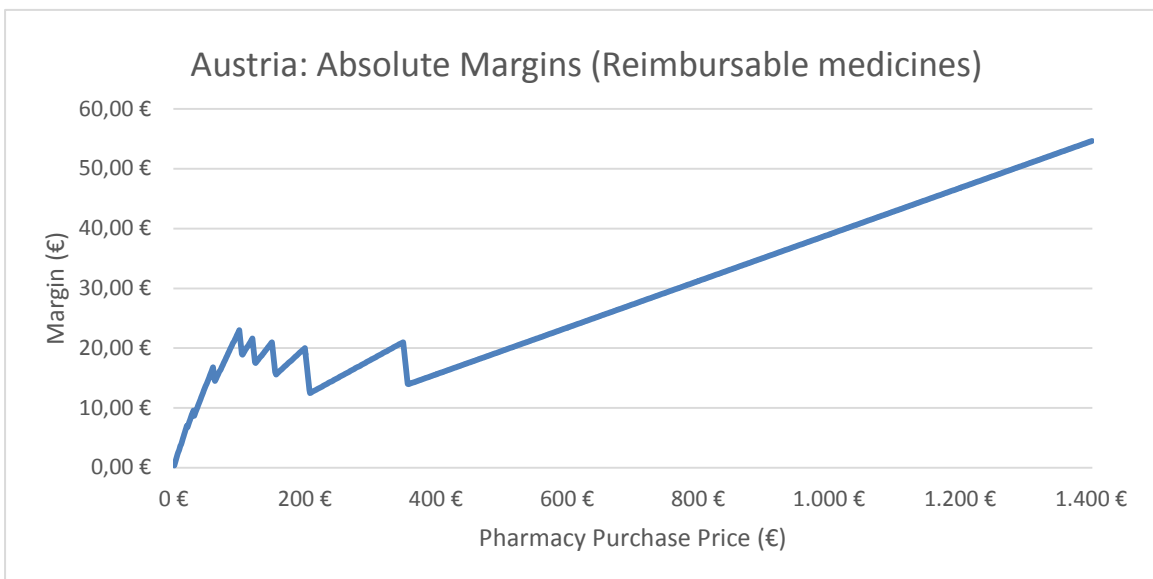


Figure 29: Austria, pharmacies, absolute margins for reimbursable medicines

For non-reimbursable medicines in pharmacies, the regulation is as follows (also 19 categories):

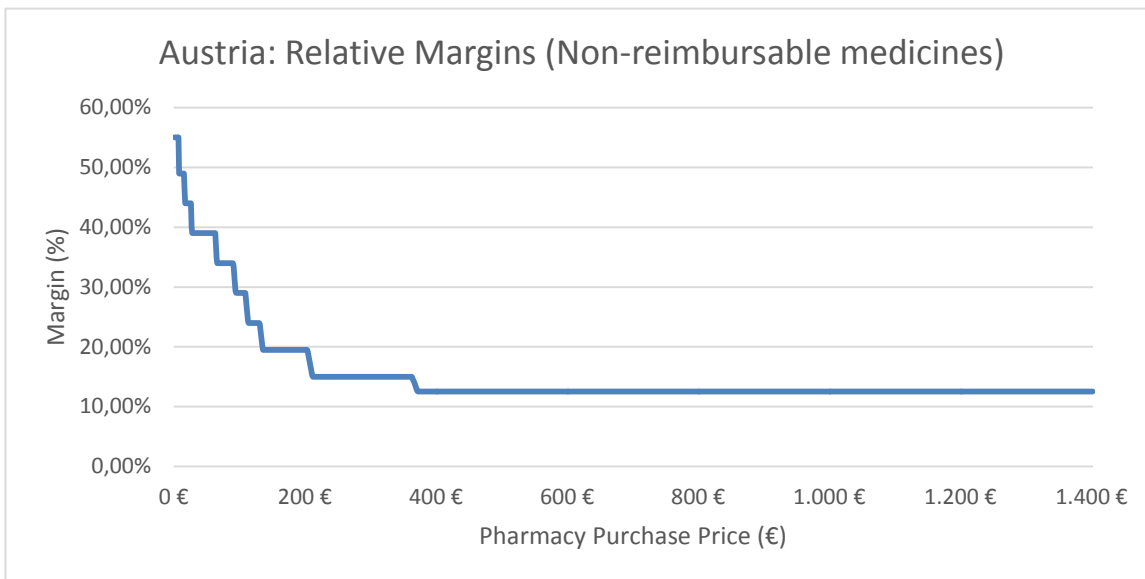


Figure 30: Austria, pharmacies, relative margins for non-reimbursable medicines

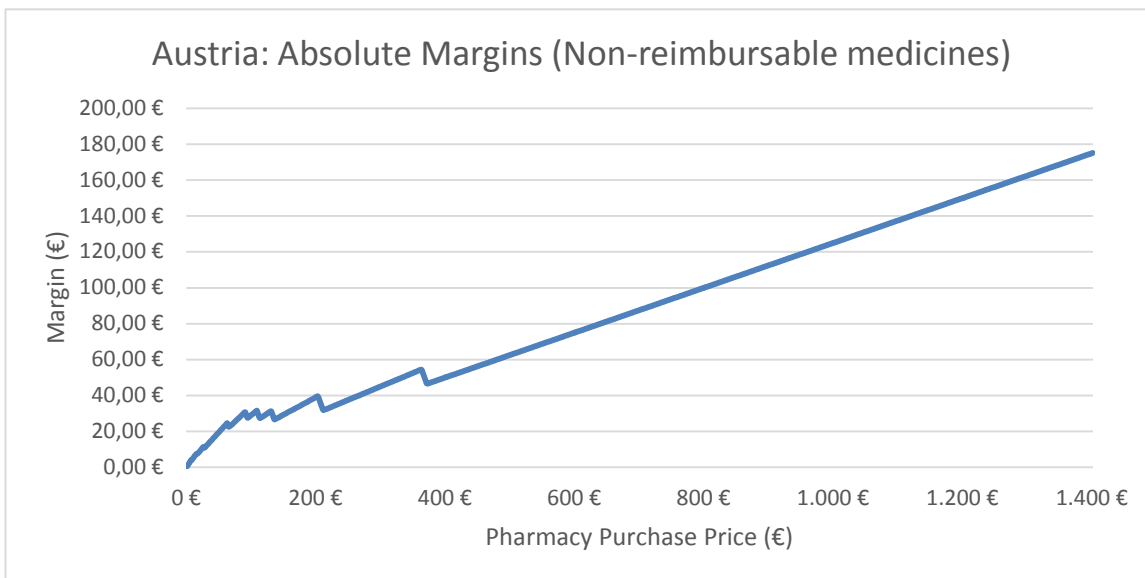


Figure 31: Austria, pharmacies, absolute margins for non-reimbursable medicines

(Note that pharmacies' margins are based upon PPP and not EFP.)

Portugal

For Portugal, the policymakers offer (the same) 6-categories' margin regulation for both wholesalers and pharmacies (Diário Da República Eletrónico, 2015). For wholesalers, the following applies

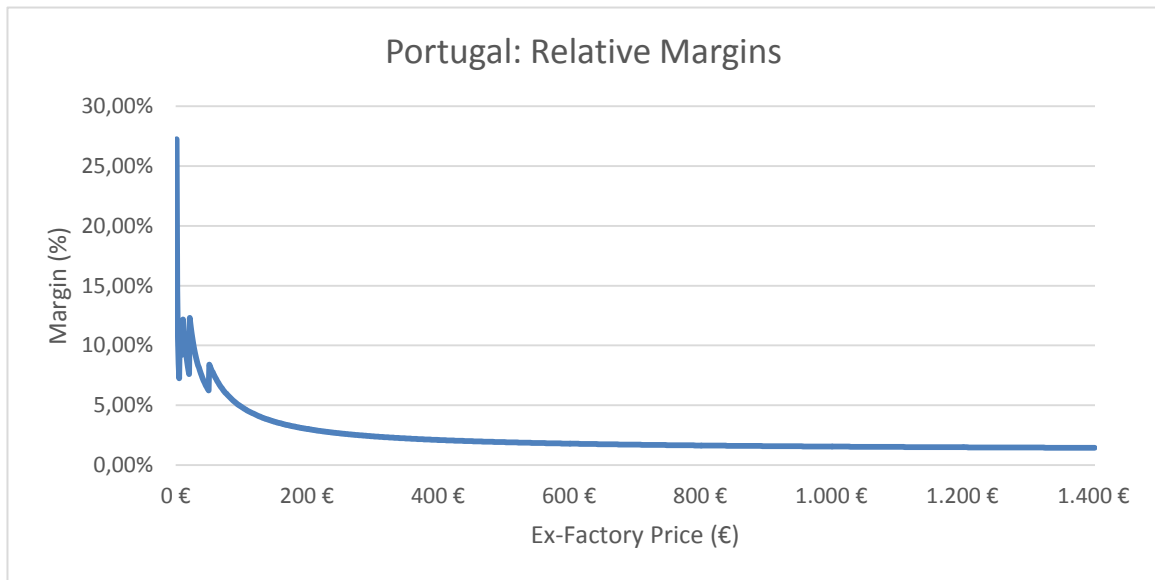


Figure 32: Portugal, wholesalers, relative margins

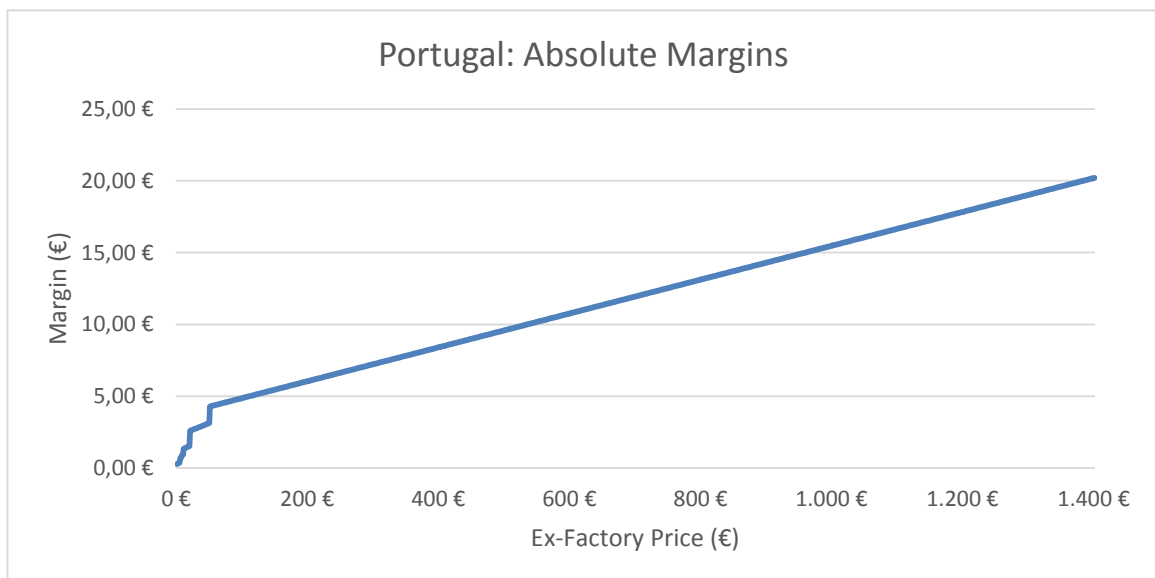


Figure 33: Portugal, wholesalers, absolute margins

For Portugal, all medicines up an EFP of 449€ signify less than 2% margin for the wholesaler.

For pharmacies, following graphical depiction is in place:

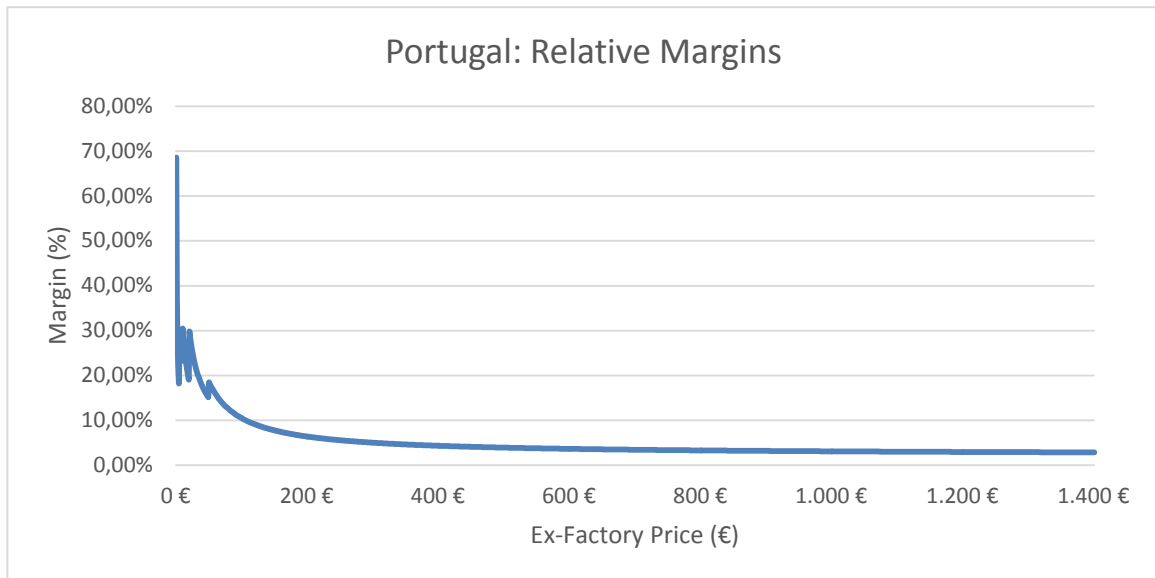


Figure 34: Portugal, pharmacies, relative margins

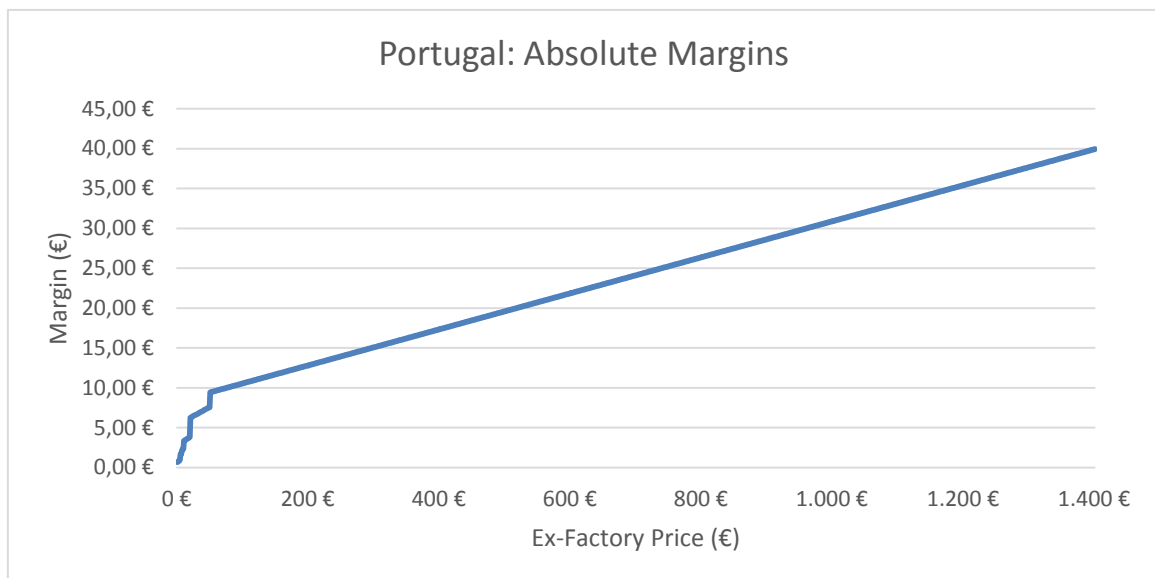


Figure 35: Portugal, pharmacies, absolute margins

Slovakia

In Slovakia, policymakers devised for the regulation of distribution margins for both levels a very complex 11 category regressive model in terms of EFP, in which on top of EFP is added a fix premium and a regressive margin based on the EFP minus the within-category lower range value (Ministerstvo zdravotníctva SR, 2011). Same ranges apply for wholesalers and pharmacies. For wholesalers, the margins are set as follows:

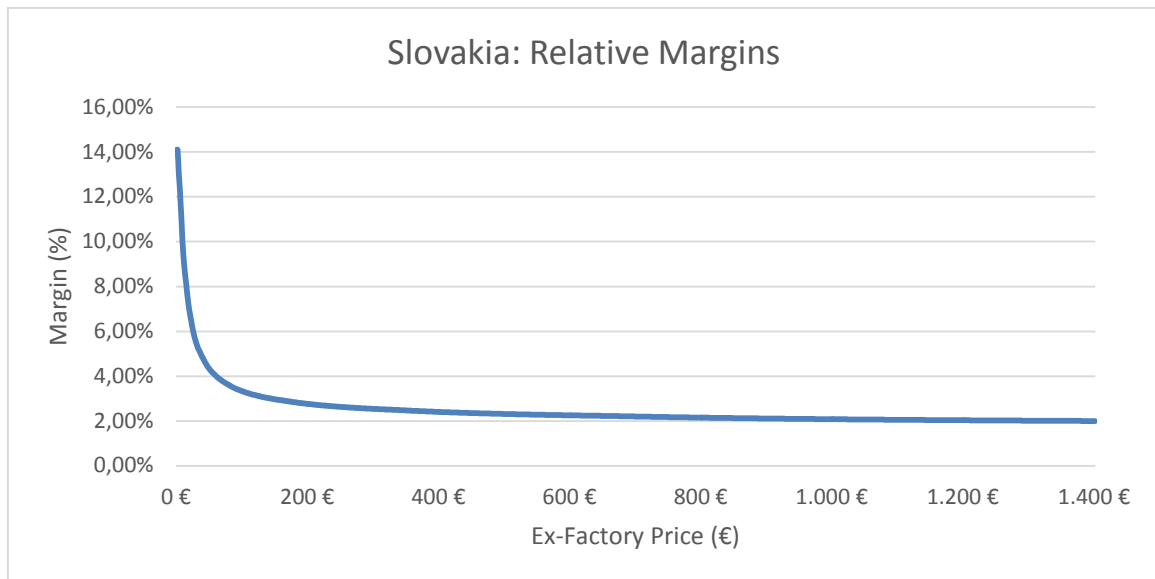


Figure 36: Slovakia, wholesalers, relative margins

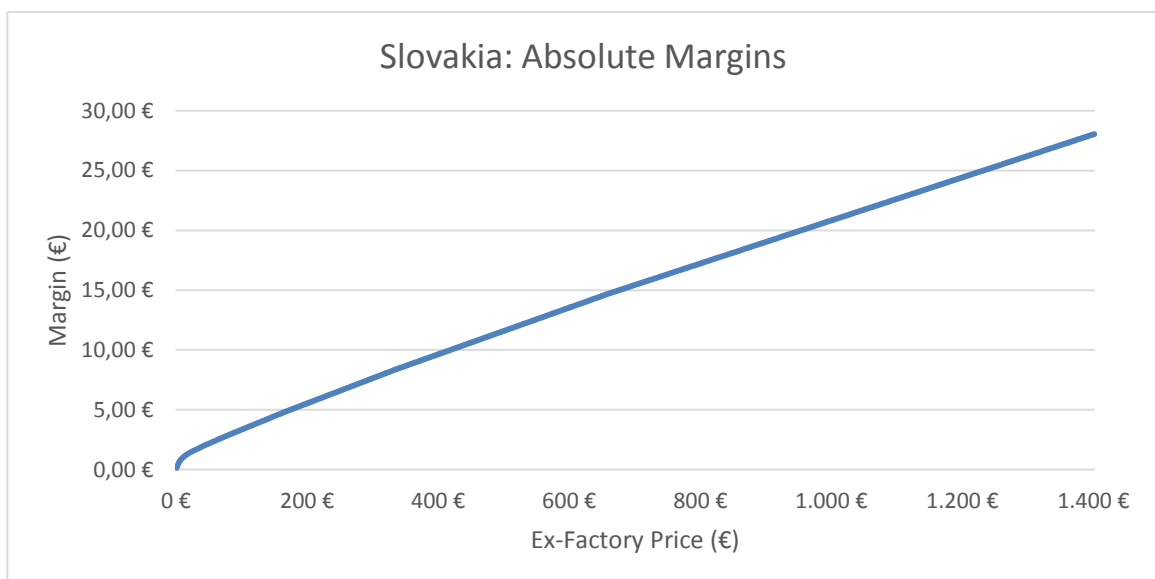


Figure 37: Slovakia, wholesalers, absolute margins

For Slovakia, all medicines up an EFP of 1416€ signify less than 2% margin for the wholesaler.

Pharmacies margins are depicted as follows:

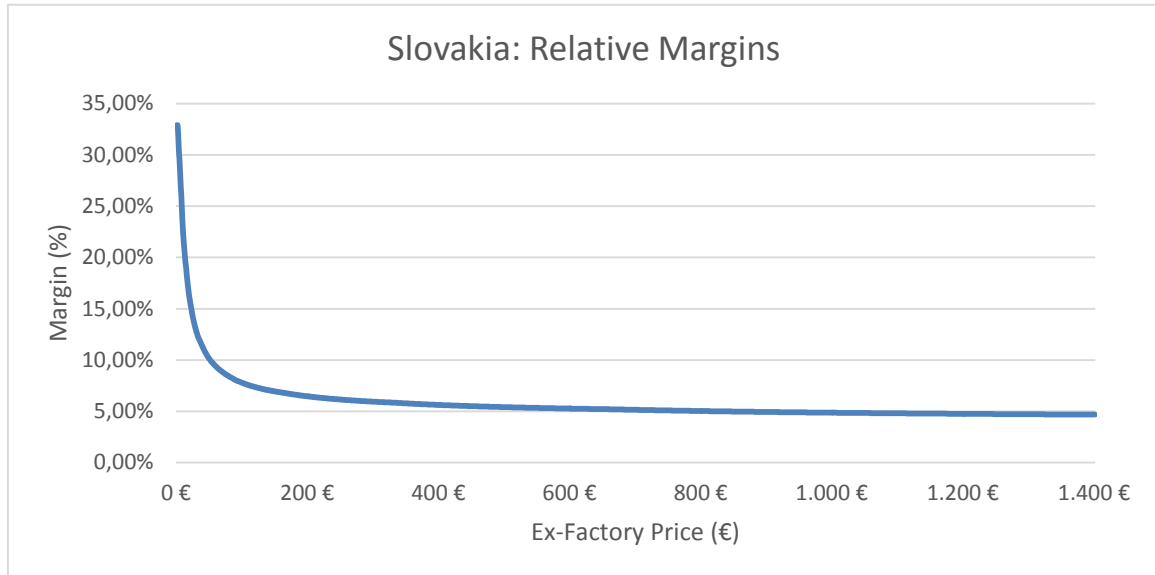


Figure 38: Slovakia, pharmacies, relative margins

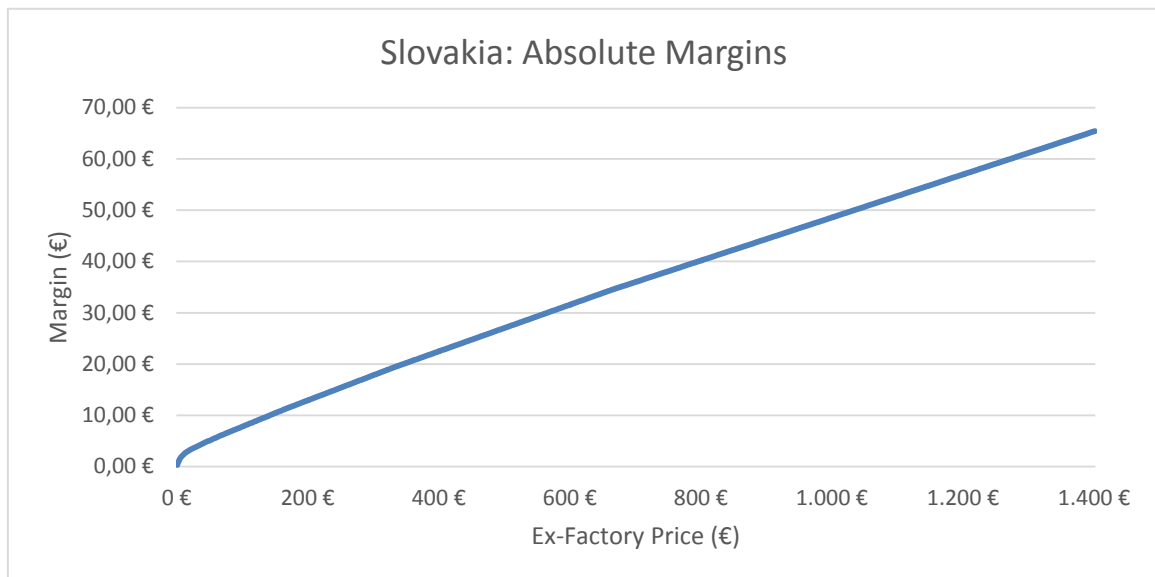


Figure 39: Slovakia, pharmacies, absolute margins

Spain

For Spain, margins are regulated both at wholesaler and pharmacy level. For wholesalers 2 categories are devised, for pharmacies 4 (Ministerio de Sanidad y Consumo, 2008).

For Spain, both regulations on wholesalers and pharmacies are portrayed by policymakers as “backward calculations”, as it was with Italy. Here, the author set forth again a conversion to “forward calculation”. Validation was not necessary, as the legislation itself showed that the conversion was accurate: the second category for both wholesalers and pharmacies margins are set as margins with absolute values, and these correspond exactly to the margin *after conversion* applied to the cut point between categories 1 and 2.²³

For wholesalers, the margins are graphed as follows:

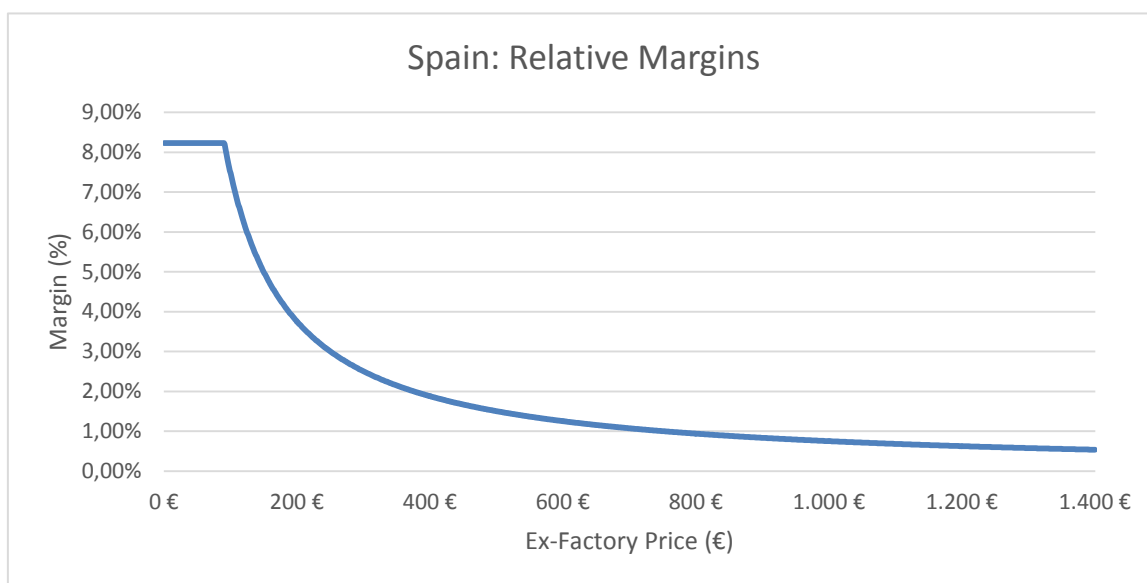


Figure 40: Spain, wholesalers, relative margins

²³ The converted values can be seen in Annex A – Spain.

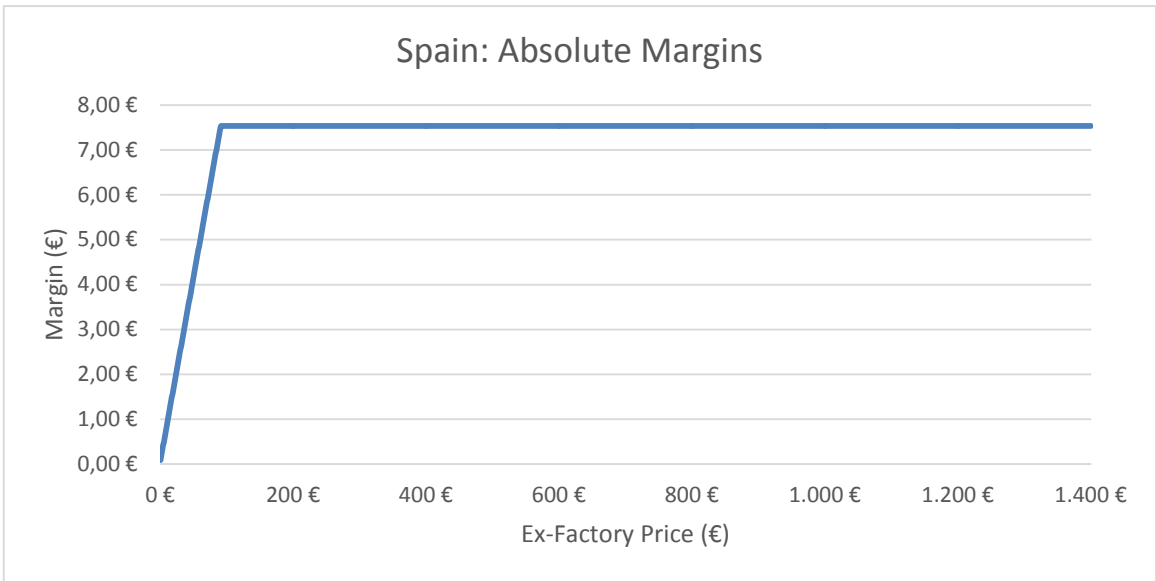


Figure 41: Spain, wholesalers, absolute margins

For Spain, all medicines up an EFP of 378€ signify less than 2% margin for the wholesaler.

The margins for pharmacies are set as follows (for the 4 categories available):

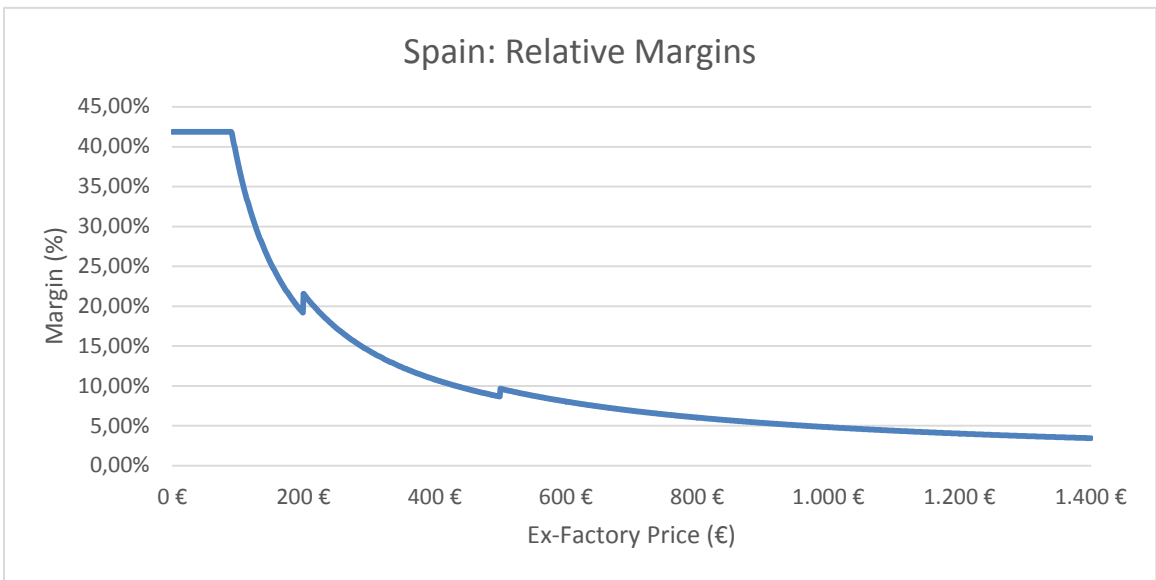


Figure 42: Spain, pharmacies, relative margins

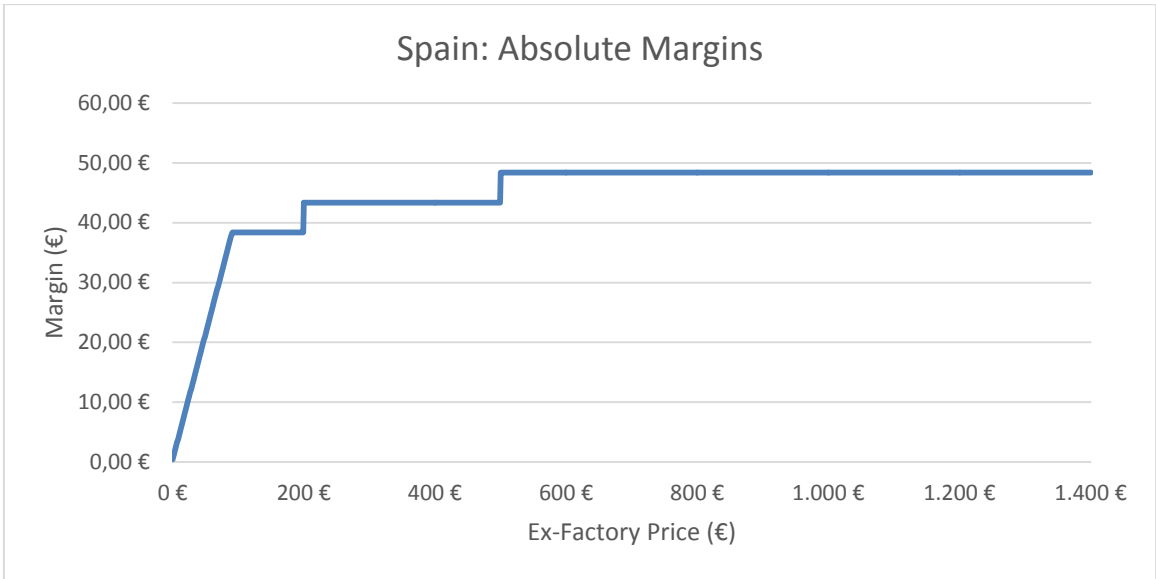


Figure 43: Spain, pharmacies, absolute margins

Germany

Germany, presented as a comparator, also regulates margins for wholesalers and pharmacies in an explicit manner, as depicted below for the 2 categories available (Bundesministerium der Justiz und für Verbraucherschutz, 2014):

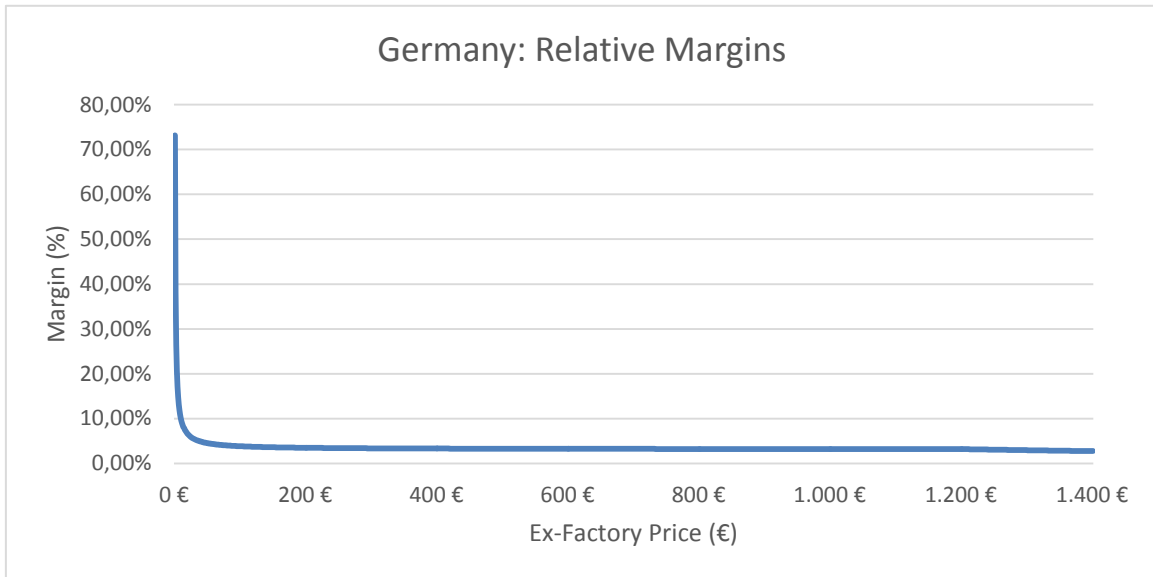


Figure 44: Germany, wholesalers, relative margins

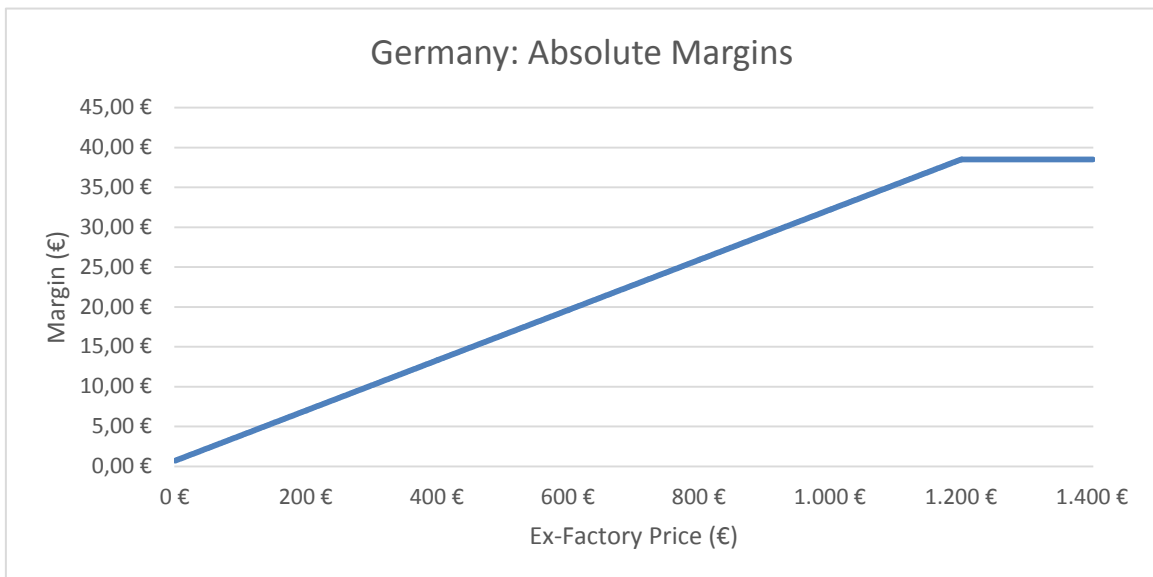


Figure 45: Germany, wholesalers, absolute margins

For pharmacies (also 2 categories), the margins are set as follows:

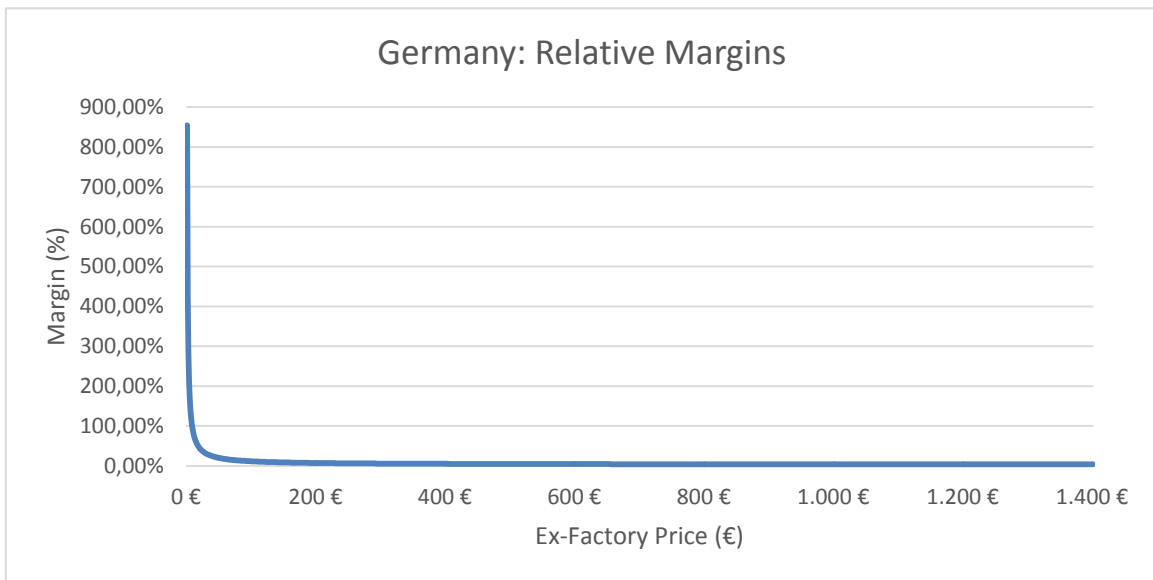


Figure 46: Germany, pharmacies, relative margins

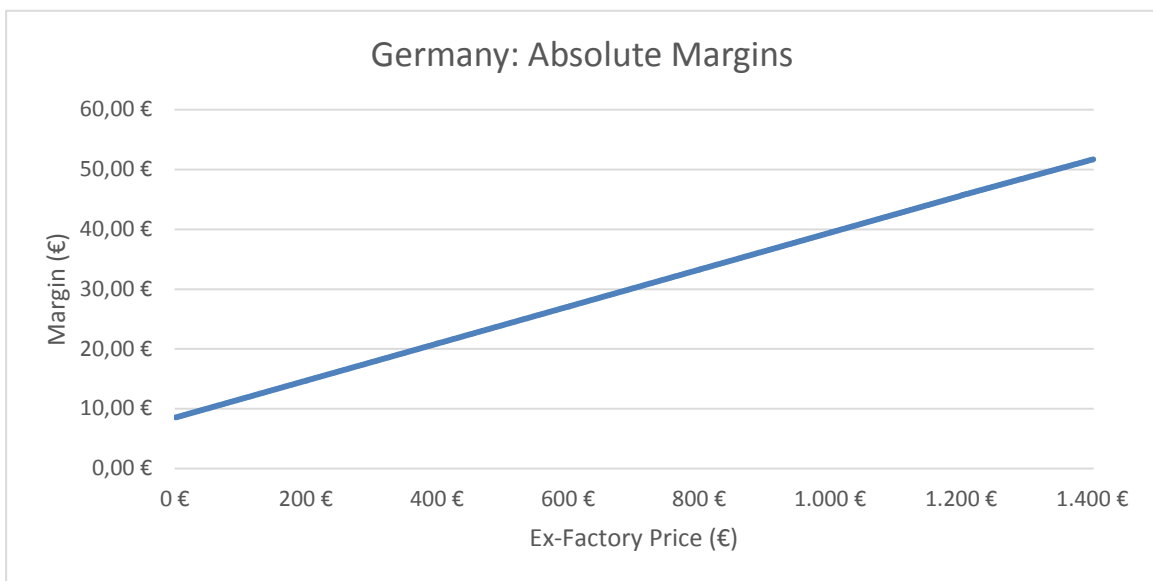


Figure 47: Germany, pharmacies, absolute margins

The abundance of examples shows the necessity for a *detailed* research and posterior *detailed* communication on the current State-of-the-art on wholesalers' margins in the EU15 Basket (and all other countries in a broader understanding, but beyond the scope of this paper). Generalizations, while easy-to-produce, are misleading as averages show no parallel in real world circumstances that drive markets for low cost versus high cost medicines, which is the axiomatic case for generics versus in-patent POMs. It is moreover vital to further *interpret* the establishment and application of margins in the context of driving forces that impact the real life settings under which they are embedded, as for subsequent countries with not so clear regulations show dynamisms that escape the shallow, first-come first-served "average market" portrayals.

Partial transparency

For the Netherlands, the legislators have set no margin whatsoever that pertains wholesaler or pharmacy level, but only caps for the maximum pharmacy purchase price and the maximum reimbursed price. This leaves ample room for WSs and pharmacies to negotiate the distribution of revenue in margins. Given that there is, nevertheless, some sort of regulated cap at individual product level before the end-user, the Netherlands fall under the “partial transparency” category (Ministry of Health, Welfare and Sports, 2014).

For the Czech Republic, there is a regulated cap for the sum of WSs’ and pharmacies’ margins. The distribution thereof is privately negotiated between both parties (Státní ústav pro kontrolu léčiv, 2010).

For the other 3 countries that fall under “partial transparency”, the legislation is clear enough on the margins for pharmacies, so that the graphical depiction is plausible. For these countries, as logic would dictate, the earliest price level upon which margins can be based on is PPP, as EFP and wholesalers’ margins cannot be confidently differentiated.

Denmark

For Denmark, policymakers only regulate the margins to be accrued to pharmacies (Sundheds- og Ældreministeriet, 2016). The conversion formula from PSP to PPP is already offered by the legislator, so reflecting the PPP is a matter of simple algebra (Danish Medicines Agency, 2016). There is only one category. The margins for pharmacies are then set as follows²⁴:

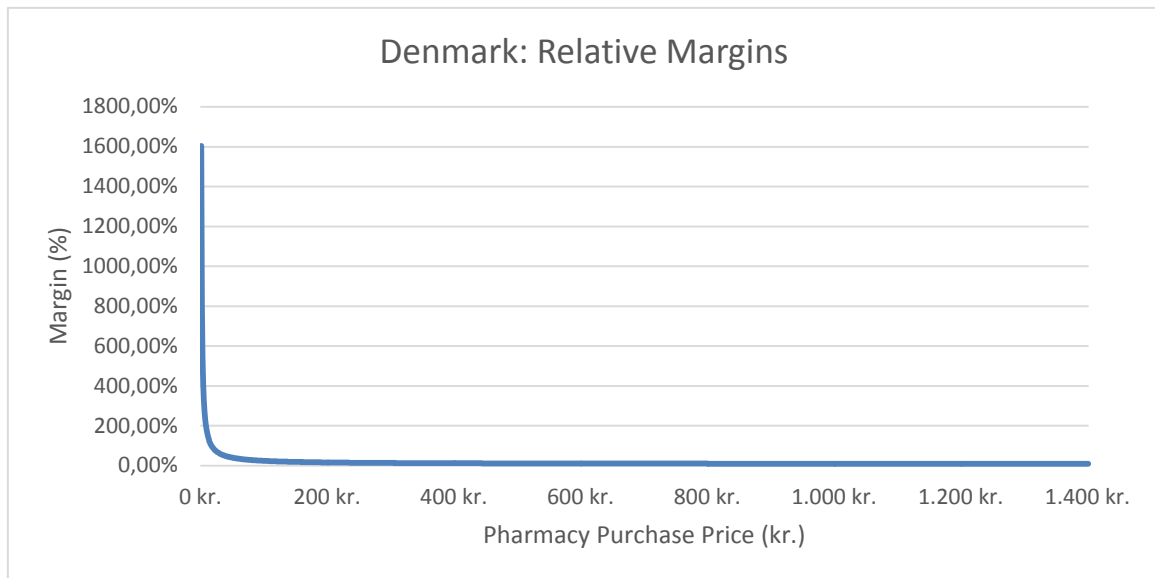


Figure 48: Denmark, pharmacies, relative margins

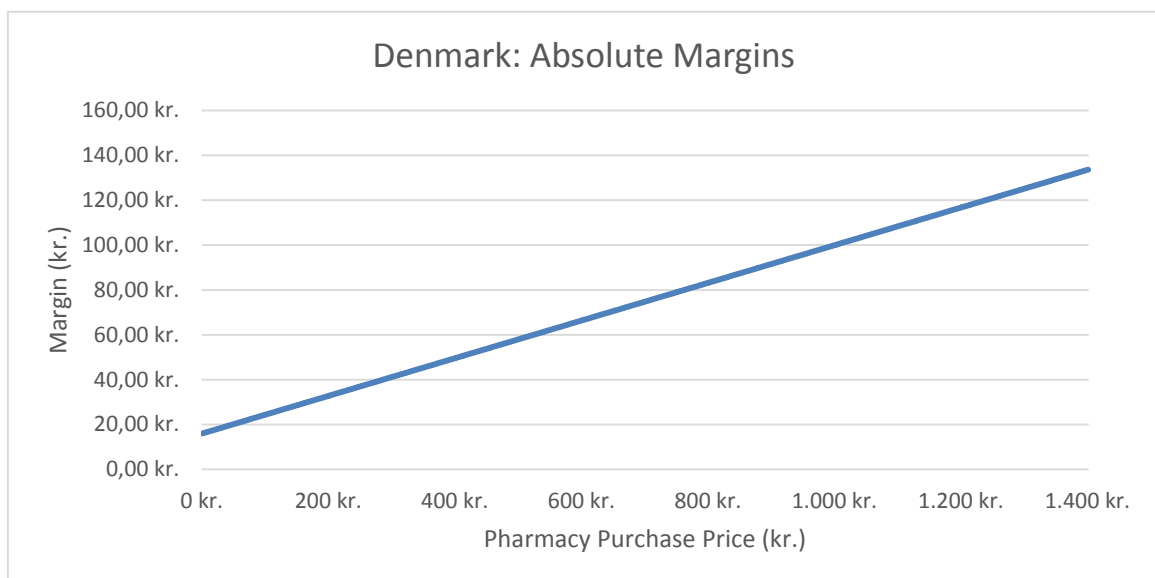


Figure 49: Denmark, pharmacies, absolute margins

²⁴ These include a general 8 kr. dispensing fee.

Finland

For Finland, the policymakers devised two schemes for regulating pharmacies margins: one for POMs and one for non-POMs. The same 5 categories apply with different markups (Finlex, 2013).

The regulated margins form POMs are set as follows:

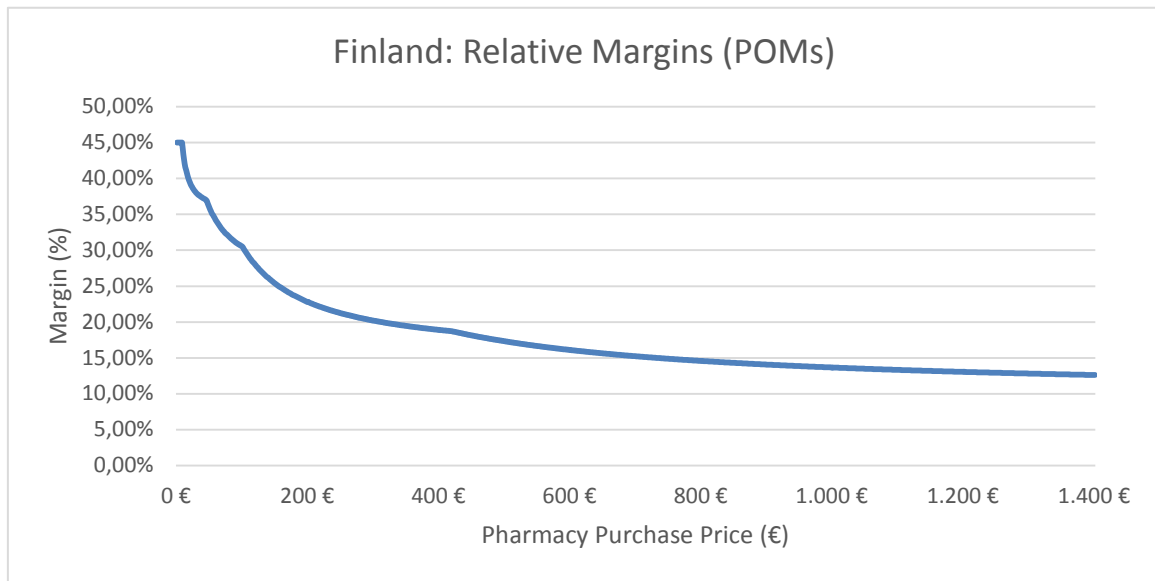


Figure 50: Finland, pharmacies, relative margins for POMs

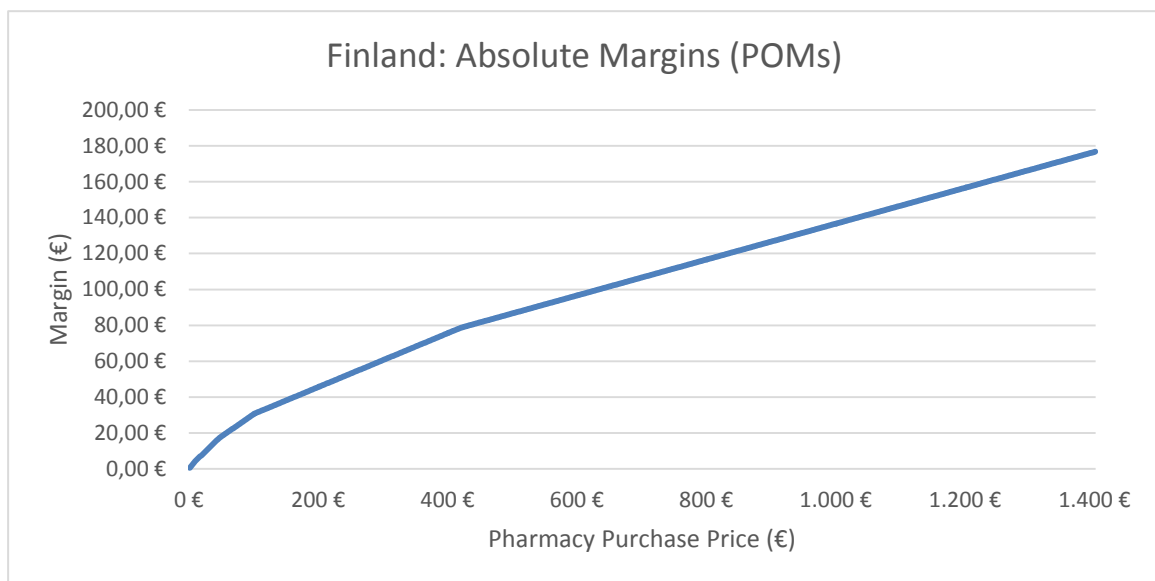


Figure 51: Finland, pharmacies, absolute margins for POMs

For non-POMs the margins are as set as follows:

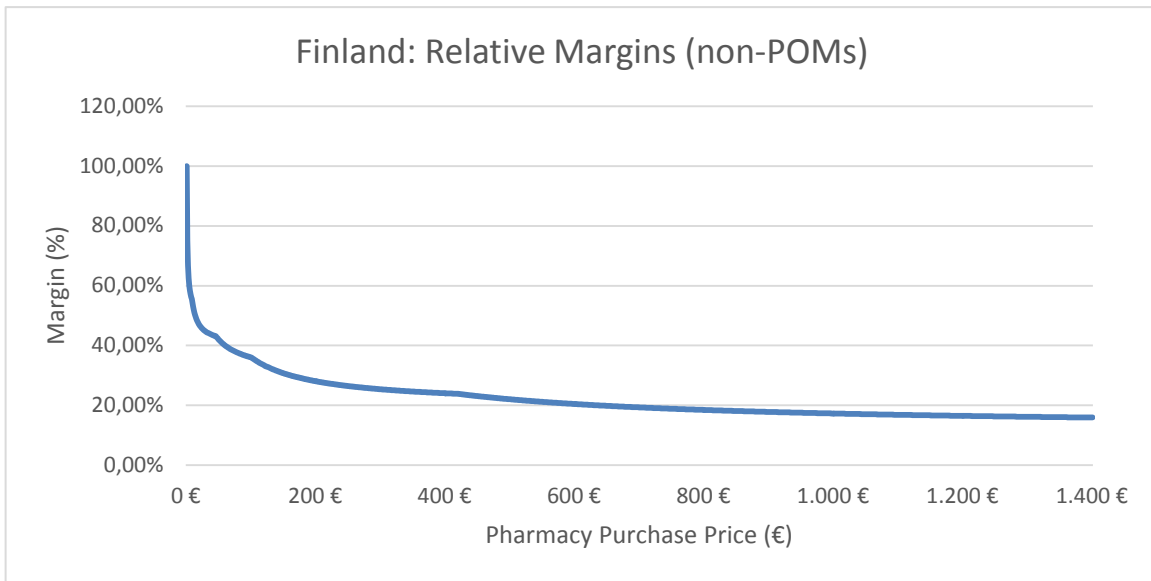


Figure 52: Finland, pharmacies, relative margins for non-POMs

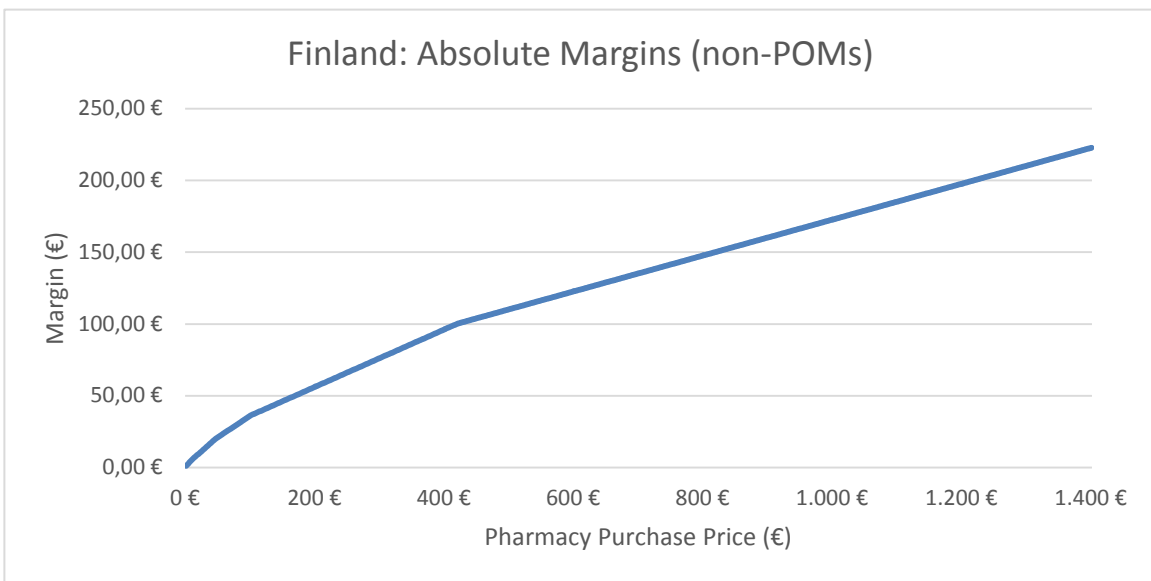


Figure 53: Finland, pharmacies, absolute margins for non-POMs

Sweden

The Swedish legislator devised two schemes for regulating pharmacies margins: one for in-patent products without generics competition and one for products with generics competition. The same 4 categories apply with different markups (Tandvårds- och läkemedelsförmånsverket, 2016).

For in patent products (without generics competition), the following are the margins to be accrued:

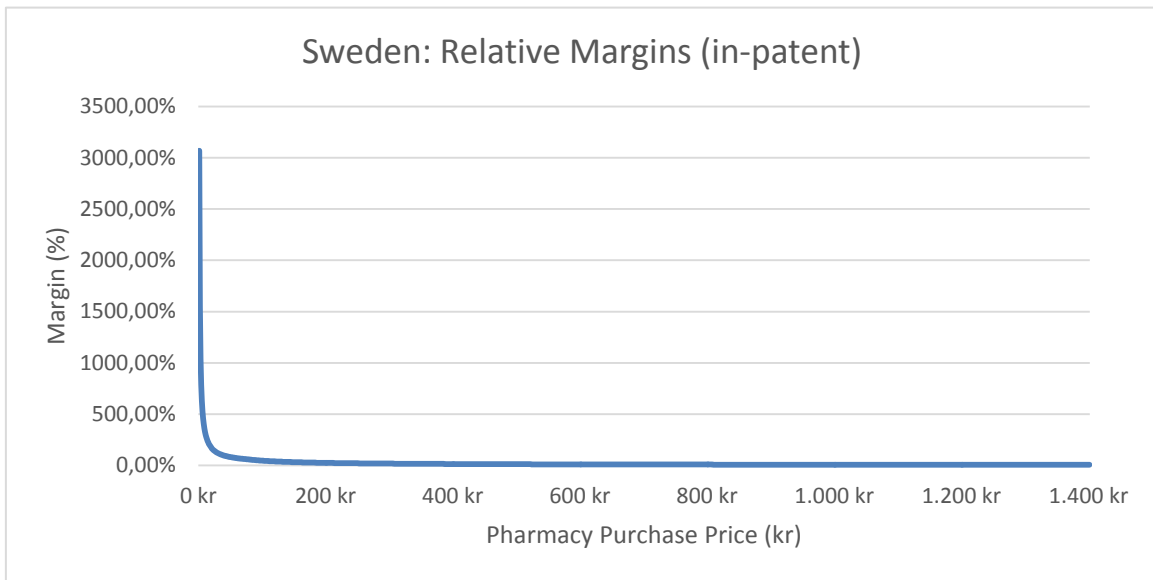


Figure 54: Sweden, pharmacies, relative margins for in-patent medicines

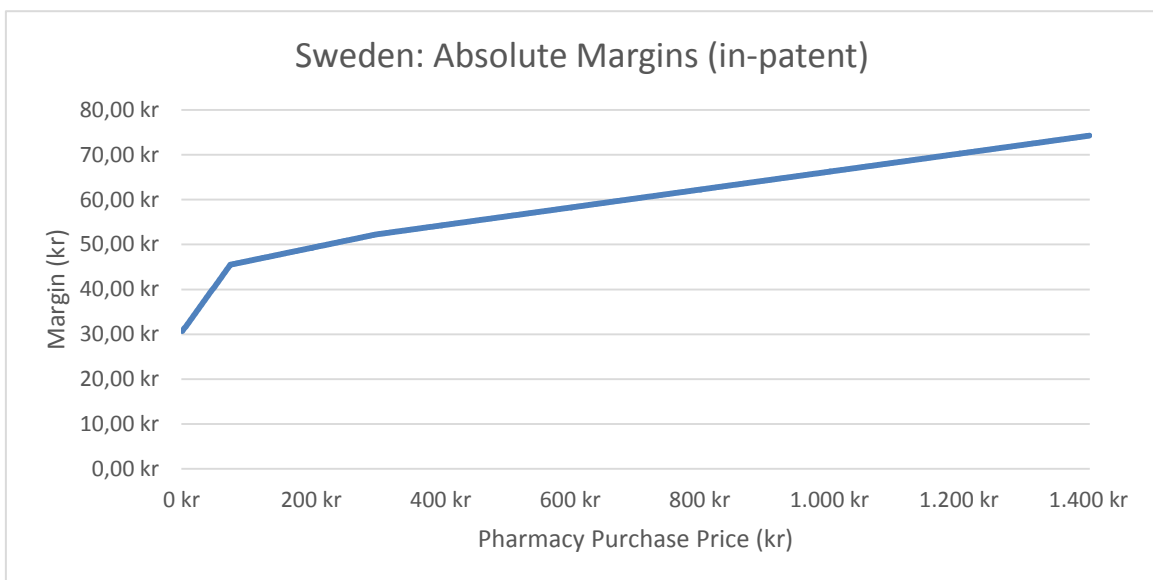


Figure 55: Sweden, pharmacies, absolute margins for in-patent medicines

For medicines with generics competition the margins are graphed as follows:

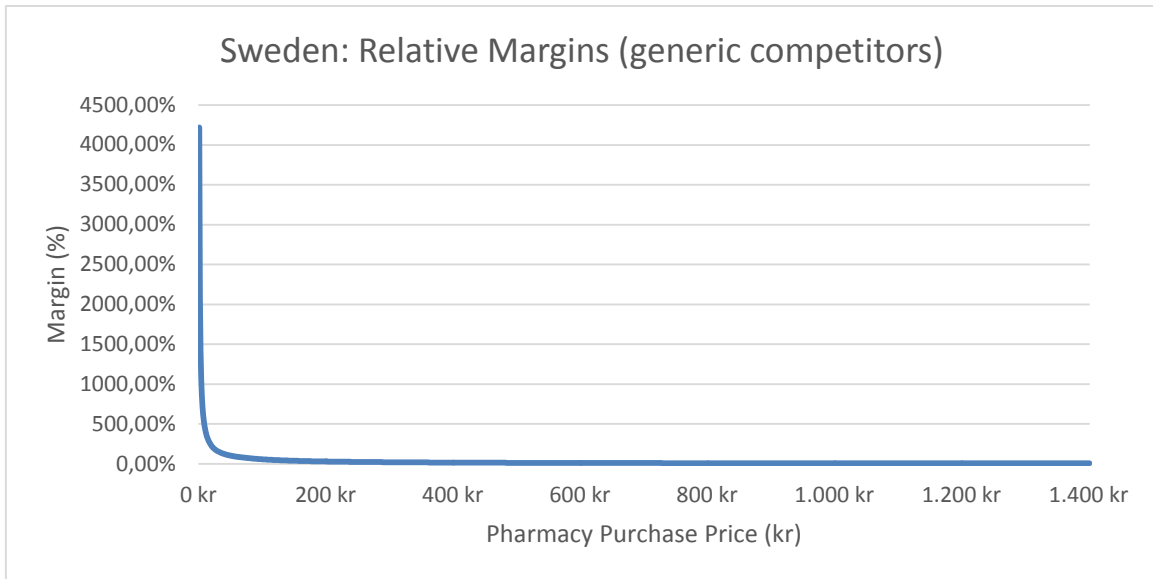


Figure 56: Sweden, pharmacies, relative margins for medicines with generics competition

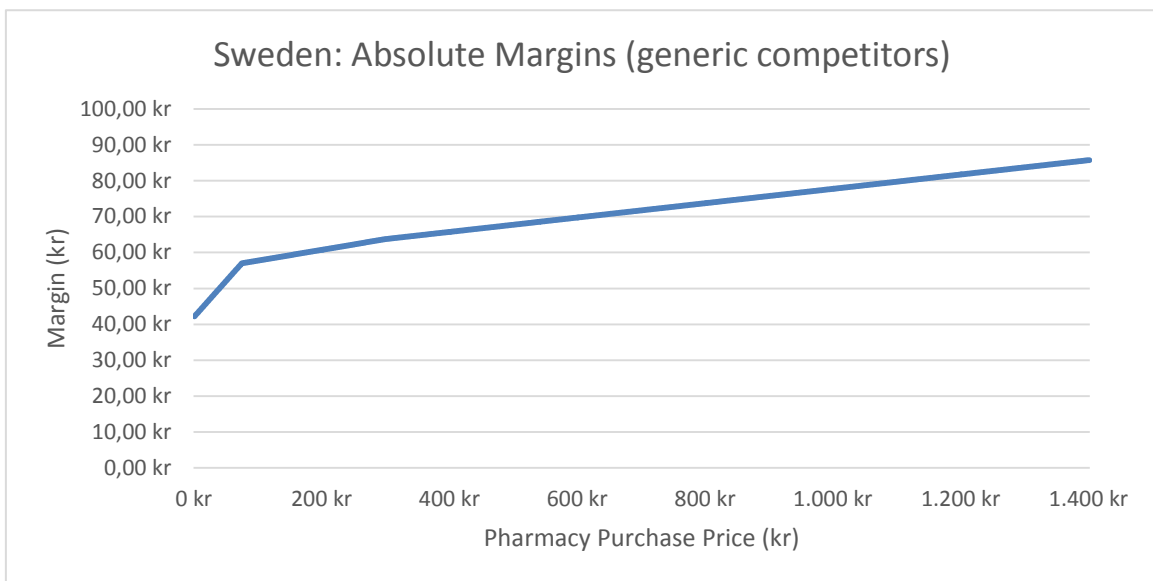


Figure 57: Sweden, pharmacies, absolute margins for medicines with generics competition

Private negotiations

For **Ireland**, the margin allocation is somewhat complicated. The wholesalers and pharmacies are restricted to a percentual margin of the pharmaceutical company selling price (currently 8%) that is distributed between WSs and pharmacies as negotiated behind closed doors between the two parties, while the pharmacies receive additional mark-ups in terms of “dispensed items” per month. This is not distinctive of in-patent POMs versus generics/OTCs medicines and margins’ distribution is unknown. Additionally, pharmacies are granted fixed premiums in amount-escalated categories regardless of the products’ nature, rendering the upstream calculation of margins for a given product impossible (Health Service Executive, 2007).

UK has a complex construct of pharmacy margins based on the total monthly revenue of a given pharmacy regardless of the medicines that make up for it. As such, the actual margin per POM (per package) falls into, again, a somewhat free-(margin)pricing model. WSs margins are *intentionally* free-enterprise regulated, subject to market forces and not political intervention (NHS Business Service Authority, 2016).

These two countries, together with Italy, are the only ones where the economic performance of the pharmacy is taken into account when deciding rebates or margin assignments. Given that Italy has previously set margins for wholesalers, at least one price level is traceable. For Ireland and UK, however, it is impossible to calculate with precision given item-dependent margins.

Given the historical cut of the findings for UK and Ireland, the results and the corresponding discussion are intrinsically coupled.

UK: nominal customs versus real transfers

Martikainen, Kivi and Linnosmaa (2005) briefly summarize the reimbursement as “The NHS pays the pharmacy the wholesale price of the pharmaceutical with a deduction of an estimated discount given by the wholesaler.” This brief introduction to wholesalers’ margins and reimbursement of payers is scarce but meaningful, as the information sources will show.

Garattini, Motterlini and Cornago (2008) note that, even though the margin of wholesalers is somehow known to be at around 12.5% – which in itself is debatable – in practice, the WSs transfer most of their margin as a discount to pharmacies for competitive reasons, averaging 9% in transference. This means that UK wholesalers would actually retain a mere 3.5% of the public price, which accounts for the logistics services provided to pharmacies downward and pharmaceutical companies upward. Given the ever growing liberalization of the distribution pathways and actors, in the aforementioned publication on price and distribution margins comparison of in-patent drugs, the aforementioned authors could only assign *actual* net distribution margins of 6.7% (wholesalers + pharmacies) to the studied products in the carried-out analysis; the net distribution margins of the seven studied countries (Belgium, France, Germany, Italy, Netherlands, Spain and UK) yielded for UK *the lowest net distributions margins* in the sample.

Carone, Schwierz and Xavier (2012, p.43) argue that “The impact of the distributors’ margins on the final retail price of prescription medicines varies strongly between EU Member states (Kanavos et al. 2011a)”. Kanavos, Schurer and Vogler (2011) in turn, reference Garattini, Motterlini and Cornago (2008) as an information source and note further down notes that “Wholesaler margins are continually squeezed downwards by pharmacies (...)”, highlighting the importance of *offered* discounts versus *actual* margins – WSs transfer a great amount of the discounts received from pharmaceutical companies in order to compete in a liberalized market, thus retaining low margins that cover the services granted. In Kanavos, Schurer and Vogler (2011), the 2007 source cited for the UK 12.5% WSs margin is not duly referenced, but can only go as to *try and estimate* offered discounts, disregarding the transfer of the latter and the resulting low margin for WSs that ultimately corresponds; it is described as “an unwritten “agreement” but widely understood to be the case”, which, being a 2007 publication, points directly at the Office of Fair Trading study on medicines distribution (Great Britain Office Of Fair Trading, 2007).

In the year 2007, Pfizer announced a new – and novel – arrangement with the wholesaler Unichem, whereby the pharmaceutical company would sell its prescription drugs solely through the aforementioned WS. This announcement was accompanied by great criticism from the wholesaler industry (Hogan Lovells, 2008), arguing a breach in EK and EC competition law, asking the OFT²⁵ (closed on April 2014) to take action. This situation led the OFT to conduct a general market study into the distribution of medicines in the UK, a

²⁵ Office of Fair Trading, Government-appointed agency of the United Kingdom that worked to ensure the abidance to competition law and the protection of consumers in the economic market regulation framework. Decommissioned in 2014, its duties where delegated to different governmental agencies.

2007 published manuscript where it is stated that “(...) although manufacturers are not legally obliged to offer wholesalers a discount of 12.5 per cent from the list price, there is general adherence to it as a ‘custom and practice’ so that in effect the PPRS constraints prices to wholesalers” (Great Britain Office Of Fair Trading, 2007, p.5).

This goes directly in line with Kanavos, Schurer and Vogler (2011) and would support the – shallow – thesis offered by Carone, Schwierz and Xavier (2012) that UK WSs margins are to be estimated at a 12.5% level. This, however, is to be taken with more than just a pinch of salt, as this reductionist statement violates the true nature of discounts in the UK medicines distribution setting when put into practice.

To illustrate the preceding concept, the OFT market study clarifies, directly after mentioning the customary discount to wholesalers (on the same page), that

The PPRS²⁶ and pharmacy reimbursement

(...) However, pharmacies generally secure a significant discount to the list price when purchasing branded medicines from wholesalers. In order to maintain pharmacy reimbursement at an agreed level, the NHS takes back some of the excess margin earned from high discount levels by using a 'clawback' mechanism. This is calculated as a percentage of the reimbursement price to pharmacies. Because pharmacies receive an agreed level of margin from the NHS, any decreases in the discounts received by pharmacies would be expected to increase the costs to the NHS as it would be able to 'clawback' less. *The actual price paid by the NHS for medicines (on average) is a combination of the list price minus clawback.*²⁷ Any reduction in pharmacy discounts would therefore feed through directly into higher medicines costs to the NHS

(Great Britain Office of Fair Trading, 2007, p.5. Emphasis added by the author).

The UK policymakers devised a payer-discount-independent strategy to regulate wholesalers' and pharmacies' margins at subsequent distribution levels, as the appointed market study reveals. It is in the uttermost interest of the NHS that discounts transferred

²⁶ PPRS (Pharmaceutical Price Regulation Scheme): The mechanism offered by the UK Department of Health to ensure the NHS is delivered branded medicines at fair prices for both parties, under voluntary agreements between pharmaceutical companies and the national payer.

²⁷ Emphasis added by the author.

from wholesalers to pharmacies remain as high as possible, so that the clawback mechanism can collect back as much as possible and thus the real costs for the NHS remain as low as achievable. This, said explicitly, means that the paid price for medicines in the UK results on the combination of list price minus clawback (that is, transferred discounts), leaving a very small room for *actual* distribution margins. Simply put: An *actual* wholesaler margin of 12.5% would render the pharmaceutical distribution chain unsustainable.

Further down, the aforementioned study states that around 9% of the amount reimbursed to pharmacies is clawed back and that wholesalers' discounts transfers to pharmacies average around 10.5%. These results, when combined with the mentioned customary (and confidential, thus not valid but only guessed/approximated) WSs' margin of 12.5% posited in Kanavos, Schurer and Vogler (2011) (extracted *a priori* from the OFT market study), *actually* mean an overall distribution margin of 3.5% with wholesalers' margins of around 2% and pharmacies' margins of around 1,5%. The pharmacies' margins are plausibly low given the *NHS Electronic Drug Tariff* that regulates further deductions based on economic performance of pharmacies (NHS Business Service Authority, 2016).

The resulting 2% wholesalers' margin accounts for the operational costs of such logistics provider companies and presents itself as a payer-discount-independent political regulation strategy that ensures fairly low prices for the payers without having to enforce direct regulatory interventions of the government on the wholesalers' markups; the rebates the pharmaceutical company could – and actually – directly offers to the NHS remain therefore unharmed.

The annotations by Carone, Schwierz and Xavier (2012)²⁸, thus, completely disregard the abysmal conceptual differences between markets for in-patent POMS and markets for generics. The latter could be subject to more “customary” measures (this itself is to be taken with a pinch of salt), whereas the in-patent POMS usually have lower rotation with higher prices, meaning wholesalers' margins as high as portrayed wouldn't be in line with the services the WSs offer (unjustified high margins for the operational costs and expected profit).

²⁸ The document published states, on the header of the second page, that „(...) the views expressed are the author's alone and do not necessarily correspond to those of the European Commission.”

If margins this high were applied to medicines with few packages sold per unit of time at higher prices, it would be in the best interest of pharmaceutical companies to forego the WSs distribution services to pharmacies and set up their own distribution channels –this concerns policymakers, which have devised mechanisms and regulations to assign to wholesalers what their operational costs and profits would be required for them to further be competitive while (down-) adjusting payers distribution costs (not to be confused with pharmaceutical companies discounts). A further example of this is the historical development of wholesalers' margins in Ireland.

Ireland: transfers (read as “actual margins”)

For the unwary reader, wholesalers' margins in Ireland are set at an absolute 8%; statutory instrument 2009 (Health professionals (reduction of payments to Community pharmacy contractors) regulations 2009) lowered the previous markup for wholesalers from 17.66% to 10%, statutory instrument 2011 (Health professionals (reduction of payments to Community pharmacy contractors) regulations 2011) lowered it to 8%, and the 2013 iteration (Health professionals (reduction of payments to Community pharmacy contractors) regulations 2013) kept it unchanged. The documents (2013 being the most recent and in force at this time) then go on to specify the margins *pharmacies* are to be assigned in terms of dispensed items per pharmacy in a month, and portraying certain special cases of additional fees (phased dispensing fee, non-dispensing fee and others pertaining extemporaneity of dispensation), with a clear annotation that the “reimbursement amount per drug item” corresponds to the mentioned “ingredient cost” (that is, EFP plus wholesalers' margin of 8%).

The plot thickens, however, if one is to look back in time and follow the steps that led to this 8% regulation and – subsequently – *interpret* them. It is in the gradual reduction of the wholesalers' margins via reduction of reimbursement to pharmacies that an understanding behind the policymakers rationale and actual legislation is to take place; the final result being the interpretation of 8% as *maximum 8%*, while actual markups (given unchanged market conditions) lie well below that figure.

With the advent of economic adversity, the 2005 Irish government decided it was time to adjust the belt on the expenditure of medicines embedded within the various community drugs' schemes that structure their reimbursement arrangements. This led to the appointment of a broad-spectrum Health Service Executive/Department of Health and

Children (HSE/DOHC) Team whose goal was to analyze the entire medicines distribution process in order to be able to reach new arrangements on production and distribution costs with manufacturers and pharmacists (and, to some extent, with wholesalers too). In the year 2006, novel arrangements were made with the Irish Pharmaceutical Healthcare Association (IPHA) and the Association of Pharmaceutical Manufacturers of Ireland (APMI) (Health Service Executive, 2007). Left was the issue of wholesalers: There was no arrangement model agreed upon between the HSE and wholesalers. The HSE hence built up a respective margin in regulation law assigned to the aforementioned ingredient costs, and indirectly controlled it through pharmacy reimbursement.

After agreements with manufacturers were undertaken, the HSE/DOHC went on to sit and negotiate with wholesalers; negotiations ended before they could begin because of legal issues that arose (non-compliance with the Competition Act of 2002). Following, the HSE/DOHC appointed INDECON to a broad economic analysis on the wholesalers market for the Irish and European contexts. Of paramount importance was for the study to assist policymakers in setting a *fair* price for payers to accrue on the wholesalers' actual services provided (see particulars and pooled conclusions in the publication from Health Service Executive, 2007).

Before then, the margin was set to be 15% on ex-factory price (EFP=100,00€, then PPP=115,00€) but was partially reinterpreted as 15% of the wholesalers selling price (PPP=117,60€ to result on an EFP=100,00€) landing in an actual margin for wholesalers of 17,66% on ex-factory price²⁹.

The then market set margin of 17.66% on ex-factory price (15% of ex-wholesaler price derived of the aforementioned misunderstanding) was unilaterally sunk to 8% after the study found that

“There is no doubt that the wholesale market is very competitive. It is also obvious that the retail pharmacists exercise their significant buying power over the wholesalers/distributors and now enjoy a very favourable business model.

(...) Retailers are paid the reimbursement price (price to wholesaler +15% margin) in respect of community drugs schemes. The reality is that wholesalers provide to retailers very significant discounts and rebates. It is estimated that wholesalers

²⁹ The margin was set as a “forward calculation”, but was misinterpreted as a “backward calculation”. See “Italy”.

currently pay over an average of half of their margin to retailers in the form of rebates and discounts.” (Health Service Executive, 2007)

Research showed – and the HSE published – that margins are known to be transferred from wholesaler to pharmacies to better attract clients and often accompanied by large-acquisitions preconditions.

If this wasn't clear and logical enough, the market structure for Ireland can then shed more light on the issue: as of the time of the study, 3 full-line wholesalers³⁰ were known in the Irish market: United Drug, Cahill May Roberts and UniPhar; nowadays there are 4 listed, with the addition of Boileau & Boyd³¹. This means that there are 4 big players competing to supply the approximately 1600 Irish pharmacies ((European Healthcare Distribution Association, 2016); since these are full-line wholesalers, the competitiveness ground is further intensified, as pharmacies mean either a *go* or *no-go*, without middle points.

The higher the competitive ground, the higher the pressure to transfer margins in such a way that net profit remains mostly unharmed; this is clearly summarized as

“The HSE/DOHC Team have made it clear to all the elements of the pharmaceutical sector that it wants to pay a fair, reasonable and transparent price to all segments.

The current arrangements in respect of Wholesale/Distribution services are not transparent. Equally costs are being incurred by wholesalers (on delivering generous trading terms to retail pharmacies) which are not appropriate for the Exchequer to reimburse.” (Health Service Executive, 2007)

It could be even assumed, from a utilitarian point of view, that pharmacies in Ireland would be interested in pursuing higher margins for wholesalers, as this would indirectly mean higher transfers to them in the supply negotiation process. This assumption would only – again – confirm the fact that wholesalers keep just a relatively small cut of their margin (to

³⁰ Full-line wholesalers are ones that supply the entire range of medicines need for a given pharmacy.

³¹ These are the (full-line) wholesalers associated in the Pharmaceutical Distributors Federation (PDF). Other short-line wholesalers are to be found in the Irish market, but these have very low diversity of pharmaceuticals and often compete with parallel imports, diverting from the competitive ground of full-line wholesalers.

cover operational costs and net profit expectations) and transfer the rest to pharmacies, meaning that any estimate on wholesalers' margins is potentially *overestimated*. Wholesalers care for an appropriate return of investment while keeping their clients, the pharmacists, happy – and the delicate equilibrium between the interests of both was made clear shortly after.

After the HSE/DOHC realized the need for change and instituted a unilateral reduction of wholesalers' margins to 8% of ex-factory price enforced by the end of 2007, pharmacies went public to confirm what the previous paragraph offered as a seemingly far-fetched assumption: In September 2006 and September 2007 the 26-pharmacies chain Hickey Pharmacies took on a case against the HSE for breach of contract, stating they could not unilaterally alter the wholesalers' margins without proper consultation, which was absent throughout the markup reduction process. This obliged the HSE to reinstate the previous 17.66% (of EFP) margin for wholesalers by the end of 2008 (Gorecki et al., 2012, pp.87ff).

The late institution of this reduction to 8% was successfully implemented under provisions of the "Financial Emergency measures in the Public Interest Act 2009 (FEMPI, No. 5 of 2009) where the legislation body was given enough decision latitude to be able to forego consultations and institute the reduction measures. Firstly came a reduction to 10% in 2009 and a further reduction to the target 8% in 2011. These rulings were, once again, challenged by the pharmacist, only this time they were not successful.³²

A pharmacy chain that makes a case against the reduction of the wholesalers' margin; this is the *most explicit evidence of wholesalers transferring their assigned margin on to pharmacies* in order to stay competitive. Policymakers saw an opportunity to adjust the wholesalers' margins to a sum that corresponds to their efforts plus financial gains while at the same time assuring continuity in distribution at no lesser quality, reducing medicine expenditure while keeping all stakeholders financially viable.

And, as mentioned before, the market structure to be found back then has remained mostly unchanged; there is still wholesalers' profitability – hence margin transfer – pressure to be expected, while the players are essentially the same. The current model is therefore not threatened or eager to change. This is best depicted as

³² This slimmed down profit in the distribution chain allotted wholesalers the margin that is due to cover their operational expenses and still make a profit worthy of the expected return of investment, exempting payers to give away additional – unnecessary – percentages that were previously transferred to (used as negotiation tools for) pharmacies.

“In sum, it is not clear that the reduction in the wholesale mark-up or possible reduction in pharmaceutical expenditure has any implications for the viability of the full-line wholesale model.” (Gorecki et al., 2012, p.93)

Often neglected, the rebates that wholesalers offer to pharmacies (actuating as margin transfers) are everything but “free”: Pharmacies must, in turn, meet certain conditions in order to receive (the most favorable) discounts from their primary wholesaler. Among other contractual conditions, a main issue is to assure the acquisition of large stocks of products – that is, the procurement of bulks of medicines in order to assure significant savings that in turn permit wholesalers to give away some of their net cut in the distribution earnings. This creates a mix of reasons jotted down in the private agendas of wholesalers: rebates secure further business with pharmacies, as well as (partially) assuring the takeover of large quantities of products. The latter may compensate for the amount of the profits foregone with the rebates offered for the first. However, the price cutting mechanisms that render wholesalers competitive still goes beyond the bulk-acquisition savings, because even when given efficiencies in acquisitions/savings are in place, wholesalers continue to offer rebates – aiming at the client-retention objective based, once again, on price competition between wholesalers.

In Ireland, pharmacies often face problems in terms of space, coupled with a deficient prevision power that impedes the correct calculation of the actual stock necessities of a given product in a given time point. Because of this, full-line wholesalers supply Irish pharmacies in a customary twice-a-day basis, but often have to do so three or even four times a day. This means that Irish pharmacies do signify higher operational costs to wholesalers than pharmacies found in other countries where the frequency of supply is lower and the stock larger. The net effect on the wholesalers’ side – given a lower than 8% (but still comparably generous) wholesalers’ margin – when reducing the pharmacy reimbursement price to squeeze down distribution profit is to be expected as little. (Gorecki et al., 2012)

Discussion

Discussion of results

Margins are proportionally *regressive* in nature.

This follows logic, and previous authors do mention the regressivity characteristic to some extent, but the state-of-the-art on the subject lacks a deep look into the rationale behind it.

This paper gives an overall look on the topic, regarding specially the almost-always graduated³³, regressive margins as a means to explain the conceptual difference between generics and non-generics markets and health policymaking goals when regulating distribution margins; generics base the economic survival of the wholesalers as low-priced medicines represent a much higher percentual margin per presentation, meaning among others profitability arising from cost saving bulks of medicines to cover fixed operational costs.

Italy is quite behind in health policymaking, as strictly (proportional) linear wholesalers' and pharmacies' margins does not comply, under any circumstance, with actual operational costs of distribution parties on the higher end of the spectrum, assigning unproportionally far too elevated distribution markups for expensive medicines that however *do not incur* in higher operational costs for the WSs. This delay in regulation change could feed the need for alternate, wholesaler independent distribution pathways (or RWAs at the most). The pharmacies sector is however cleverly incentivized, what rebates accounts, as for geographically differentiated pharmacies accrue different rebates to the system payer. This motivates policymaking to save money in a level other than the actual per-package price of a product.

For Ireland, for example, the policymakers devised mechanisms to reduce rents in the distribution chain thus achieving more bang for the buck without compromising quality of service – supply further assured all other things being equal – or economic viability of the distribution players.

³³ This notion makes reference to the fact that regulations are almost always separated into consecutive categories of prices upon which different regulation for the different distribution parties apply.

In terms of goals of politics, the general notion is that margins (understood under a discounts perspective) granted to wholesalers and pharmacies accommodate logistics service provider fees ensuring the uptake of big numbers of products (lots of products, lower prices) while assuring continued quality in delivery to the end-user, this all within a down-squeeze of profit along the distribution chain.

It remains crystal clear that margins assigned to wholesalers and pharmacies accommodate all logistic services – read costs – provided while still remaining profitable. Policymakers have shown to easily identify margins that are above the threshold of expected profitability of wholesalers and that are used to lure pharmacists as transfers – and thus act on it, steering policies towards *fair*, economically viable margins that accommodate distributors' costs while rendering the distribution system economically sustainable.

A content weakness is the fact that – for countries such as UK and Ireland – confidentiality stays in the way of a subjective, reliable appraisal of factual, numbers-based regulation of distribution. In this respect, the current paper analyzes qualitatively such regulations but does not propose any regulation margin in numbers, as this would signify guessing under uncertainty. This, in turn, would prove methodologically inconsistent and irreproducible.³⁴

As a rule of thumb, countries where regulations are private, only qualitative interpretations are to be made, as guessing under such uncertainty would be scientifically irresponsible.

Another weakness is the lack of a comparison of pharmacies on an item-independent level, e.g. the incentives pharmacies have to not dispense a drug or not keeping a large stock of a given medicine. This item-independent issues are non-comparable among countries and are thus beyond the scope of this paper.

For countries where margins were found and were objectively appraised in their mathematical extent, a comparison is due. This will be graphically depicted in the following figure, but only for wholesalers was this task undertaken. For pharmacies, many different price levels were referred to by the regulations, thus rendering a portrayal methodologically impossible.³⁵

³⁴ As a rule of thumb, countries where regulations are private, only qualitative interpretations are to be made, as guessing under uncertainty is scientifically irresponsible.

³⁵ For the few countries where wholesalers' margins were not expressed on a base of EFP, the required conversion to EFP was made, as to render all numbers comparable on parallel.

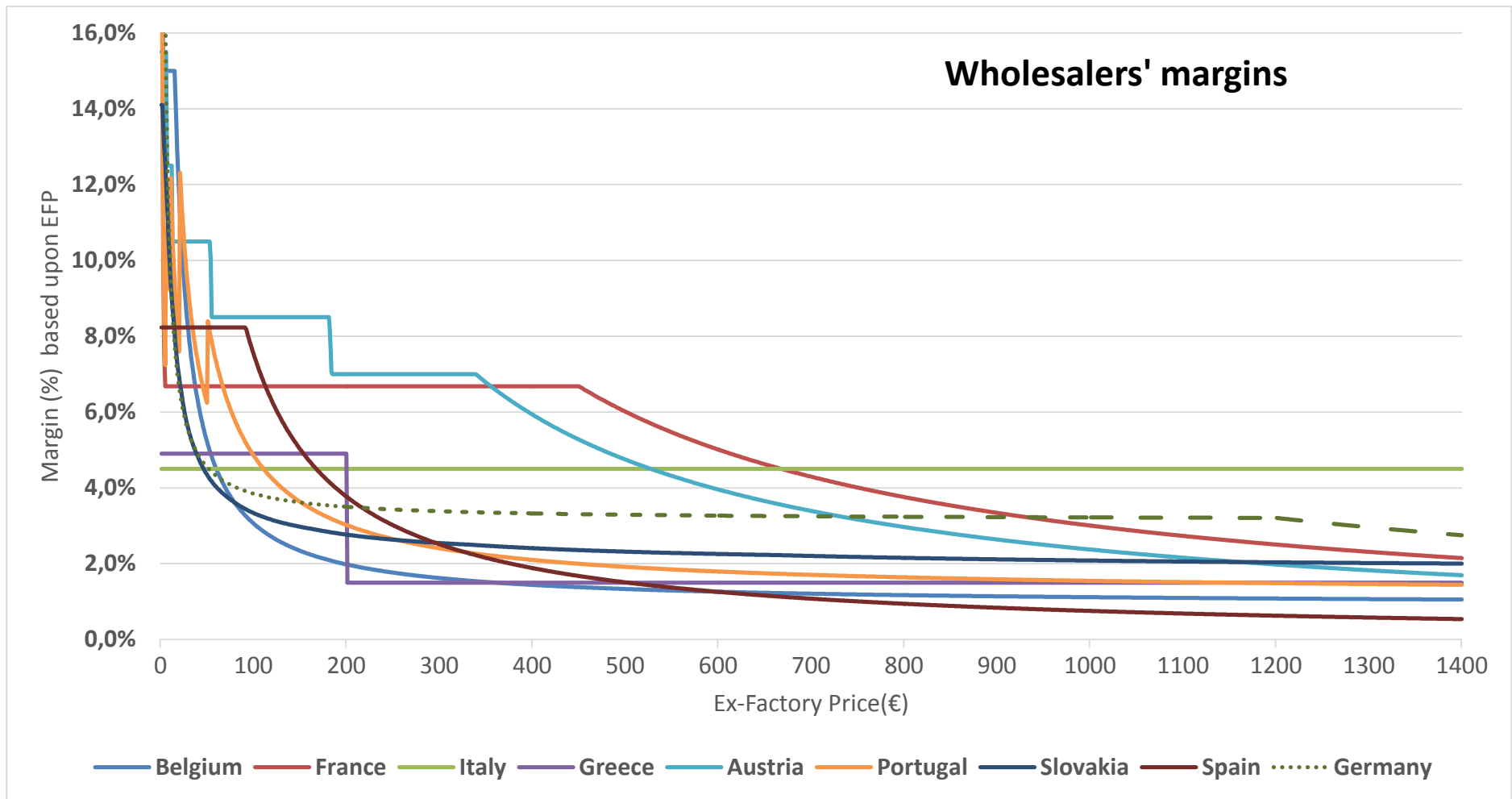


Figure 58: Wholesalers' margins for the EU15 Basket of countries

Note: Margins are shown as percentage (%) over ex-factory price accrued to wholesalers for the mentioned countries (all countries were this information was available. The vertical axis was set – at the author's discretion – at a maximum of 16% for pragmatic purposes.

The assumption bias was actively avoided, as only comparable data was compared and non-accessible data was not approximated (given uncertainty conditions). As such, the gravity of the issue was not over- or underestimated. Graphical depictions were only delivered where methodologically possible and objectively pertinent. Presumptions were not necessary for reviewing the data, so directional bias was avoided. No other author had, up until now, reviewed data in such a detailed manner.

Horizontal and vertical integration

Given the opening of markets and the further regulating factors that shape distribution chains, the trend in the last few years has been to *integrate* – to merge small stakeholders into bigger aggregated entities with higher accompanying bargaining power. Integration can be present in two ways:

- Horizontal integration: Case being pharmacies in Ireland, which now belong to a chain operating almost 50% of all pharmacies in the country. Horizontal integration results from emerging competition in terms of newly arranged agreements between pharmaceutical companies and pharmacies or the use of wholesalers as mere transporters (sole agents).
- Vertical integration: e.g. in Sweden, where pharmaceutical companies devise own distribution services that skip wholesalers altogether and go direct to pharmacies to deliver ex-factory products. This theoretical approach sees in reality an everlasting need of wholesalers in some – debatably many – cases, the latter being but more delivery-oriented intermediaries who do not actually own the products at any moment, thus working not in the interest of making business with pharmacists, but as warehouses and transport for the pharmaceutical company and as such working in their terms and conditions.

Though not directly conditioning regulations on margins for wholesalers (but more conditioned by them), horizontal integration models (on the rise) are changing the way price handling is done. As an unspoken rule, these fusions between small participants leading to bigger affiliated groups tend to equip the latter with precise and valuable bargaining tools, as the market share of such merged companies increases. The vertical models tend to “cut the middle man”, consequently resulting in plausible (yet nominal, not always actual) savings. (Kanavos, Schurer and Vogler, 2011, pp.31ff.).

Discussion of the database

The present paper deserves a section that discusses the importance of approaching literature that does not withstand scientific scrutiny, as it supports the foundations of the literature gap to be filled.

For the topic of distribution margins, the problem was not necessarily the lack of literature on the subject, but more the lack of reproducibility within the literature available. The three main sources used for comparison, Kanavos, Schurer and Vogler, 2011, Carone, Schwierz and Xavier, 2012 and Vogler et al., 2015 all commit the generalization sin, as for margins are regressive in nature and should only be studied in the light of ever-increasing prices accompanied by ever-decreasing margins.

Additionally, none of these publications set out to actually analyze distribution margins in a profound manner; while Kanavos, Schurer and Vogler, 2011 come the nearest to an extensive analysis, the publication fails in doing so by not referencing properly the given averages they present. Carone, Schwierz and Xavier, 2012 and Vogler et al., 2015 were carried out for purposes other than the analysis of the topic developed in this paper.

Further weaknesses lies is the fact that Kanavos, Schurer and Vogler, 2011 and Carone, Schwierz and Xavier, 2012 express wholesalers' margins in terms of PPP (%) and pharmacies' margins in terms of PRP (%). This means that they assume a "backward calculation", were the margin is to be calculated upon a price level that already contains the margin (on top) to be calculated.³⁶ However, regulations as expressed by policymakers are almost exclusively presented for wholesalers' margins in terms of EFP and for pharmacies' margins in terms of PPP. The incongruences between the literature and the actual regulations in terms of the price level they refer to are not addressed or healed in any of the aforementioned papers. Vogler et al., 2015 makes no clear reference as to the price level upon which the calculation is to be based upon.

The mathematical methodology used by the authors is not expressed anywhere in the papers and cannot be comprehended (with the little information given), greatly hindering the reproducibility of results. A detailed criticism on this methodology level is beyond the scope of this paper.

³⁶ For further discussion, see Italy.

The present discussion appraises in enough length the thematic to provide a *reproducible* interpretation of distribution margins in the European Member States studied. The following table summarizes the raw regulation information to be interpreted when approaching margins:

Country	Wholesalers		Pharmacies	
	Number of categories	Type of margin	Number of categories	Type of margin
Austria	10	Regressive	19	Regressive
Belgium	3	Regressive	2	Regressive
Czech Republic	-	-	-	-
Denmark	-	-	1	Regressive
Finland	-	-	5	Regressive
France	3	Regressive	5	Regressive
Germany	2	Regressive	2	Regressive
Greece	2	Regressive	20	Regressive
Ireland	-	-	-	-
Italy	1	Linear	1	Linear
Netherlands	-	-	-	-
Portugal	6	Regressive	6	Regressive
Slovakia	11	Regressive	11	Regressive
Spain	2	Regressive	4	Regressive
Sweden	-	-	4	Regressive
UK	-	-	-	-

Notes:

1. As publicly available margins are (exponentially) regressive for all but one land, it is methodologically impossible to build averages without a specific price range. This would violate the principle of market segmentation according to price (namely, generics vs in-patent for the vast majority of cases).
2. "Regressive" means that the percentual relation of margin to product price regresses/decreases; for countries where the pharmacies are accrued fixed fees per product dispensed, the author interprets these as regressive (a fixed fee is percentually decreasing in terms of ever-increasing product price). The actual absolute value is only to be interpreted in light of its (relative) proportionality.
3. For Belgium and Austria, categories are based upon reimbursable medicines.

Denmark and Italy both have 1 category (Denmark only for pharmacies' margins). However, given that Denmark accrues to pharmacies a flat fee-for-service along with a percentual portion, the *total proportional margin* for pharmacies will be lower as the

product price increases. The Italian policymaker only offers a percentual margin for both wholesalers and pharmacies, meaning that for every calculable product price, both parties will receive a *proportionally constant* – thus linear – margin.

The latter table is to be interpreted only when accompanied by **Figure 58**, in order to fully understand the relative length and breadth of regressivity of margins for all studied countries with the exception of Italy.

As for the literature base upon which the present results and discussion are founded, they are assumed as the current legislation in force for every country studied. Where regulation was to be converted – for uniformity purposes – a validation of the resulting conversion was always sought after. A deeper discussion of own methods follows.

Discussion of own method

Given the confidentiality aspect of the majority of contracts between pharmaceutical industries and their respective appointed wholesalers and the (eventual) subsequent private negotiations with pharmacies, most of the assumptions derived from the information presented in this study are accompanied by a varying degree of subjectivity – the atomization of information without duly informed interpretations makes it further complex to make deterministic inferences. It thus follows logic that information pieces have to be left out when these are not readily available for the general public – this limits the length of results but increases their reproducibility.

Of due mention is the language barrier. The author of the present paper is fluent in English, German and Spanish – thus sources coming from UK, Ireland, Germany, Austria and Spain were directly revised from the original source in the original language. Given, however, that the native tongue of the author is Spanish, all romance languages were to some degree understandable und relatable even without translation – meaning Portuguese, French and Italian, further accounting for Portugal, France, Belgium and Italy.

The latter countries were nonetheless translated with the help of Google Translate before jotting down the subsequent result. All other countries' results were only possible with the help of the translating tool. It is worth mentioning that, even though the non-official translations limit to some extent the reliability of results, most countries share common regulation structures and, as the author deepened in the topic, the interpretation of such

schemes in light of previous legislations was facilitated, as such common structures were identifiable on a language-independent basis.

The language barrier proved most challenging for Czech Rep, where the information found on a snowball fashion was little and further research was greatly hindered by the complexity of the language.

The inclusion and exclusion criteria were knowingly too general for rigorous, standardized academic research (literature research), but this was necessary due to both the fact that language was an imposed barrier on literature procurement as well as that grey literature allows for only generalized materials and methods to be applied upon. As mentioned, information acquisition was eventually proven the most efficient through a continuous snowball fashion.

The decision to skip averages altogether has been discussed in detail and is methodologically the absolute right decision – this, of course, comes at the expense of rendering the present paper, to some degree, incomparable with the current literature base. Still, the author firmly believes the current work fills the literature gap found in the scientific method when (scientific) scrutiny is applied to the state-of-the-art on the subject.

Conclusion and Outlook

Prevailing – outdated – distribution models rely on the acquisition of large quantities of a medicine resulting in low individual revenue. The current, dynamic market conditions put a great deal of pressure on wholesalers that in the last few years have had to come up with novel services for pharmacies and even patients in order to stay in the competition. The obligation to fulfill a public service in delivering drugs in a timely manner, be it through regular orders or emergency requests, accompanied by a rich competition, results in ever diminishing net retail margins, conducting the market to greater consolidation and affiliation (Kanavos, Schurer and Vogler, 2011).

Kanavos, Schurer and Vogler (2011, p.83) argue 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.”. Though invisible to patients, who primarily care about access-to-medicine issues and derived costs, the seemingly high costs of distribution coupled with questionably rich output services have pushed pharmaceutical companies more and more towards RWAs and DTP models which in turn can well balance the acquired distribution expenditures. This, of course, results in market forces that drive even greater consolidation and affiliation that has a foreseeable consequence for WSs (and pharmacies) in seeking to profit from economies of scale. The consecutive further reductions of margins within a persistent sustainable market are proof in itself that operative costs and profitability of distribution parties are lower in net costs than outdated regulations would assume and accrue.

In layman’s terms, low-rotation, high-priced medicines are to be distributed at low – *thus appropriate* – margins if the interested distribution parties wish to remain competitive; this is known to the legislators, who in turn squeeze down profit along the distribution chain in an ever-decreasing manner, rendering all regulations intrinsically (exponentially) regressive. Perfect examples are UK and Ireland, portrayed in detail in the results; even where strict numerical information is not available, margins are to be squeezed down as much as possible.

Noncompliance with this premise would lead (and has lead hitherto) pharmaceutical companies to coming up with distribution schemes such as RWMs or sole agency models that cope with seemingly unmatched price/performance services that distribution parties would be accrued, were the legislators not aware of the necessity for regressivity.

The current literature on distribution margins in the European Union is in fact scarce and outdated. There are no papers that focus solely and specially on the problematic of distribution margins, being it a topic that gets buried in formal, structural market studies that respond to current financial challenges driving legislators to seek general, often country-independent, saving solutions in health care systems. It is however of prime importance that the literature base for the specific case of markups assignation in the distribution chain of pharmaceuticals is tackled and enriched with responsibility, given that it prompts the dialogue of pharmacies, wholesalers and pharmaceutical companies with policymakers that ensures holistic system savings while securing financial viability for all actors in place.

The few literature references that are often cited by stakeholders (e.g. Carone, Schwierz and Xavier 2012, Kanavos, Schurer and Vogler, 2011) incur in the *generalization* sin – averages are thrown around without range specification, proper analysis or methodological caveats, not to mention the lack of accountability for most deductions lacking duly referenced literature support.

The current delivered appraisal is of course not without limitations – confidentiality and language barriers being the two most important ones discussed in the previous chapter. As such, the current work is to be put under the same scientific scrutiny as previous literature and is to be measured under the same controlled circumstances.

A particular case is that of Italy; policymakers have to eventually go regressive, otherwise the system will collapse by distribution of high priced medicines, or prices will be pushed down backwards so much that pharmaceutical companies will have to consider withdrawing products from the market due to issues of financial unsustainability.

Data could be further analyzed as pharmacies' margins could be leveled on one price level, as it was done in this paper for wholesalers – if possible. The issue with pharmacies is that regulations are so complex that a conversion would not only be cumbersome but would also add unnecessary complexity to the issue, making it eventually unclear. Also to note is the abundance of item-independent fees, margins and rebates that pharmacies are

accrued or applied, which make it almost impossible to portray a broad landscape in a generalized fashion. For pharmacies, further research is recommended that focuses solely on the incentives they receive to appropriately deliver the products to the end-user – or restrain from delivering, in some cases.

Following the latter train of thought, a clear segmentation of distribution margins between wholesalers and pharmacies has to be undertaken, as the regulations that command the profit of both arms are very different between both parties but somehow similar within parties. For this, separate studies for wholesalers and pharmacies could be undertaken.

Further studies that focus solely on market segmentation of medicines are needed (low-priced versus high-priced), as well as a broader study of this topic for the EU28 Basket. This was not possible due to the academic fashion of this work and its subsequent specific conditions.

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Declaration of Independent Work

I hereby declare that I wrote this thesis without any assistance and used only the aids listed. Any material taken from other works, either as a quote or idea have been indicated under 'Bibliography'.

Mario Alberto Gomez Camacho
Enrollment Number 2226766

Annex A: Regulations listed in tabular form

Regulation of wholesalers and pharmacies margins by country:

1. Belgium
2. France
3. Italy
4. Greece
5. Austria
6. Portugal
7. Slovakia
8. Spain
9. Germany
10. Denmark
11. Finland
12. Sweden

For information integration and derivation purposes, the present paper focuses on in-patent POMs reimbursable in their context³⁷.

All numbers are to be rounded to the second decimal place. Bibliographical references for all countries in the Annex can be found in the body of the paper duly cited.

Fewer comments are to be found in the sections to the right pertaining pharmacies, as the latter are often accompanied by item-independent margins/fees that cannot be generalized in the following tabular manner.

Because of stylistic reasons (reasonably low number of tables in the main body of the paper), tables hereafter are not indexed; they are however properly named – for the information they contain – at the top of every table.

³⁷ The topic of reimbursability is not only beyond the scope of this paper, but its actual value in the discourse about margins is little, as different countries have extremely different health care financing and reimbursement structures, rendering them non-comparable with one another at this level.

Belgium

Wholesalers, reimbursable medicines:

<p>0€ < EFP < 2,33€ + 0,35€</p> <p>2,33€ ≤ EFP ≤ 15,33€: + 15,00% of EFP</p> <p>EFP > 15,33€ + 2,30€ + 0,90% of (EFP - 15,33€)</p>	<p>Embedded within a proportionally regressive <i>turn</i> proportionally constant <i>turn</i> proportionally regressive model, by a price point of 196,55€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 15% (1,5€), whilst a 1000€ EFP would only mean a margin of 1,16% (11,16€).</p>
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Wholesalers, non-reimbursable medicines:

<p>0€ < PSP ≤ 23,99€: + 13,10% of PSP</p> <p>PSP > 23,99€ + 2,18€</p>	<p>Embedded within a proportionally constant <i>turn</i> proportionally regressive model, by a price point of 109€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ PSP would mean a margin for the wholesaler of 13,1% (1,31€), whilst a 1000€ PSP would only mean a margin of 0,22% (2,18€).</p> <p>Note that margins are calculated upon the Pharmacy Selling Price (PSP).</p>
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Pharmacies, reimbursable medicines:

<p>0€ < EFP < 60,00€ + 6,04% of EFP</p> <p>EFP > 15,33€ + 3,624€ + 2,00% of (EFP - 60,00€)</p>	<p>Proportionally constant <i>turn</i> proportionally regressive model.</p>
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Pharmacies, non-reimbursable medicines:

<p>0€ < PSP < 23,99€ + 31,00% of PSP</p> <p>PSP > 23,99€ + 7,44€</p>	<p>Proportionally constant <i>turn</i> proportionally regressive model.</p> <p>Note that margins are calculated upon the Pharmacy Selling Price (PSP).</p>
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France

Wholesalers:

<p>0€ < EFP < 4,50€ + 0,30€</p> <p>4,50€ ≤ EFP ≤ 450 €: + 6.68% of EFP</p> <p>EFP > 450€ 30,06 €</p>	<p>Embedded within a proportionally regressive <i>turn</i> proportionally constant <i>turn</i> proportionally regressive model, by a price point of 1503€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 6,68% (0,668€), whilst a 1000€ EFP would only mean a margin of 3% (30,06€).</p>
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Pharmacies:

<p>0€ < EFP < 1,91€ + 0,00€</p> <p>1,92€ ≤ EFP ≤ 22,90€: + 25,50 % of (EFP - 1,92€)</p> <p>22,91€ ≤ EFP ≤ 150,00€: + 5,35€ + 8,50% of (ApU-22,91€)</p> <p>150,01€ ≤ EFP ≤ 1.500,00€: 16,15€ + 6% of (EFP – 150,01€)</p> <p>> 1.500 € + 97,15 €</p>	<p>Proportionally constant <i>turn</i> proportionally regressive model.</p>
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Italy

Wholesalers:

0,00€ < EFP < ∞€: + 4,50% of EFP	Embedded within a proportionally constant model, all EFP prices signify a margin for the wholesaler of 4,50%.
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Pharmacies:

0,00€ < EFP < ∞€: + 45,54% of EFP	Proportionally constant model.
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Greece

Wholesalers:

<p>0€ < EFP ≤ 200€: + 4,9% of EFP</p> <p>EFP > 200€ + 1,5% of EFP</p>	<p>Embedded within a 2-step proportionally constant model, a 10€ EFP would mean a margin for the wholesaler of 4,9% (0,49€), whilst a 1000€ EFP would only mean a margin of 1,5% (15€).</p>
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Pharmacies:

<p>0€ < PPP < 50,00€ + 30,00% of PPP</p> <p>50,00€ < PPP < 100,00€ + 20,00% of PPP</p> <p>100,00€ < PPP < 150,00€ + 16,00% of PPP</p> <p>150,00€ < PPP < 200,00€ + 14,00% of PPP</p> <p>200,01€ < PPP < 300,00€ + 12,00% of PPP</p> <p>300,01€ < PPP < 400,00€ + 10,00% of PPP</p> <p>400,01€ < PPP < 500,00€ + 9,00% of PPP</p> <p>500,01€ < PPP < 600,00€ + 8,00% of PPP</p> <p>600,01€ < PPP < 700,00€ + 7,00% of PPP</p> <p>700,01€ < PPP < 800,00€ + 6,50% of PPP</p> <p>800,01€ < PPP < 900,00€ + 6,00% of PPP</p> <p>900,01€ < PPP < 1000,00€ + 5,50% of PPP</p> <p>1000,01€ < PPP < 1250,00€ + 5,00% of PPP</p> <p>1250,01€ < PPP < 1500,00€</p>	<p>20-step proportionally constant model.</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p>
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<p>+ 4,25% of PPP 1500,01€ < PPP < 1750,00€ + 3,75% of PPP 1750,01€ < PPP < 2000,00€ + 3,25% of PPP 2000,01€ < PPP < 2250,00€ + 3,00% of PPP 2250,01€ < PPP < 2500,00€ + 2,75% of PPP 2500,01€ < PPP < 2750,00€ + 2,50% of PPP 2750,01€ < PPP < 3000,00€ + 2,25% of PPP</p>	
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Austria

Wholesalers, reimbursable medicines:

<p>0€ < EFP ≤ 6,06€: + 15,5% of EFP</p> <p>6,07€ ≤ EFP ≤ 6,22€: EFP + WHsM max. 7€</p> <p>6,23€ ≤ EFP ≤ 12,11€: + 12,5% of EFP</p> <p>12,12€ ≤ EFP ≤ 12,32€: EFP + WHsM max. 13,62€</p> <p>12,33€ ≤ EFP ≤ 53,78€: + 10,5% of EFP</p> <p>53,79€ ≤ EFP ≤ 54,77€: EFP + WHsM max. 59,43€</p> <p>54,78€ ≤ EFP ≤ 181,68€: + 8,5% of EFP</p> <p>181,69€ ≤ EFP ≤ 184,22€: EFP + WHsM max. 197,12€</p> <p>184,23€ ≤ EFP ≤ 339,14€: + 7% of EFP</p> <p>EFP ≥ 339,15€: + 23,74€</p>	<p>Embedded within a looping proportionally constant <i>turn</i> proportionally regressive model, by a price point of 1187€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 12,5% (1,25€), whilst a 1000€ EFP would only mean a margin of 2,37% (23,74€).</p>
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Wholesalers, non-reimbursable medicines:

<p>0€ < EFP ≤ 6,06€: + 17,5% of EFP</p> <p>6,07€ ≤ EFP ≤ 6,22€: EFP + WHsM max. 7,12€</p> <p>6,22€ ≤ EFP ≤ 12,11€: + 14,5% of EFP</p> <p>12,12€ ≤ EFP ≤ 12,33€: EFP + WHsM max. 13,87€</p> <p>12,34€ ≤ EFP ≤ 53,78€: + 12,5% of EFP</p> <p>53,79€ ≤ EFP ≤ 54,74€:</p>	<p>Embedded within a looping proportionally constant <i>turn</i> proportionally regressive model, by a price point of 1526€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 14,5% (1,45€), whilst a 1000€ EFP would only mean a margin of 3,05% (30,52€).</p>
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<p>EFP + WHsM max. 60,50€</p> <p>54,75€ ≤ EFP ≤ 181,68€:</p> <p>+ 10,5% of EFP</p> <p>181,69€ ≤ EFP ≤ 184,17€:</p> <p>EFP + WHsM max. 200,76€</p> <p>184,18€ ≤ EFP ≤ 339,14€:</p> <p>+ 9% of EFP</p> <p>EFP ≥ 339,15€:</p> <p>+ 30,52€</p>	
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Pharmacies, reimbursable medicines:

<p>0€ < PPP ≤ 10,00€:</p> <p>+ 37,00% of PPP</p> <p>10,01€ ≤ PPP ≤ 10,15€:</p> <p>PPP + PsM max. 13,70€</p> <p>10,16€ ≤ PPP ≤ 20€:</p> <p>+ 35,00% of PPP</p> <p>20,01€ ≤ PPP ≤ 20,45€:</p> <p>PPP + PsM max. 27,00€</p> <p>20,46€ ≤ PPP ≤ 30,00€:</p> <p>+ 32,00% of PPP</p> <p>30,01€ ≤ PPP ≤ 30,94€:</p> <p>PPP + PsM max. 39,60€</p> <p>30,95€ ≤ PPP ≤ 60,00€:</p> <p>+ 28,00% of PPP</p> <p>60,01€ < PPP ≤ 62,44€:</p> <p>PPP + PsM max. 76,80€</p> <p>62,45€ ≤ PPP ≤ 100,00€:</p> <p>+ 23,00% of PPP</p> <p>100,01€ < PPP ≤ 104,24€:</p> <p>PPP + PsM max. 123,00€</p> <p>104,25€ ≤ PPP ≤ 120,00€:</p> <p>+ 18,00% of PPP</p> <p>120,01€ < PPP ≤ 124,21€:</p> <p>PPP + PsM max. 141,60€</p> <p>124,22€ ≤ PPP ≤ 150,00€</p>	<p>Looping proportionally constant <i>turn</i> proportionally regressive model.</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p>
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<p>+ 14,00% of PPP</p> <p>150,01€ < PPP ≤ 155,45€: PPP + PsM max. 171,00€</p> <p>155,46€ ≤ PPP ≤ 200,00€: + 10,00% of PPP</p> <p>200,01€ < PPP ≤ 207,55€: PPP + PsM max. 220,00€</p> <p>207,56€ ≤ PPP ≤ 350,00€: + 6,00,00% of PPP</p> <p>350,01€ < PPP ≤ 357,07€: PPP + PsM max. 371,00€</p> <p>PPP > 357,08€ + 3,90% of PPP</p>	
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Pharmacies, non-reimbursable medicines:

<p>0€ < PPP ≤ 7,29€: + 55,00% of PPP</p> <p>7,30€ ≤ PPP ≤ 7,58€: PPP + PsM max. 11,30€</p> <p>7,59€ ≤ PPP ≤ 15,70€: + 49,00% of PPP</p> <p>15,71€ ≤ PPP ≤ 16,25€: PPP + PsM max. 23,40€</p> <p>16,26€ ≤ PPP ≤ 26,25€: + 44,00% of PPP</p> <p>26,26€ ≤ PPP ≤ 27,19€: PPP + PsM max. 37,80€</p> <p>27,20€ ≤ PPP ≤ 63,09€: + 39,00% of PPP</p> <p>63,10€ < PPP ≤ 65,44€: PPP + PsM max. 87,70€</p> <p>65,45€ ≤ PPP ≤ 90,74€: + 34,00% of PPP</p> <p>90,75€ < PPP ≤ 94,26€: PPP + PsM max. 121,60€</p> <p>94,27€ ≤ PPP ≤ 108,99€:</p>	<p>Looping proportionally constant <i>turn</i> proportionally regressive model.</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p>
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<p>+ 29,00% of PPP</p> <p>109,00€ < PPP ≤ 113,38€:</p> <p>PPP + PsM max. 140,60€</p> <p>113,39€ ≤ PPP ≤ 130,80€:</p> <p>+ 24,00% of PPP</p> <p>130,81€ < PPP ≤ 135,73€:</p> <p>PPP + PsM max. 162,20€</p> <p>135,74€ ≤ PPP ≤ 203,43€:</p> <p>+ 19,50% of PPP</p> <p>203,44€ < PPP ≤ 211,39€:</p> <p>PPP + PsM max. 243,10€</p> <p>211,40€ ≤ PPP ≤ 363,30€:</p> <p>+ 15,00% of PPP</p> <p>363,31€ < PPP ≤ 371,37€:</p> <p>PPP + PsM max. 417,80€</p> <p>PPP > 371,37€</p> <p>+ 12,50% of PPP</p>	
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Portugal

Wholesalers:

<p>0€ < EFP ≤ 5€: + 0,25€ + 2,24% of EFP</p> <p>5€ < EFP ≤ 7€: + 0,52€ + 2,17% of EFP</p> <p>7€ < EFP ≤ 10€: + 0,71€ + 2,12% of EFP</p> <p>10€ < EFP ≤ 20€: + 1,12€ + 2,00% of EFP</p> <p>20€ < EFP ≤ 50€: + 2,20€ + 1,84% of EFP</p> <p>EFP > 50€ + 3,68€ + 1,18% of EFP</p>	<p>Embedded within an escalated proportionally regressive model, by a price point of 448,78€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 9,27% (0,927€), whilst a 1000€ EFP would only mean a margin of 1,55% (15,48€).</p>
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Pharmacies:

<p>0€ < EFP ≤ 5€: + 0,63€ + 5,58% of EFP</p> <p>5€ < EFP ≤ 7€: + 1,31€ + 5,51% of EFP</p> <p>7€ < EFP ≤ 10€: + 1,79€ + 5,36% of EFP</p> <p>10€ < EFP ≤ 20€: + 2,80€ + 5,05% of EFP</p> <p>20€ < EFP ≤ 50€: + 5,32€ + 4,49% of EFP</p> <p>EFP > 50€ + 8,28€ + 2,26% of EFP</p>	<p>Escalated proportionally regressive model.</p>
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Slovakia

Wholesalers:

<p>0€ < EFP ≤ 2,66€: + 14,10% of EFP</p> <p>2,67€ < EFP ≤ 5,31€: + 0,37€ + 11,10% of (EFP – 2,66€)</p> <p>5,32€ < EFP ≤ 7,97€: + 0,67€ + 8,10% of (EFP – 5,31€)</p> <p>7,98€ < EFP ≤ 13,28€: + 0,88€ + 5,10% of (EFP – 7,97€)</p> <p>13,29€ < EFP ≤ 23,24€: + 1,16€ + 3,30% of (EFP – 13,28€)</p> <p>23,25€ < EFP ≤ 39,83€: + 1,48€ + 2,70% of (EFP – 23,24€)</p> <p>39,84€ < EFP ≤ 73,03€: + 1,93€ + 2,40% of (EFP – 39,83€)</p> <p>73,04€ < EFP ≤ 165,97€: + 2,73€ + 2,25% of (EFP – 73,03€)</p> <p>165,98€ < EFP ≤ 331,94€: + 4,82€ + 2,10% of (EFP – 165,97€)</p> <p>331,95€ < EFP ≤ 663,88€: + 8,31€ + 1,95% of (EFP – 331,94€)</p> <p>EFP > 663,88€ + 14,78€ + 1,80% of (EFP – 663,88€)</p>	<p>Embedded within a proportionally constant <i>turn</i> proportionally regressive model regressive model, by a price point of 1415€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 9,84% (0,98€), whilst a 1000€ EFP would only mean a margin of 2,08% (20,83€).</p>
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Pharmacies:

<p>0€ < EFP ≤ 2,66€: + 32,90% of EFP</p> <p>2,67€ < EFP ≤ 5,31€: + 0,87€ + 25,90% of (EFP – 2,66€)</p> <p>5,32€ < EFP ≤ 7,97€: + 1,56€ + 18,90% of (EFP – 5,31€)</p> <p>7,98€ < EFP ≤ 13,28€: + 2,06€ + 11,90% of (EFP – 7,97€)</p> <p>13,29€ < EFP ≤ 23,24€: + 2,70€ + 7,70% of (EFP – 13,28€)</p>	<p>Proportionally constant <i>turn</i> proportionally regressive model.</p>
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<p>23,25€ < EFP ≤ 39,83€: + 3,46€ + 6,30% of (EFP – 23,24€)</p> <p>39,84€ < EFP ≤ 73,03€: + 4,51€ + 5,60% of (EFP – 39,83€)</p> <p>73,04€ < EFP ≤ 165,97€: + 6,37€ + 5,25% of (EFP – 73,03€)</p> <p>165,98€ < EFP ≤ 331,94€: + 11,25€ + 4,90% of (EFP – 165,97€)</p> <p>331,95€ < EFP ≤ 663,88€: + 19,38€ + 4,55% of (EFP – 331,94€)</p> <p>EFP > 663,88€ + 34,48€ + 4,20% of (EFP – 663,88€)</p>	
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Spain

Wholesalers:

0€ < EFP ≤ 91,63€: + 8,23% of EFP EFP > 91,63€ + 7,54€	Embedded within a proportionally constant <i>turn</i> proportionally regressive model, by a price point of 377€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 8,23% (0,823€), whilst a 1000€ EFP would only mean a margin of 0,75% (7,54€).
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Pharmacies:

0€ < EFP ≤ 91,63€: + 41,88% of EFP 91,63€ < EFP ≤ 200,00€: + 38,37€ 200,00€ < EFP ≤ 500,00€: + 43,37€ EFP > 500,00€ + 48,37€	Proportionally constant <i>turn</i> proportionally regressive model.
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Germany

Wholesalers:

<p>0€ < EFP ≤ 1200€: + 0,70€ + 3,15% of EFP</p> <p>EFP > 1200€ + 0,70€ + 37,80€</p>	<p>Embedded within a proportionally regressive model, by a price point of 1925€, the margin for the wholesaler lies at 2%. Under this scheme, a 10€ EFP would mean a margin for the wholesaler of 10,15% (1,06€), whilst a 1000€ EFP would only mean a margin of 3,85% (38,50€).</p>
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Pharmacies:

<p>0€ < EFP ≤ 1200€: + 8,51€ + 3,00% of (103,15% of EFP + 0,70€)</p> <p>EFP > 1200€ + 8,51€ + 3,00% of (EFP + 37,80€)</p>	<p>Proportionally regressive model.</p>
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Denmark

Pharmacies:

<p>0kr. < PPP < ∞kr.: + 15,96kr. + 8,40% of PPP</p>	<p>Proportionally regressive model.</p> <p>Currency difference within labile markets makes it irresponsible for margins to be converted to €</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p> <p>Includes 8 kr. dispensing fee.</p>
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Finland

Pharmacies, POMs:

<p>0€ < PPP ≤ 9,25€: + 45,00% of PPP</p> <p>9,26€ ≤ PPP ≤ 46,25€: + 0,92€ + 35,00% of PPP</p> <p>46,26€ ≤ PPP ≤ 100,91€: + 5,54€ + 25,00% of PPP</p> <p>100,92€ ≤ PPP ≤ 420,47€: + 15,63€ + 15,00% of PPP</p> <p>PPP > 420,47€ + 36,65€ + 10,00% of PPP</p>	<p>Proportionally constant <i>turn</i> proportionally regressive model.</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p>
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Pharmacies, non-POMs:

<p>0€ < PPP ≤ 9,25€: + 0,50€ + 50,00% of PPP</p> <p>9,26€ ≤ PPP ≤ 46,25€: + 1,43€ + 40,00% of PPP</p> <p>46,26€ ≤ PPP ≤ 100,91€ + 6,05€ + 30,00% of PPP</p> <p>100,92€ ≤ PPP ≤ 420,47€: + 16,15€ + 20,00% of PPP</p> <p>PPP > 420,47€ + 47,68€ + 12,50% of PPP</p>	<p>Proportionally regressive model.</p> <p>Note that margins are calculated upon the Pharmacy Purchase Price (PPP).</p>
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Sweden

Pharmacies, medicines without generic competition:

0kr < PPP ≤ 75,00kr: + 30,50kr + 20,00% of PPP 75,00kr < PPP ≤ 300,00kr: + 43,25kr + 3,00% of PPP 300,00kr < PPP ≤ 50.000,00kr: + 46,25kr + 2,00% of PPP PPP > 50.000,00kr: + 1.046,25kr	Proportionally regressive model. Note that margins are calculated upon the Pharmacy Purchase Price (PPP).
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Pharmacies, medicines with generic competition:

0kr < PPP ≤ 75,00kr: + 42,00kr + 20,00% of PPP 75,00kr < PPP ≤ 300,00kr: + 54,75kr + 3,00% of PPP 300,00kr < PPP ≤ 50.000,00kr: + 57,75kr + 2,00% of PPP PPP > 50.000,00kr: + 1.057,75kr	Proportionally regressive model. Note that margins are calculated upon the Pharmacy Purchase Price (PPP).
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