Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector



Wolfengasse 4/7, A-1010 Vienna Tel: (+43 1) 513 20 07 <u>ipf@ipf-ac.at</u> This report has been commissioned by the European Healthcare Distribution Association (GIRP).

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Authors: Evelyn Walter, Alexandra Lazic-Peric

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A-1010 Vienna, Wolfengasse 4

Tel.: +43-1-513 20 07 E-mail: <u>ipf@ipf-ac.at</u>

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List of abbreviations

B2B business to business

bn billion

DE Germany

DIO Days Inventory Outstanding

DPO Days Payable Outstanding

DSO Days Sales Outstanding

DTP Direct to Pharmacy

e.g. for example

EC European Commission

EDI Electronic Data Interchange

ES Spain

EU European Union

FR France

FTE Full-time equivalent

GDP Gross Domestic Product

GIRP European Healthcare Distribution

Association – Groupement International

de la Repartition Pharmaceutique

HTA Health Technology Assessment

IPF Institute for Pharmaeconomic Research

IT Italy

min minute

NL The Netherlands

Over the counter

OTC

The European Pharmaceutical Wholesale Sector

3PL 3rd Party Logistic Provider

PPRS Pharmaceutical Price Regulation Scheme

PSO Public Service Obligation

RWA Reduced Wholesale Arrangement

RX Prescription drug

SDP Standard Operatin Procedures

SKU Stock Keeping Unit

UK The United Kingdom

VAT Value Added Tax

Executive Summary

This paper presents the results of an independent study conducted by IPF – the Institute for Pharmaeconomic Research – and commissioned by the European Healthcare Distribution Association (GIRP).

The study seeks to analyse the structures, characteristics, efficiency and performance of pharmaceutical full-line wholesalers as the main distributors of medicinal products in Europe, also in the context of alternative distribution systems, and to compare these findings with the results from the GIRP-IPF study conducted in 2011. The present study attempts to highlight the different functions and added value services offered towards supply chain partners and the public, as well as its macroeconomic impact (input-output-integration and multiplying effects). It also illustrates the supply-chain partners' satisfaction with the distribution systems they use. In order to assess stakeholders' satisfaction with their distribution system, two surveys were circulated: one to pharmacists in Europe's key markets (DE, ES, FR, IT, NL and UK) and one to pharmaceutical manufacturers worldwide. Results outline the motivation of pharmaceutical manufacturers for selecting certain distribution models and explain which services level pharmacists considered to be most valuable. Both qualitative and quantitative research based on primary and secondary data was used to illustrate the performance of the pharmaceutical full-line wholesale sector as a whole. Due to the fact that the results of this study reflect the responses of a random sample, the findings should be considered as a trend.

Key findings

- ▶ The pharmaceutical distribution landscape has changed and became more complex since the last study conducted in 2011, however pharmaceutical full-line wholesalers still occupy a central position in the supply chain.
- ▶ Pharmaceutical full-line wholesalers ensure a safe, rapid, continuous and cost-effective supply of medicinal products throughout Europe.
- The implementation of wholesalers right to be supplied by the pharmaceutical industry combined with Public Service Obligations (PSO) for wholesalers guarantees an adequate and continuously available range of medicinal products to meet the requirements of a specific geographical area and the delivery of the requested supplies within a very short time frame across the entire area in question. However, the right for pharmaceutical full-line wholesalers to be supplied by the industry is currently only in place in three EU countries (Belgium, France and Germany).

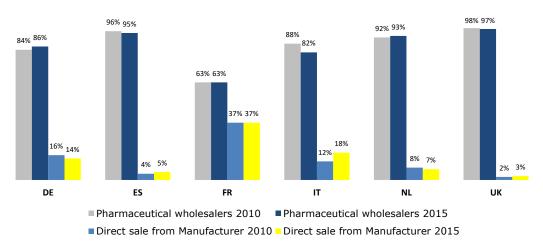
- ▶ The main aspects distinguishing pharmaceutical full-line wholesalers from other distributors in the supply chain are the fact that they carry the full range of medicinal products and that they are the owners of their stocks.
- ▶ The satisfaction of pharmacists and pharmaceutical manufacturers with their respective delivery and distribution systems varies.
- ➤ The services offered by pharmaceutical full-line wholesalers, such as high delivery frequency or access to and availability of the full product range, ensure that even the most isolated patients can receive the most specialised medicinal products in a safe and timely manner.
- ▶ Added value services are among the key competitive advantages of the pharmaceutical wholesaling sector. These services will be of growing importance in the future.
- Pharmaceutical full-line wholesalers pre-finance nearly the entire medicinal product market and secure the cash flow in the healthcare system.
- ▶ A lack of pharmaceutical full-line wholesalers would lead to a dramatic increase in the number of transactions between all involved actors in the medical supply chain as well as to high additional costs for pharmacies.
- ► Therefore, the existence of pharmaceutical full-line wholesalers is essential for the efficient functioning of the European healthcare sector.

Pharmaceutical Distribution in Europe

- ▶ In some countries, the pharmaceutical distribution landscape has changed over the last five years; some of the most significant changes were the increase of direct sales or the development of new pharmaceutical distribution models, but pharmaceutical full-line wholesalers still have a central position in the supply chain.
- ▶ Nearly three-quarters of all medicinal products sold in Europe are distributed through pharmaceutical full-line wholesalers. Most of the medicinal products, namely 93.3%, distributed via this distribution channel are sold to retail pharmacies, followed by hospital pharmacies with 5.5% and 1.3% to drugstores or dispensing doctors.
- Pharmaceutical full-line wholesalers carry the complete assortment of medicinal products required by pharmacies/patients in their country and provide a wide range of added value services to manufacturers and pharmacies to the benefit of patients and the public.

- ▶ By holding the full range of medicinal products on stock, full-line wholesalers ensure for example that manufacturers' supply problems in the event of an emergency (e.g. pandemics) are mitigated.
- ▶ In the EU-26 + CH + NO in 2015, 752 pharmaceutical full-line wholesalers operated 1,490 warehouses or operating sites, served 180,743 retail and hospital pharmacies and dispensing doctors and supplied 520 million people with medicinal products.
- More than 85% of the pharmaceutical wholesale sales to the retail market were generated by pharmaceutical full-line wholesalers in the study's six target countries (DE, ES, FR, IT, NL, UK). In 2016, 115 pharmaceutical full-line wholesalers operated 637 operating sites and served 105,353 dispensing points in these countries and therefore supplying more than 336 million citizens with vital medicines.
- Due to the existence of Public Service Obligations (PSO) for pharmaceutical full-line wholesalers in some countries, they have to handle all medicinal products, whereas pharmaceutical short-liners and direct sales distributors can decide to predominantly distribute specialty, high volume and high margin products ("cherry picking").
- ▶ In some of the observed countries, the market growth rates of the pharmaceutical full-line wholesaling sector rise slowly. This is largely due to the growing importance of alternative distribution systems such as Direct-to-Pharmacy (DTP) and Reduced Wholesale Agreements (RWA) in the UK, as well as the increase of direct sales in several other countries. Increasingly, high value, high-innovation products are being distributed through alternative distribution channels and negatively affect pharmaceutical full-line wholesalers' turnover.
- Quantity restrictions and price regulations, which aim to curb pharmaceutical expenditure, also negatively impact the pharmaceutical wholesalers' margins and subsequently their turnover. The increasing number of expiring patents (including biopharmaceuticals) leads to a growing number of cheaper products on the market.
- ➤ On the other hand, the remuneration for the distribution of very high priced medicines is capped in most countries and the capped amounts are mostly insufficient to finance and carry the risk for these medicines.
- In 2015, pharmaceutical full-line wholesalers generated a total turnover of €141 billion in the EU-26 + CH + NO. Compared to 2010 it was a moderate increase of 5 billion. The turnover in the key market (DE, ES, FR, IT, NL, UK) amounts to €92 billion in the year 2015.





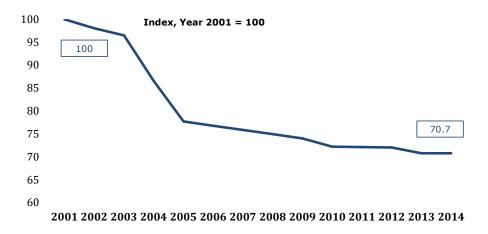
^{*} Currently, there are no wholesalers in the UK carrying the full range of products.

Source: QuintilesIMS 2010-2015, IPF research 2016

Overview of the regulatory framework

- ▶ Due to a mix of pharmaceutical price-regulation mechanisms, pharmaceutical prices differ significantly across Europe.
- Direct supply-side-conducted regulatory measures of medicine prices, such as direct and indirect price controls, discounts and rebates, external and internal reference pricing, fundamentally influence the profit margin of pharmaceutical wholesalers.
- ▶ Due to the fact that the majority of EU countries have regulated wholesale margins (with the exceptions of Denmark, Finland, the Netherlands, Sweden, Switzerland and the UK, which have entered into private negotiations with manufacturers), pharmaceutical full-line wholesalers have almost no possibility to control their margins.

B: Development of average wholesale margin in DE, ES, FR, IT, NL, UK, 2001-2014



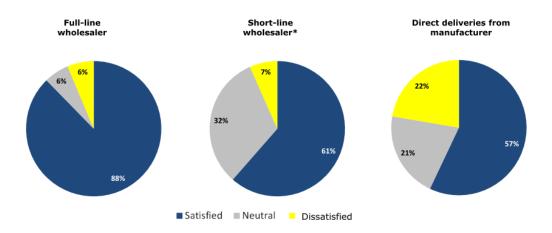
Source: IPF research 2015

➤ The index of wholesale margins has steadily decreased since 2001 from 100 to 71 over the course of the last 15 years.

Supply chain partners' perceptions of the distribution sector

- One central issue of the present study was to analyse the satisfaction of the supply chain partners, industry and pharmacists, concerning their pharmaceutical distribution system.
- Compared to the previous study (2011), the present study has a broader approach and includes the perceptions and perspectives of the pharmaceutical industry. This new dimension was included to render the study more complete and the perspectives surrounding the quality, efficiency and reliability of the healthcare distribution sector more encompassing and comprehensive.
- ▶ The **pharmacist survey** was circulated among pharmacists in the six key European markets (France, Italy, Spain, the Netherlands, Germany and the United Kingdom).
- ▶ In the six observed countries, the large majority of the responding pharmacists were satisfied with the distribution through pharmaceutical full-line wholesalers. Overall, the findings show that there is a high level of satisfaction with pharmaceutical full-line wholesalers. These positive responses demonstrate the importance of this distribution system to pharmacists.

C: Overall satisfaction with the distribution system

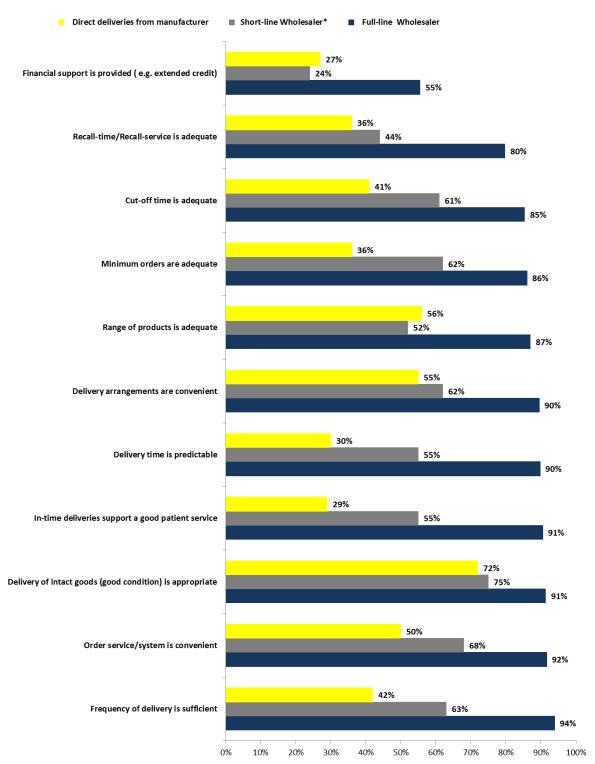


*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'

Source: IPF research 2016, Pharmacist survey 2016

➤ Similarly, 90% of pharmacists in all six target countries felt that the service level performance of pharmaceutical full-line wholesalers was very high.

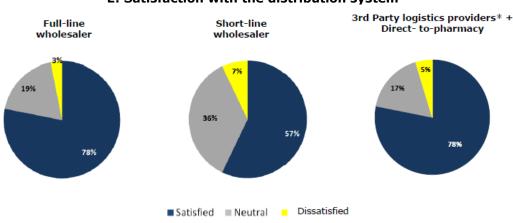
D: Service offering - pharmacists' agreement



*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'

Source: IPF research 2016, Pharmacist survey 2016

- ► The survey of pharmaceutical companies was disseminated globally and the results of the survey were not evaluated at the level of individual countries.
- ▶ 60% of the respondents indicated that their companies operated on an international level, 12% of the respondents have operations on the European level and 28% operated on the national level.
- ▶ The majority of the responding manufacturers were satisfied with their supply chain partners.



E: Satisfaction with the distribution system

Source: IPF research 2016, Manufacturer survey 2016

- Pharmaceutical manufacturers were asked to indicate their reasons and motivations for using a certain distribution system. The most commonly cited reasons for using pharmaceutical full-line wholesalers were:
 - high delivery frequency
 - ensuring product availability
 - o transportation function
 - o stock-keeping function and stock security as well as the
 - o financial function.

^{*} **Pre-wholesaling is included in 3** party logistic providers; a pre-wholesaler is an agent acting on behalf of a manufacturer and is responsible for the storage and distribution of the manufacturer's products to other wholesalers and to hospitals: manufacturer -> (pre-wholesaler) -> pharmaceutical full-line wholesaler -> public pharmacy -> patient

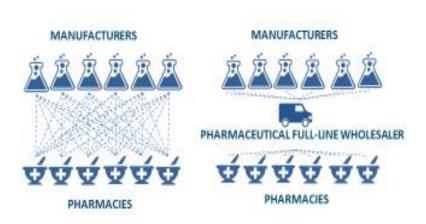
Efficiency of pharmaceutical full-line wholesaling

- ➤ To evaluate an industry's efficiency, a variety of core indicators associated with the main functions of pharmaceutical full-line wholesalers were used in this study: the full supply and stock-keeping function; the immediate medicines availability and delivery function; the bundling function (pooling of different products in one delivery); the quality assurance function and the financing function.
- ▶ The importance of the different functions offered by the pharmaceutical full-line wholesalers are highlighted on the basis of the core indicators. For example, as regards the full-supply function, pharmaceutical full-line wholesalers carry and distribute the complete assortment of products in range and depth to meet the needs of those with whom they have normal business relations. The number of items on stock can range up to 100,000 different products, depending on the size of the market and the number of products authorised to be marketed. The average number of products on stock for the six listed countries is 57,176.
- ▶ The storage and delivery of medicinal products within a framework that ensures immediate availability is of crucial importance for patients and their caretakers or medical professionals.
- ➤ Since demand for specific medicinal products varies considerably and according to season, pharmaceutical full-line wholesalers manage complex flows of medicinal products. They hold a safety stock of medicines in order to meet unexpected peaks in normal demand patterns as well as unforeseen events, such as pandemics, that lead to increased demand in medicinal products.
- ➤ To guarantee short-term availability of medicinal products, pharmaceutical full-line wholesalers have optimised their warehouse management and offer efficient last mile delivery systems, which allow them to hold the full range of available products and to make medicines available immediately, even in times of disruptions of supplies and unexpected demand.
- ▶ The immediate availability and accessibility of vital medicines is essential in ensuring patient adherence to medicine and treatment schemes. The delivery function thus gets the right medicines to the right patients at the right time in a safe and efficient manner.
- According to the survey conducted among pharmacists in the six observed countries, the average perceived delivery time of pharmaceutical full-line wholesalers is 4.6 hours, with an average of 16.02 perceived deliveries per week. These figures are based on deliveries received during pharmacies'

regular opening hours, excluding weekends and out of business hour deliveries, but including deliveries to pharmacies in remote areas.

- ▶ The bundling function is of high value to pharmacies, as it reduces the time spent by an individual pharmacy on ordering, receiving and processing invoices from the various manufacturers whose products it sells. On a weighted average, pharmaceutical full-line wholesalers pool products from 18.8 different manufacturers per delivery. This figure has increased by 0.5 from 18.3 pooled products in 2011 to 18.8 in 2015. Pharmaceutical manufacturers are incapable of offering this delivery service, as they only hold their own products on stock and their warehouses are generally further away from pharmacies.
- ▶ Through their bundling function, pharmaceutical full-line wholesalers create significant efficiencies in the medicines supply chain. Without pharmaceutical full-line wholesalers, the additional costs associated with product distribution would have to be paid by manufacturers, pharmacies, health insurance funds and ultimately, by patients.
- ▶ In the six countries observed, the continuous supply of medicinal products involves more than 795.6 million¹ transactions between pharmacies, pharmaceutical full-line wholesalers and manufacturers in 2015. Without pharmaceutical full-line wholesalers this number would increase dramatically to 99.4 billion transactions per year.

F: Distribution chain with and without intermediaries



Approx. 100 billion transactions

Less than 800 million transactions

Source: Gümbel 1985, IPF research 2016

 $^{^{\}rm 1}$ Calculation based on national pharmaceutical full-line wholesalers.

- The average individual process steps in pharmacies include determining order demand, transmitting orders, receiving and storing deliveries, and checking the delivery note and invoice. By comparing the process costs in pharmacies with the different supply routes, the difference in time expenditure and monetary cost (with respect to a single delivery) can be shown: one direct delivery from a manufacturer to a pharmacy is €3.87 more expensive than **one** delivery from a pharmaceutical full-line wholesaler.
- ▶ If there were no pharmaceutical full-line wholesalers, pharmacy process costs would increase from € 7,590 to € 203,224 per year.

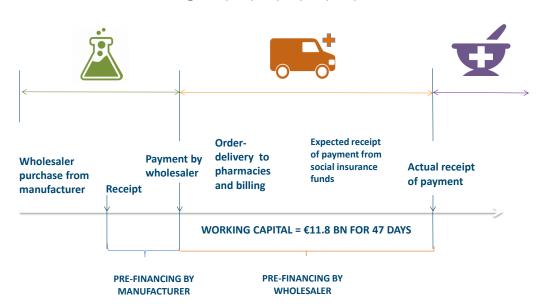
G: Scenario: Impact on process costs per pharmacy per year (pharmaceutical full- line wholesalers vs. direct sales from manufacturers) in DE, ES, FR, IT, NL, UK, 2015



Source: EUROSTAT, Pharmacy questionnaire, IPF research 2016

- Pharmaceutical full-line wholesalers are actively involved in ensuring medicine safety and have established robust quality assurance systems as defined by various regulatory requirements and standards, such as the Good Distribution Practice Guidelines and ISO certifications.
- ▶ Pharmaceutical full-line wholesalers assume a pre-financing function towards manufacturers and pharmacies that is typically not offered by other distribution models.

- Pharmaceutical full-line wholesalers finance nearly the entire medicinal product market, guarantee the continuous supply of all medicinal products and secure the cash flow of pharmacies. Pharmacies depend on this financing function for their economic sustainability; without it they are not able to afford to stock their shelves with all necessary medicines and medicinal products. Pharmacists therefore must rely on pharmaceutical fullline wholesalers to deliver the required products just in time.
- This financing function results in pharmaceutical full-line wholesalers permanently financing an average €11.8 bn, corresponding to a period of 47 days.



H: Financing* DE, ES, FR, IT, NL, UK, 2015

Source: IPF research 2015

- ▶ Added-value services are growing in importance, not only for the financial sustainability of the healthcare distribution sector, but also to fulfil the needs and demands of manufacturers, pharmacists, and patients in an ageing society. The added-value created by pharmaceutical full-line wholesalers offers manufactures, retail pharmacies, other healthcare providers and ultimately patients additional benefits.
- Input-Output analysis using an extended Leontief-model shows that pharmaceutical full-line wholesalers have a significant macroeconomic impact. Each Euro invested in the pharmaceutical full-line wholesale sector generates on average €2.01 in the six countries observed. Each additional job offered by pharmaceutical full-line wholesalers generates 1.94 additional jobs in the economy as a whole.

^{*} As payment periods of pharmaceutical full-line wholesalers are representative for all wholesalers in the markets observed, the pre-financing calculation is based on the figures provided by national pharmaceutical full-line wholesalers.

Future trends and developments in the healthcare distribution

- ▶ The economic and regulatory challenges will likely persist and increase in the foreseeable future. Pharmaceutical full-line wholesalers will continue to be confronted with growing product polarisation (a widening gap between low and high priced products), an increase in high-value medicines on the pharmaceutical market, a steady decline in wholesale margins, increasing financial and administrative burdens arising not only from the implementation of national and European legislation, but also from governmental cost-cutting measures to reduce healthcare expenditures and subsequently, increasing trends towards market consolidation.
- Pharmaceutical full-line wholesalers have begun to offer an expanded range of added-value services in order to complement their full product range with a full range of services. Attesting to pharmaceutical full-line wholesalers' ability to innovate and to respond to market challenges in a flexible way, it is likely that such services will continue to grow in the future and will take on new directions and dimensions as technology and clients' needs evolve.
- Pharmaceutical full-line wholesalers recognise that the future is digital and are digitalising not only their internal operations and processes but also their services. Digitalisation in terms of connection between pharmaceutical full-line wholesalers and pharmacies is very well established (eg. EDI), however connections with the industry for order and invoice processing still remains at a low level (use of faxes) in several countries. It is therefore likely that the industry and pharmaceutical full-line wholesalers will increasingly look to digitalisation of their ordering and invoice interfaces.
- Pharmaceutical full-line wholesalers have realised that good corporate conduct makes good business sense and are embedding social, environmental and economic responsibility, the so-called "triple bottom line" of people, planet and profit, into their core business strategies. Corporate responsibility increases the value of the company in the long term and promotes innovations that benefit society.
- As both the global dynamics of the healthcare distribution sector as well as the needs and information requirements of the healthcare stakeholders change, collaboration and cooperation will become of increasing importance. While such trends and tendencies have already been observed in other sectors (such as the automotive industry), the pharmaceutical market remains predominantly structured in non-interacting silos.
- ▶ In order to progress from this demarcated thinking of the past and to capitalise on the value of the broad and diversified expertise of the supply chain partners, pharmaceutical full-line wholesalers are uniquely positioned to actively engage in and drive collaborations and partnerships between all

supply chain stakeholders. Such collaborative efforts will become a priority in the provision of better services, adhering to compliance measures that effectively fulfil their intent, and in improving patient outcomes.

Conclusion:

- ➤ The effective and efficient functioning of the healthcare industry in Europe is maintained by pharmaceutical full-line wholesalers, which fund and hold stocks and therefore provide necessary working capital, especially to pharmacies.
- Pharmaceutical full-line wholesalers help reduce transaction costs, secure a safe, rapid and continuous supply of medicinal products and help generate value along the pharmaceutical supply chain by providing both core and added-value services.
- Pharmaceutical full-line wholesalers are vital and reliable partners for policy makers: together with political decision-makers, pharmaceutical manufacturers, pharmacies, other healthcare professionals, insurers, and patient representatives, they help to find strategies and solutions for the current and future challenges in the European pharmaceutical and healthcare sectors.
- As pharmaceutical full-line wholesalers struggle with an increasingly difficult market and regulatory environment, consolidation will continue to fundamentally change the structure and dynamics of the sector.
- ▶ The combined effects of growing product polarisation, the increase in highvalue medicines and the inaccessibility of these products to pharmaceutical full-line wholesalers in some countries, a steady decline in wholesale margins, increasing regulatory burdens and continued trends towards market consolidation, will continue to force pharmaceutical full-line wholesalers to think outside and beyond the box.

1 Introduction

The pharmaceutical wholesale sector is under pressure. The past five years have been a period of change in the industry and industry participants have had to contend with a wide range of competing variables. One of the key developments shaping the industry has been the move away from the traditional wholesale model. An increasing number of upstream manufacturers have adopted new distribution models that involve just one or a very limited number of wholesalers in the distribution of their branded pharmaceuticals. Due to continuous market consolidation, the number of pharmaceutical full-line wholesalers has decreased.

The profit mark-up in the pharmaceutical wholesale market is just within the range of 3% to 13% in Europe. Many of the key medicines and medicinal products in the market place are losing their patent protection and, as a result, the pharmaceutical wholesale sector is entering a crucial and defining period. The increased volume of generic products within the pharmaceutical sector is likely to reduce prices and, as a result, to reduce profit margins within the wholesale sector.

Healthcare austerity measures combined with the effect of patent loss have dampened the growth of the pharmaceutical wholesale market. At the same time, the implementation of the Public Service Obligations (PSO) in some countries obligate full-line wholesalers to permanently guarantee an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short period of time over the whole of the area in question. In a market defined by increasing consolidation, price polarisation and increasingly burdensome legislative obligations, pharmaceutical full-line wholesalers are faced with growing financial pressures and challenges.

The aim the study commissioned by GIRP seeks to analyse the structures, characteristics, efficiency and performance of pharmaceutical full-line wholesalers as the main providers of medicinal products, also in the context of alternative distribution systems. The study attempts to highlight the different functions and added-value services offered towards supply chain partners and the public as well as its macroeconomic impact (input-output-integration and multiplying effects). The study illustrates the supply chain partners' satisfaction with the distribution systems they use. Results of two questionnaires circulated for this purpose outline pharmaceutical manufacturers' motives for selecting certain distribution models and explain which service level offered towards pharmacists is considered as valuable.

2 Approach and Methodology

Purpose of the study

The aim of this study is to analyse the role and functions of the pharmaceutical full-line wholesalers as the main provider of medicinal products in comparison to alternative distribution systems. The important role as vital link between pharmaceutical manufacturers and pharmacies is not analysed only from an economic viewpoint. The focus of the present study was to illustrate the role the pharmaceutical full-line wholesale industry plays within the health care system as a whole, which is not always visible to the public and to capture the supply chain partner attitudes, mainly regarding satisfaction, with the pharmaceutical full-line wholesalers. This study uses qualitative and quantitative research based on primary and secondary data to illustrate the performance of the pharmaceutical full-line wholesale sector.

Nine research questions were developed in order to prove the value of the pharmaceutical full-line wholesaling model:

- ▶ What is the role of pharmaceutical full-line wholesalers in the European pharmaceutical distribution sector and how can it be reflected by core indicators?
- ▶ What functions do pharmaceutical full-line wholesalers offer towards their supply chain partners and in which way do they contribute towards their efficiency?
- ▶ What services do pharmaceutical full-line wholesalers provide and what is the created added value for of the pharmaceutical supply chain and for the public?
- ▶ How pharmaceutical full-line wholesalers were squeezed through regulation?
- ▶ How satisfied are the supply-chain partners pharmacists and manufactures with the distribution systems they use?
- Which service level offered towards pharmacists was considered as valuable and how pharmacists classify the 'safety of medicines' delivered via pharmaceutical full-line wholesalers?
- ▶ What is the motivation of pharmaceutical manufacturers for selecting certain distribution models?
- ▶ What is the pharmaceutical full line wholesale sector's contribution to the overall economy – how much value added and jobs are created by pharmaceutical fullline wholesalers?
- ▶ What are the challenges faced by the pharmaceutical wholesale sector and how could future trends affect the pharmaceutical distribution landscape?

Data source

The study considers core indicators representative for all countries of the European Union. Due to the fact that France, Germany, Italy, the Netherlands, Spain and the United Kingdom (UK) represent the biggest European pharmaceutical markets; in-depth analyses for these countries were made. Moreover, these countries are defined as key markets in this study.

The necessary data were obtained from primary and secondary sources:

- ▶ First, two sets of online surveys were developed to obtain information about pharmacists' and manufacturers' perceptions, respectively. Both surveys were carried out electronically from December 2015 to May 2016. The pharmacist survey was circulated among pharmacists in the six key European markets (France, Italy, Spain, the Netherlands, Germany and the United Kingdom), whereas the survey of pharmaceutical companies was disseminated globally, as pharmaceutical companies pursue global strategies.
 - The total number of manufacturers who participated in the survey was 123.
 - The collection of data from pharmacists was carried out at the country level; therefore data and analysis are available for each country. Due to the lack of responses from Spain and the Netherlands, individual country results are not available; these have been included in the overall analysis for all countries.
- ➤ Second, additional data was provided by the European Healthcare Distribution Association (GIRP), consisting of GIRP's annual report and key statistical data gathered from its members.
- ▶ Third, data has been sourced from QuitilesIMS.
- ▶ Further systematic literature research, which verified the empirical findings.

The following notes have to be considered when reading the study:

- ▶ The wholesale sector's sales are computed on a pharmacy purchase price level before discounts and without value added tax.
- ▶ The findings of the manufacturers' and pharmacists' surveys have to be considered as a snap shot of the individual's opinion at a particular moment in time. Moreover, the results are illustrating a trend.
- ▶ The data from manufacturer and pharmacies are presented on an aggregated level and therefore none of the statements in this report can be attributed to any of these companies or pharmacies individually.

3 Pharmaceutical Distribution in Europe

This chapter gives a brief overview of the European pharmaceutical distribution landscape. First, the role of the pharmaceutical wholesale sector in the context of the distribution system is described and second, the magnitude of the pharmaceutical wholesale sector described by turnover and market share is presented.

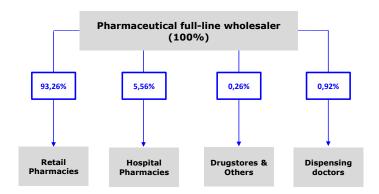
3.1 The role of the pharmaceutical wholesale sector

The pharmaceutical distribution landscape had changed in the recent past, but pharmaceutical full-line wholesalers still occupy a central position in the supply chain (see also "Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector", IPF 2012). Some of the most significant changes were the increase of direct sales or the development of new pharmaceutical distribution models. The primary interest of pharmaceutical manufacturer in profiting from the efficient movement of products to patients, the payer's interest to offer these products at the lowest price and the patient's interest in an immediate access remain constant.

In Europe, the majority of medicinal products reach the patient through the traditional distribution pathway: manufacturer \rightarrow (pre-wholesaler) \rightarrow pharmaceutical full-line wholesaler \rightarrow retail pharmacy \rightarrow patient. In some cases, a pre-wholesaler is part of the supply chain, linking the manufacturer and the pharmaceutical full-line wholesaler.

Nearly three-quarters of all medicinal products which are sold in Europe are distributed through pharmaceutical full-line wholesalers. Most of the medicinal products, namely 93.3%, distributed by pharmaceutical full-line wholesalers are sold to retail pharmacies, followed by hospital pharmacies with 5.5% and 1.3% to drugstores or dispensing doctors, figure 1) (GIRP data 2015).

Figure 1: Percentage of medicinal products (quantity) distributed by pharmaceutical fullline wholesalers in DE, ES, FR, IT, NL, UK*, 2015



* Please note that in UK no wholesaler stocks all medicinal products due to market conditions Source: GIRP data 2015, IPF research 2016

The main aspect distinguishing pharmaceutical full-line wholesalers from other distributors in the supply chain is the fact that they carry the full range of medicinal products. France, Germany, Italy and Spain have national Public Service Obligations (PSOs). The aim of these obligations is to guarantee that through a permanently available, adequate range of medicinal products, the requirements of a specific geographical area – no limitation of "logistical easy" areas – are met and requested medicinal products can be delivered immediately over the whole area in question. Under 'normal' market conditions, this is not guaranteed (GIRP 2009).

The principle of Public Service Obligation could defend the wholesale industry against profit cuts due to DTP schemes. DTP schemes transfer the business relationship with pharmacists to the pharmaceutical industry, which not only gives the pharmaceutical manufacturer a detailed transparency to prescribers' behaviour but also provide the opportunity to influence retail behaviour. DTP leads to business-model switch from the current full-line approach to a short-line approach, where wholesalers would exclusively distribute high-value/low-volume and low-value/high-volume medicines (IHS 2008).

Under the pharmaceutical full-line model, wholesalers make no difference between fast-moving or seldom used, but equally vital medicinal products. By holding the full range of medicinal products on stock, full-line wholesalers ensure for example that manufacturers' supply problems in the event of an emergency (e.g. pandemics) do not compromise a critical situation (Walter et al. 2012).

Given their critical role, it is not surprising that pharmaceutical full-line wholesalers operate under strict legal frameworks, such as the Community Code 2001/83/EC relating to medicinal products for human use, recently updated by the Falsified Medicines Directive - Directive 2011/62/EU - (European Parliament 2010) as well as the Good Distribution Practice Guidelines of Medicinal Products for Human Use published in 1994.

According to the European Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94C63/03), which are currently submitted for revision, pharmaceutical wholesale distributors must comply with regulation in the following areas:

- personnel (training, etc.)
- returns (non-defective medicinal products, recalls, counterfeits, etc.)
- documentation (orders, procedures, records)
- self-inspections
- premises and equipment (receipt, storage, temperature)
- provisions of information to Member States in relation to wholesale activities
- deliveries to customers

Source: European Economic Community 1994 (GDP Guidelines 94C63/03)

EU-26* + CH + NO Key Markets** 28 Countries 6 Countries 752 Wholesalers 1) 115 Wholesalers 1) 1,490 Operating Sites 637 Operating Sites 180,743 Dispensing Points2) 105,353 Dispensing Points2) **520,317,139** Inhabitants 336,429,786 Inhabitants 1)National and regional wholesalers; 2)Pharmacies, hospital pharmacies and dispensing * EU-28 without Malta and Cyprus ** DE, ES, FR, IT, NL, UK

Figure 2: Dimensions of pharmaceutical full-line wholesaling, 2015

Source: EUROSTAT, GIRP data 2015, IPF research 2016

In the last decade, nearly all EU countries have seen mergers in the wholesale sector and a decline in the number of operating wholesaler companies. Figure 2 highlights the dimension of the pharmaceutical full-line wholesalers in the EU-26 + CH + NO in 2015, where 752 pharmaceutical full-line wholesalers operate 1,490 warehouses or operating sites, serve 180,743 retail and hospital pharmacies and dispensing doctors and supply 520 million people with medicinal products (EUROSTAT 2015, GIRP data 2015).

More than 85% of the pharmaceutical retail wholesale sales were generated by full-line wholesalers in the observed six countries. In these countries 115 pharmaceutical full-line wholesalers operated 637 operating sites and served 105,353 dispensing points which supplied more than 336 million citizens (EUROSTAT 2015, GIRP data 2015).

752 pharmaceutical full-line wholesalers ensured a safe, rapid, continuous and cost-effective supply of medicines and medical products for the 26 countries of the European Union plus Norway and Switzerland in 2015

3.2 European pharmaceutical distribution landscape

This section explains the distribution system of the key European markets under consideration in this study. Most of the distribution systems in the European Union are multichannel systems with full-line wholesaling, short-line wholesaling and direct sales (GIRP data 2015).

Pharmaceutical full-line wholesalers operate on a national or regional level. In the case of national distribution, pharmaceutical full-line wholesalers have established nationwide distribution networks, with strategically placed warehouses. Regional wholesalers only serve retail pharmacies, hospitals and other dispensing sites in a limited geographical area (Walter et al. 2012).

Due to the fact that neither European nor national legislation offers clear definitions or classifications of the operators in the distribution chain, most national authorities grant a high number of distribution licenses. As a result, a wide and diverse range of different operators are active in the supply chain, even in markets where their activities are theoretically prohibited (for example in France and Spain) (GIRP 2015).

Table 1 gives an overview of key features of the pharmaceutical distribution systems in the key markets observed.

Table 1: Overview of key features of the pharmaceutical distribution systems in DE, ES, FR, IT, NL, UK, 2015

	DE	ES	FR	IT	NL	UK
Type of distribution system	multichannel	multichannel	multichannel	multichannel	multichannel	multichannel
Distribution through	Full-line wholesaling, short-line wholesaling, direct sales	Full-line wholesaling, direct sales	Full-line wholesaling, direct sales	Full-line wholesaling, direct sales	Full-line wholesaling, short-line wholesaling, direct sales	Full-line wholesaling*, short-line wholesaling, direct sales, DTP, RWA
National full-line wholesaler	5	1	3	5	5	3
Regional full-line wholesaler	7	39	4	36	1	6
National PSOs	Yes	Yes	Yes	Yes	No	No
DTP	No	No	No	No	n.a.	Yes

^{*} Currently, there are no wholesalers in the UK carrying the full range of products as none of the operators receive the full range of medicinal products, due to market conditions.

Source: GIRP data 2015

3.3 Market share

The market growth rates of the full-line wholesaling sector in some observed countries are decreasing or remaining relatively stable due to the growing importance of alternative distribution systems such as DTP and RWA in the UK, as well as the increase of direct sales in many other countries. Mainly highly innovative products are distributed increasingly through alternative distribution channels and negatively affecting the wholesale turnover (Thormann et al. 2007, GIRP data 2015). Measured in quantity in the six analysed countries between 3% and 37% were delivered directly (figure 3).

Quantity and price regulations, which curbing pharmaceutical expenditure, negatively impact the turnover of the wholesale sector mainly by reduced margins (see chapter "Regulation"). Also the increasing number of patents expiring (including biopharmaceuticals), leading to a growing number of cheaper products.

The above mentioned market developments lead to change in pharmaceutical portfolios of the pharmaceutical full-line wholesale model.

Due to their public service function, pharmaceutical full-line wholesalers have to handle all medicinal products, whereas pharmaceutical short-liners and direct sales distributors can decide to predominantly distribute specialty, high volume and high margin products ("cherry picking") (GIRP 2009, GIRP 2011).

In 2015, pharmaceutical full-line wholesalers generated a total turnover of \leqslant 141 billion in the EU-26 + CH + NO. Compared to 2010 it was a moderate increase of 5 billion. The turnover in the key market (DE, ES, FR, IT, NL, UK) exhibits \leqslant 92 billion in the year 2015 (GIRP data 2015).

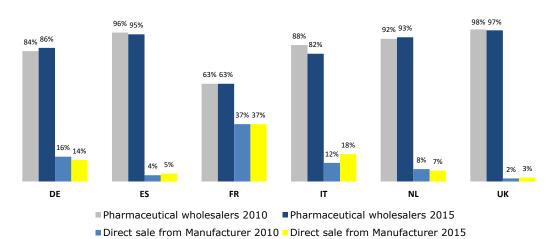


Figure 3: Turnover (units) by distribution channel – retail market in DE, ES, FR, IT, NL, UK*, 2010 & 2015

Source: IMS health 2010-2015, IPF research 2016

^{*} Currently, there are no wholesalers in the UK carrying the full range of products

In 2015, pharmaceutical full-line wholesalers generated a total turnover of €141 billion in the EU-26 + CH + NO.

In the six analysed countries the enormous turnover of €92 billion was generated by only 115 wholesale companies, which hold 637 operating sites. They guarantee the continuous supply of 105,353 dispensing points and for the 336 million citizens of the observed key markets (GIRP 2015, EUROSTAT 2015).

4 Overview of the regulatory framework

In European healthcare systems expenditures for medical goods, including pharmaceuticals, account for 12% – 36% of total healthcare expenditures and are therefore a major concern for decision-makers (OECD 2016). On average, EU countries devoted 8.8% of their GDP to health spending in 2015. Among EU Member States and the selected countries, Germany allocated the highest share to health (11.1%), followed by France and the Netherlands (at 11% and 10.8%, respectively). The share of health spending in GDP was lowest in Romania and Latvia at below 6% (OECD 2016).

Pharmaceutical expenditures significantly differ across EU Member States and range from 6.7% of total healthcare expenditure in Denmark to 28.4% in Greece. Among the six selected countries, Spain has the highest percentage of total health expenditures for pharmaceuticals (17.9%), followed by France (15%) and Germany (14.5%). The lowest percentage is exhibited by the Netherlands (7.6%) and the UK (12.2%) (OECD 2016).

Due to a different mix of pharmaceutical price-regulation mechanisms, pharmaceutical prices differ significantly across countries. According to a European price comparison conducted by the Institute for Pharmaeconomic Research (IPF) for the year 2014, the exfactory prices indices (based on standard-unit (SU) prices; European average price (100) showed that Denmark (159) had the highest price index, and the Czech Republic (56) had the lowest (Walter et al. 2015). The purchasing power differences among European countries were not considered in this illustration. The price indices of the six target countries were 116 for Germany, 102 for France, 96 for Italy, 90 for Spain, 84 for the Netherlands and 60 for the UK respectively.

In most countries, wholesale remuneration is calculated according to a percentage-based margin system. Therefore, the pharmaceutical wholesale industry is directly and indirectly affected by different price-regulation mechanisms. Indirectly, the wholesale industry is affected by decreases in medicine prices and cuts in pharmacy remuneration (price decreases lead to lower remuneration and in many countries margins for high-priced products are capped), and directly, it is affected by changes in the wholesale remuneration.

In addition to the regulation of prices and remuneration, pharmaceutical wholesalers are significantly impacted by increased cost pressures resulting from various new legislative and regulatory measures such as the new GDP guidelines introduced in 2013, the Falsified Medicines Directive (requiring batch number recording), the Delegated Regulation on medicines verification as well as the new regulations on medical devices and in-vitro diagnostics, which put new obligations for product verification procedures. It is important to note that, on account of these measures as well as indirect and direct price and remuneration regulation, gains resulting from an increase in wholesalers' productivity are no longer realistic.

4.1 Price regulation in the pharmaceutical market

Control over pharmaceutical prices is either direct or indirect. Direct controls occur through price determination on the market using a specific pricing methodology (e.g. reference pricing); indirect controls, for example, occur via the rate-of-return on capital invested or return-on-sales. The former scheme is in operation, albeit in different forms and in different pharmaceutical market segments, in the majority of EU member states. The latter applies only to the UK and is referred to as the Pharmaceutical Price Regulation Scheme (PPRS) (Kanavos 2001).

European countries use a variety of *reimbursement regulations*. All countries have either a positive or negative list that specifies which medicines are publicly covered (positive list) or are excluded from public coverage (negative list). Furthermore, several countries use Cost-Benefit-Analysis or Health Technology Assessment (HTA)² to determine whether a medicine should be reimbursed or not. Although HTA is commonly used for new innovative medicines entering the market, many countries use HTA procedures for a subset of medicines with an added therapeutic value.

Health policies may also aim to *control prices directly or indirectly*. This may be done through price freezes and cuts, mandatory discounts and rebates granted by pharmaceutical manufacturers to purchasers. Payback/clawback policies aim at preventing budget overshooting by claiming refunds from the industry once a target budget is exceeded. Increasingly, public tendering is used to increase price competition and to reduce purchase prices. (Carone et al. 2012)

With increasing use of *discounts and rebates*, which are often 'hidden price cuts', policy makers create a situation in which the surveyed list prices may provide – at best – only an indication of but do not reflect actual prices paid (Vogler et al. 2012).

The most commonly used discounts and rebates are price reductions and refunds linked to sales volume. Other types like in-kind support, price-volume and risk-sharing agreements are also implemented. Usually a mix of various types of discounts and rebates are used. Many of these arrangements are confidential (Vogler et al. 2012). Discounts and rebates can be designed to be shared by all actors (pharmaceutical companies, wholesalers, pharmacies) in the pharmaceutical supply chain (e.g. in Spain). In some countries, companies have the choice between price reductions or payments back to public payers (Vogler et al. 2012), whereas in other countries pharmaceutical companies offer "hidden discounts" to payers.

A multiplicity of price control variations exists. In some countries, there is a set maximum amount for reimbursement. This is usually calculated on the basis of the actual price of a medicine, or in relation to the prices of other similar medicines on the market (internal reference pricing), or, by comparing the prices of neighbouring countries (external reference pricing).

Including Cost-Effectiveness-Analysis, Cost-Utility-Analysis or Budget-Impact-Analysis. Cost-Benefit-Analysis is used as synonym term for both Cost-Effectiveness-Analysis and Cost-Utility-Analysis.

The European Pharmaceutical Wholesale Sector

At present, 20 EU Member States use *internal reference pricing* in order to set the price to be paid by the public payers. They do so by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group. Internal reference pricing is a system of determining the maximum price to be reimbursed by a third payer ("reference price"). The patient pays the difference between the retail price and the "reference price", in addition to any co-payment arrangement. The "reference price" applies to all pharmaceuticals within the corresponding group of products (Carone et al. 2012).

Table 2: Overview of regulation in the pharmaceutical market in the European Union

	Reimbursement Regulation				Direct Price Regulation		Indirect Price Regulation											
	Medication Lists		Evaluation						contribut	ntribut		Price	Inter-	generic substitution	Regulation	legal PSO		
Country	Positive List	Negative List	Benefit Analysis	Cost- Benefit Analysis*	Free Pricing**	Ascertain ment of Price	Price Negotiation	Discounts	ions to reimburs ement	Reimburs ements	Profit Control	Intervent ions	national Price Referencing	by	of whol- esalers margin	on whole- salers	DTP	RWA
AT	yes	yes	yes	yes	yes	no	yes	yes	yes	no	no	yes	yes	no	yes	no	yes	yes
BE	yes	no	yes	yes	no	yes	no	no	yes	yes	no	yes	yes	yes	yes	yes	n.a.	n.a.
BG	yes	no	n.a.	n.a.	no	yes	no	n.a.	n.a.	n.a.	no	yes	yes	no	yes	no	no	no
CY	yes	no	n.a.	n.a.	no	yes	no	n.a.	n.a.	n.a.	no	yes	yes	n.a.	n.a.	n.a.	n.a.	n.a.
CZ	yes	no	n.a.	n.a.	no	yes	no	no	yes	no	no	yes	yes	yes	yes	yes	yes	yes
DE	no	yes	yes	yes	yes	no	no	yes	yes	no	no	yes	yes	yes	yes	yes	no	n.a.
DK	yes	no	yes	yes	yes	no	no	no	no	no	no	yes	yes	yes	no	no	n.a.	n.a.
EE	yes	no	n.a.	n.a.	no	yes	yes	n.a.	yes	n.a.	no		yes	yes	yes	no	no	no
ES	no	yes	yes	yes	no	yes	no	yes	yes	yes	no	yes	yes	yes	yes	yes	no	yes
FI	no	yes	yes	yes	no	yes	no	no	yes		no	yes	yes	yes	no	yes	yes	no
FR	yes	no	yes	yes	yes	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no	no
GB	no	yes	yes	yes	yes	no	no	no	no	yes	yes	yes	yes	no	no	no	yes	yes
EL	no	yes	yes	yes	no	yes	no	no	yes		no	yes	yes	yes	yes	yes	yes	n.a.
HU	yes	yes	yes	yes	no	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	yes	n.a.
HR	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	no	yes	no	no	yes
IE	yes	no	yes	yes	no	no	yes	no	no	yes	no	yes	yes	yes	no	n.a.	yes	yes
IT	yes	no	yes	yes	no	no	yes	yes	yes	yes	no	yes	yes	yes	yes	yes	no	no
LT	yes	no	n.a.	n.a.	no	yes	no	n.a.	yes	n.a.	n.a.	no	yes	yes	yes	no	yes	yes
LU	yes	no	yes	yes	no	yes	no	n.a.	n.a.	n.a.	n.a.	no	yes	yes	yes	yes	no	yes
LV	yes	no	n.a.	n.a.	no	yes	yes	yes	yes	n.a.	n.a.	yes	yes	yes	yes	yes	yes	n.a.
MT	n.a.	n.a.	n.a.	n.a.	yes	no	no	no	no	no	no	no	yes	n.a.	n.a.	n.a.	n.a.	n.a.
NL	yes	yes	yes	yes	no	yes	no	n.a.	yes	no	no	yes	yes	no	no	no	no	no
NO	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	yes	no	yes	no	no
PL	yes	no	yes	yes	no	yes	yes	no	no	no	no	yes	yes	yes	yes	yes	yes	yes
PT	yes	no	yes	yes	no	yes	no	no	yes	yes	no	yes	yes	yes	yes	yes	n.a.	n.a.
RO	yes	no	n.a.	n.a.	no	yes	no	n.a.	n.a.	n.a.	n.a.	yes	yes	yes	yes	yes	yes	yes
SE	yes	yes	yes	yes	yes	no	no	no	no	no	no	yes	no	yes	no	no	yes	yes
SI	yes	no	n.a.	n.a.	no	yes	no	n.a.	n.a.	n.a.	n.a.	no	yes	yes	yes	yes	no	yes
SK	yes	no	no	no	no	yes	no	no	yes	no	no	yes	yes	yes	yes	yes	no	no

Source: Cassel & Ulrich 2014, GIRP data 2015

International or external reference pricing is one commonly employed instrument to control the prices of pharmaceuticals that are protected by intellectual property rights and benefit from a legal monopoly (in-patent medicines). Currently, 24 EU Member States use some form of external reference pricing (see Table 2) (Ruggeri et al. 2013). Sweden and the UK are the only exceptions. The number of countries considered within a country basket varies, ranging between 4 and 24 countries. The most referenced countries are France (19), followed by the UK and Germany (17), Austria, Spain and Slovakia (16), Belgium, Denmark, Finland, the Netherlands and Italy (15). The least referenced countries are Croatia (acceded to the EU in July 2013) (5), and non-EU countries: Switzerland (2), Iceland (3) and Norway (6) (Toumi et al. 2014).

Table 3 shows the reference countries included in the country basket for price determination using external reference pricing (directly influenced) in the six selected countries. As the six countries were also located in various country baskets (indirectly influenced), price determination based on external reference pricing has a much wider impact.

Ruggeri et al. 2013 presents the multiple relationships of external reference pricing using the following example: Germany reduces the price for a given medicine that is marketed in all countries by $\[\in \]$ 1; this would reduce domestic prices by $\[\in \]$ 0.27–0.29 in the Netherlands, $\[\in \]$ 0.21–0.23 in Ireland and $\[\in \]$ 0.07 in Austria. As Austria is in the country basket that includes the Netherlands and Ireland, prices in Austria would fall by an additional $\[\in \]$ 0.08. The cumulative (direct and indirect) impacts of a price change in Germany, therefore, would result in a total reduction of $\[\in \]$ 0.15 in the price of that medicine in Austria (Ruggeri et al. 2013).

Table 3: Direct and indirect reference states of the selected six countries

	Directly influenced	Indirectly influenced				
France	Germany, UK, Spain & Italy	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Portugal, Romania, Slovenia, Slovakia & Sweden				
Germany	Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Slovakia & UK	Croatia, Cyprus, Estonia, Germany, Hungary, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Malta, Poland, Romania, Sweden & Slovenia				
Italy	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Sweden, Slovenia, Slovakia & UK	Liechtenstein & Switzerland				
Netherlands	Belgium, France, Germany & UK	Austria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Sweden, Slovenia & Slovakia				
Spain	Austria, Belgium, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Malta, Portugal, Slovenia & Slovakia	Croatia, Czech Republic, Denmark, Hungary, Ireland, Lithuania, Luxembourg, Latvia, Poland, Romania, Spain, Sweden, Slovenia & UK				

Source: Ruggeri et al. 2013

Generic substitution refers to the practice whereby pharmacists are induced or mandated to dispense the cheapest bioequivalent medicine. This practice is mandatory in 8, indicative in 13 and disallowed in 5 EU Member States, as dispensing the cheapest medicine indirectly influences the profit margin of wholesalers and pharmacists.

Direct supply-side-conducted regulatory measures of medicine prices, such as direct and indirect price controls, discounts and rebates, external and internal reference pricing, fundamentally influence the profit margin.

4.2 Development of the wholesale margins

As referred to above, price changes in recent years have had a negative impact on wholesalers' margins. Due to the fact that the majority of EU countries have regulated wholesale margins (with the exceptions of Denmark, Finland, the Netherlands, Sweden, Switzerland and the UK, which have entered into private negotiations with manufacturers), pharmaceutical full-line wholesalers have almost no possibility to control their margins. In addition thereto, they cannot influence the demand of medicinal products or their prices, as these are mostly regulated by the national authorities. In the EU, the average wholesale margins for the total retail market range from 3% in Sweden to 13% in Luxemburg, measured as a percentage mark-up of the manufacturing price (IPF Survey, 2015).

Fixed % based **Regressive** % Mixed fee and % Fee for service model based model based model model • no % decline in price • % declines in price Fixed amount and % · Who is the client? based amount per pack > Manufacturer bands bands no absolute maximum Most models are limited Better coverage of fixed > Pharmacy by an absolute maximum > Payer ria Czech Republic Portugal Slovenia Lithuania Kingdom

Figure 4: Overview of Wholesalers' Remuneration Models

^{*}UK: PPRS, however, most branded medicines are distributed through Reduced Wholesale Arrangements (RWA) and Direct-to-Pharmacy (DTP)

Source: GIRP 2016

Pharmaceutical full-line wholesaling has a B2B (business to business) function, meaning that wholesalers not only suffer from the reduction of their own margin, but also feel the knock-on effect of a reduction in the pharmacy margin or a reduction in the prices of medicinal products.

100 Index, Year 2001 = 100
95 100
90
85
80
75 70.7
70
65
60
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014

Figure 5: Development of average wholesale margin in DE, ES, FR, IT, NL, UK, 2001-2014

Source: IPF research 2015

The index of wholesale margins has steadily decreased since 2001 from 100 to 71 during last 15 years.

Both direct and indirect measures have led to an average reduction of 29.3% in the wholesaler mark-up since 2001. This means, for example, that a wholesaler's mark-up of 15% in 2001 will have decreased to 10.6% in 2014.

Despite decreasing margins, pharmaceutical full-line wholesalers have continuously expanded their service offer and quality guarantee. With the introduction of Public Service Obligations (PSO) in some countries, pharmaceutical full-line wholesalers safeguard "public responsibility" towards governments. Such obligations, if put on pharmaceutical full-line wholesalers, guarantee that an adequate range of medicinal products are permanently available and that the requirements of a specific geographical area can be met immediately. In addition thereto, PSOs can also prevent "cherry picking", as they help to prevent an increase in pharmaceutical full-line wholesalers' responsibilities and a lack or decrease in short-liners' and manufacturers' responsibilities (Roland Berger 2010). This cannot be guaranteed under 'normal' market conditions (GIRP 2009). Within the European Union, 16 countries fulfil PSOs, including, France, Germany, Italy and Spain.

An important role and function of pharmaceutical full-line wholesalers is the fact that they allow market access also to small and medium-sized pharmaceutical companies whose products would otherwise face significant problems (e.g. high investment, etc.) in accessing the market.

Finally, it can be summarised that wholesalers are squeezed between the price regulations of pharmaceutical products they distribute, the nature of competition and the legal requirements (e.g. GDP), and of PSOs (if in place), which are – in some cases - responsible for very low net margins. Also, the direct involvement of manufacturers in distribution has changed the ways in which the sector operates. These are discussed in detail in the following chapters.

5 Supply chain partners' perceptions of the distribution sector

A central issue of the present study is to analyse the satisfaction of the supply chain partners, pharmaceutical manufacturers and pharmacists, concerning their pharmaceutical distribution system. The supply chain, in general, is defined as the network of organisations that are involved, through upstream and downstream linkages, in the different processes and activities that produce value in the form of products and services delivered to patients.

The previous study conducted in 2011, investigated, for the first time, pharmacists' levels of satisfaction with their pharmaceutical suppliers. Similarly, the current study seeks to examine pharmacists' present levels of satisfaction so as to be able to offer a comparative analysis and to detect potential or arising concerns with the different distribution channels. Compared to the previous study, the present study has a broader approach and includes additional supply chain partners, namely the pharmaceutical industry. It also includes new elements within the survey, such as questions pertaining to service level improvements and medicine safety.

Two sets of online surveys were developed to obtain information about pharmacists' and manufacturers' perceptions of their supply distribution systems. Both surveys were carried out electronically from December 2015 to May 2016. The pharmacist survey was circulated among pharmacists in six key European markets (Germany, France, Italy, the Netherlands, Spain and the United Kingdom), representing 74% of the total wholesale sales in terms of value. The survey of pharmaceutical companies, on the other hand, was disseminated globally. The global approach to the manufacturers' questionnaire is based on the fact that pharmaceutical companies pursue global strategies. The total number of pharmacists who participated in the study is 376. In total 123 pharmaceutical companies responded to the survey.

Both questionnaires (for pharmacists and manufacturers) were set up in a similar fashion and included the following six main sections:

- General information
- Type of system used for supply or distribution
- Satisfaction with the distribution system
- Areas for improvements in the service level
- Safety of medicines (only pharmacists)
- Future trends e.g. risks and chances of the distribution system

Please note the following while reading the results of this study:

- ▶ Major results and charts are presented in the text below as well as in Annex 2. The original questionnaires are presented in Annex 3 and Annex 4. Future trends, risks and chances, are discussed in chapter 7.
- ▶ For some sections of the questionnaire, respondents were asked to indicate their levels of satisfaction. In order to do so, respondents were given five possible response options: very satisfied, satisfied, neutral, dissatisfied and very dissatisfied. In order to simplify the results and the graphical depictions throughout this study, the term "satisfied" was used to summarise the two categories "very satisfied" and "satisfied"; the term "dissatisfied" was used to refer to the response options "dissatisfied" and "very dissatisfied".
- ▶ For some sections of the questionnaire, respondents were asked to indicate their *levels of agreement* with statements presented in the questionnaire. In order to do so, respondents were given five possible response options: strongly agree, agree, neutral, disagree and strongly disagree. In order to simplify the results and the representation of data, the term "agree" was used to summarize the two categories "strongly agree" and "agree", while the term "disagree" was used to refer to the categories "disagree" and "strongly disagree".
- ▶ Due to the fact that the results of this study reflect the responses of a random sample, the findings should be considered as a trend rather than results of a representative sample of the entire pharmacy and industry sectors. Moreover, it is important to note that satisfaction levels as well as the services provided by the different distribution systems are difficult to compare due to respondents' diverse expectations and standards.
- ▶ The main source of potential bias relates to how the survey questions were phrased. It is possible that due to sectoral, structural and market differences between countries and cultures, respondents may have interpreted the survey questions and vocabulary in slightly different ways. In order to minimise bias arising from linguistic and associational differences in each country, the translated versions of the pharmacy questionnaires (German, French, Spanish and Italian) were sent to pharmacists in the respective target countries for linguistic verification. The online questionnaire addressed to Dutch pharmacists was not translated as English is widely used and understood.

5.1 Pharmacists' survey

The pharmacist survey was circulated among pharmacists in the six key European markets (Germany, France, Italy, the Netherlands, Spain and the United Kingdom). The collection and analysis of data was carried out as follows:

The collection of data from pharmacists was carried out at the country level; therefore data and analyses are available for each country. Due to low response rates from pharmacists in the Netherlands and Spain, the figures collected are scientifically insignificant and have not been presented in the country level findings. Instead, these have been included in the overall analysis for all countries.

Due to country-specific developments regarding distribution models in the UK, results for all kinds of wholesalers were aggregated. In Italy and France short-line wholesalers do not operate due to regulatory restrictions. In France, pharmaceutical distributors other than pharmaceutical full-line wholesalers are referred to as "pharmaceutical non-full-line wholesale sources" for the purposes of this study.

5.1.1 Distribution system used by pharmacists

Overall, the findings show that there is a high level of satisfaction with pharmaceutical full-line wholesalers. Pharmacists' high and positive response rate demonstrate the importance of this distribution system to pharmacists. As regards pharmacists' satisfaction with their supply system, 88% of pharmacists were satisfied with the pharmaceutical full-line wholesale model.

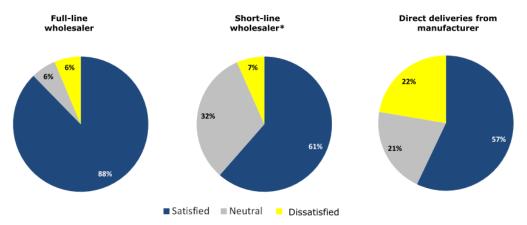


Figure 6: Overall satisfaction with the distribution system

*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'

Source: IPF research 2016, Pharmacist survey

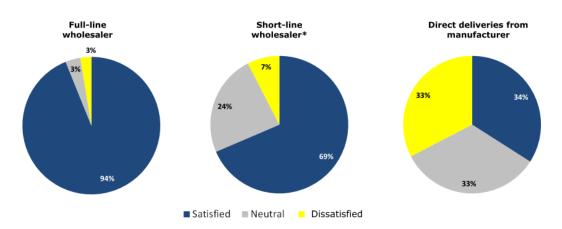


Figure 7: Overall satisfaction with the delivery time

*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'

Source: IPF research 2016, Pharmacist survey

According to their responses, 94% of pharmacists were satisfied with pharmaceutical full-line wholesalers' delivery time.

Similarly, 90% of pharmacists in all six target countries felt that the service level performance of pharmaceutical full-line wholesalers was very high. In particular, pharmacists felt that the delivery frequencies of pharmaceutical full-line wholesalers were sufficient (94%) and that their order systems were convenient (92%). Detailed results of each service level item can be found in Annex 2.

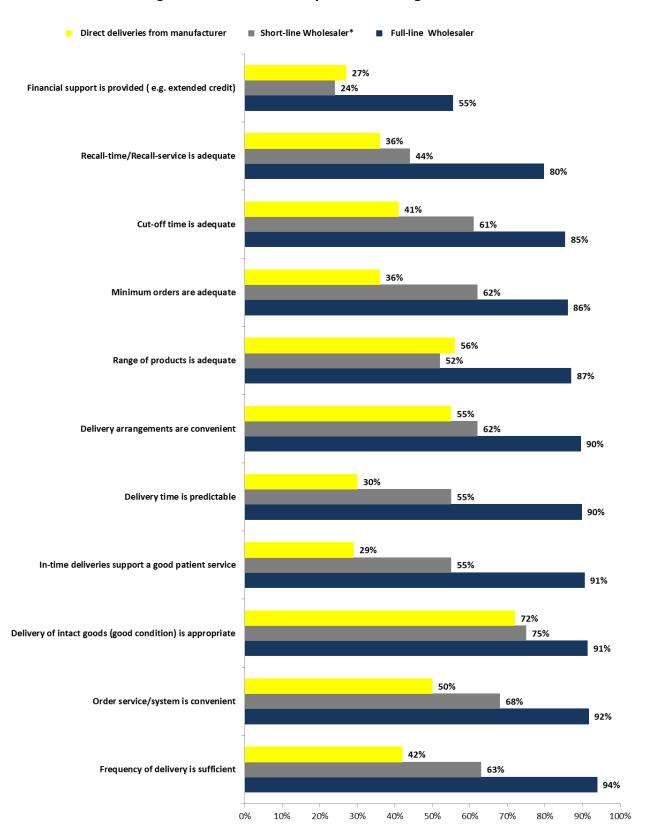


Figure 8: Service level - pharmacists' agreement

*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'
Source: IPF research 2016, Pharmacist survey

The above results demonstrate pharmacists' high levels of satisfaction with the range and quality of services offered by pharmaceutical full-line wholesalers, which provide a "one-stop shop" and deliver medicines just-in-time in the right quantity and quality.

The last part of the questionnaire regarding the 'Safety of medicines' also showed high levels of satisfaction with pharmaceutical full-line wholesalers: More than 90% of pharmacists answered that the safety of medicines during transportation was adequate, that the cold-chain was respected and that pharmaceutical full-line wholesalers offered protection against falsified medicines.

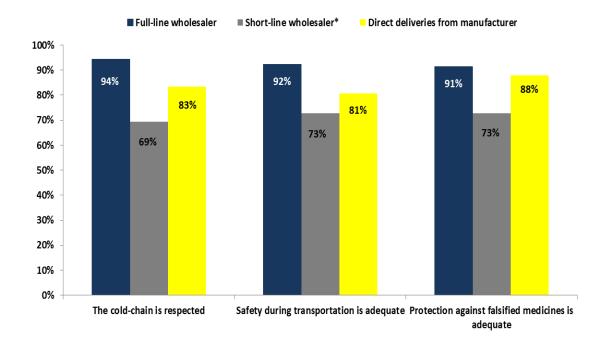


Figure 9: Safety of medicines - pharmacists' agreement

*in countries where short-liners do not exist (i.e. France), we refer to pharmaceutical 'non-full-line wholesale sources'

Source: IPF research 2016, Pharmacist survey

5.1.1.1 Individual country-level results

France:

According to the survey, 95% of French pharmacists responded that they were very satisfied with the pharmaceutical full-line wholesale model. Only 5% of the pharmacists did not reply to this question. Compared with the previous study in 2011, satisfaction levels among French pharmacists have increased: In 2011, 91% of pharmacists were satisfied with the pharmaceutical full-line wholesale model. The high response rate and the fact that 95% of pharmacists indicated that they were very satisfied with their medicines

supply via pharmaceutical full-line wholesalers, confirms the high importance of pharmaceutical full-line wholesalers to French pharmacists.

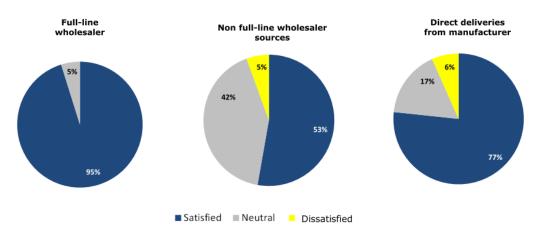


Figure 10: Overall satisfaction with the distribution system

Source: IPF research 2016, Pharmacist survey

French pharmacists also expressed very high levels of satisfaction with pharmaceutical full-line wholesalers' delivery time. In fact, 100% of French respondents expressed their satisfaction with the delivery time offered by pharmaceutical full-line wholesalers. This figure has increased from 96% in 2011 to 100% in 2016.

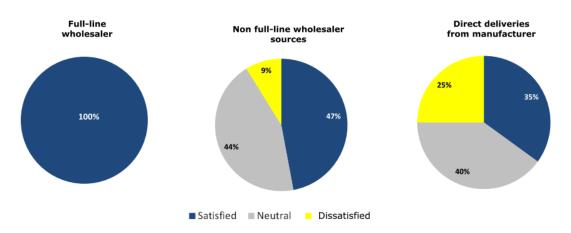


Figure 11: Satisfaction with the delivery time

Source: IPF research 2016, Pharmacist survey

A clear majority (77%) of those pharmacists who took part in the survey in France affirmed that they bought innovative products from a pharmaceutical full-line wholesaler. 70% of respondents indicated that they purchased other branded medicines from pharmaceutical full-liners, 52% used pharmaceutical full-liners to purchase generics, and only 15% of pharmacists used pharmaceutical full-line wholesalers to obtain OTC products.

In this case, the majority of pharmacists (71%) indicated that they purchased OTCs directly from the manufacturer.

Innovative medicines

Other branded medicines

Generics

OTC

13%

14%

15%

77%

Wholesaler

Other**

Figure 12: Distribution systems used by French pharmacists for the following product categories

Other**: GROUPEMENT, Plateforme groupement, giphar, centrale achat groupement, plateforme, plateforme groupement, réimportateur

Source: IPF research 2016, Pharmacist survey

Referring to the service level, French pharmacists also considered the performance of pharmaceutical full-line wholesalers to be very high. 95% of respondents provided positive feedback on the service level offered by their pharmaceutical full-line wholesalers. Detailed results of each item can be found in Annex 2.

Similarly, the results of the section 'Safety of medicines' show that 90% of pharmacists feel that pharmaceutical full-line wholesalers respect the cold-chain, protect against falsified medicines, and ensure the safety of medicines during transportation.

Detailed results are listed in Annex 2.

Germany:

The results of the German survey show that the acceptance and importance of pharmaceutical full-line wholesalers is very high among pharmacists. Concerning pharmacists' satisfaction levels, 94% of pharmacists were satisfied with the pharmaceutical full-line wholesale model.

Full-line wholesaler

Short-line wholesaler

Jorect deliveries from manufacturer

10%

22%

50%

Satisfied

Neutral

Direct deliveries from manufacturer

10%

22%

Figure 13: Overall satisfaction with the distribution system

Source: IPF research 2016, Pharmacist survey

100% of respondents were fully satisfied with the delivery time offered by their pharmaceutical full-line wholesaler. Compared with the study results from 2011, these figures have improved significantly. Previously only 79% of pharmacists were satisfied with the performance of their pharmaceutical full-line wholesaler and 92% were satisfied with the delivery time.

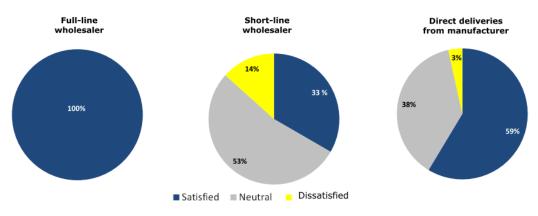


Figure 14: Satisfaction with the delivery time

Source: IPF research 2016, Pharmacist survey

67% of German pharmacists indicated that they obtained innovative medicines from a pharmaceutical full-line wholesaler, 72% used the pharmaceutical full-line wholesaler to purchase other branded medicines, and more than half of the pharmacists answered that they chose the pharmaceutical full-line wholesale model to purchase generics (65%) and OTC products (51%).

Innovative medicines

Other branded medicines

OTC

3%

2%

33%

44%

51%

Full-line wholesaler

Short-line wholesaler

Short-line wholesaler

Other**

Figure 15: Distribution systems used by German pharmacists for the following product categories

Other**: Reimports

Source: IPF research 2016, Pharmacist survey

The performance of pharmaceutical full-line wholesalers is considered to be very high among German pharmacists. 100% of pharmacists are satisfied with pharmaceutical full-liners' deliveries of intact goods, the predictability of delivery times and the delivery-frequency. Detailed results of each item can be found in Annex 2.

The results of the section 'Safety of medicines' show that the performance of pharmaceutical full-line wholesalers is considered to be very high among pharmacists. In particular, pharmacists felt that pharmaceutical full-line wholesalers respected the cold-chain adequately, protected against falsified medicines and ensured the safety of medicines during transportation.

Italy:

In Italy, the results of the survey show similar satisfaction trends and tendencies as in Germany.

The high level of satisfaction among Italian pharmacists (98%) as well as the high levels of satisfaction with pharmaceutical full-line wholesalers' delivery time (94%) attests to the fact that the pharmaceutical full-line wholesaling model plays an important role in Italy. As country specific data was not available during the 2011 study, a comparison of the evolution of satisfaction levels among Italian pharmacists is not possible.

Full-line wholesaler

2%

4%

15%

98%

Satisfied Neutral Dissatisfied

Figure 16: Overall satisfaction with the distribution system

Source: IPF research 2016, Pharmacist survey

94% of Italian pharmacists were fully satisfied with the delivery time offered by their pharmaceutical full-line wholesaler. A comparison with the previous study results is not possible, because country specific data was not available during the 2011 study.

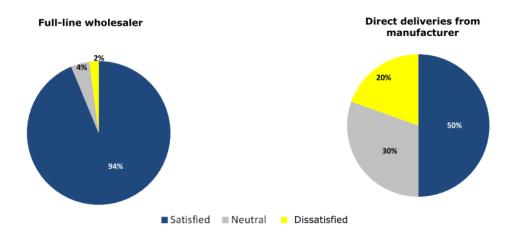


Figure 17: Satisfaction with the delivery time

Source: IPF research 2016, Pharmacist survey

75% of those Italian pharmacists that participated in the survey indicated that they bought innovative products from a pharmaceutical full-line wholesaler, 62% indicated that they purchased other branded medicines from them, and 75% purchased generics and 65% purchased OTC products from pharmaceutical full-line wholesalers.

Innovative medicines

Other branded medicines

Generics

OTC

1%

23%

35%

65%

Full-line wholesaler

Other**

Direct deliveries from manufacturer

Figure 18: Distribution systems used by Italian pharmacists for the following product categories

Other**: Parallel imports

Source: IPF research 2016, Pharmacist survey

The section of the survey pertaining to wholesalers' service level also elicited positive responses from Italian respondents. On average, more than 95% felt that pharmaceutical full-line wholesalers offered a high level of service. Detailed results are listed in Annex 2.

The results of the section 'Safety of medicines' also show very high levels of satisfaction among Italian pharmacists: 96% considered the degree of protection provided by pharmaceutical full-line wholesalers against falsified medicines to be adequate.

United Kingdom:

In general, the findings of the UK survey show that the majority of pharmacists in the United Kingdom were satisfied with their distribution system. Due to the particular nature of the UK healthcare distribution context, short and pharmaceutical full-line wholesalers were pooled together into one group for the purpose of this study. They will henceforth be referred to generically as **'wholesalers'**.

72% of pharmacists in the UK indicated that they were satisfied with the wholesale model. 11% of respondents were dissatisfied with this model.

Wholesaler*

Direct deliveries from manufacturer**

22%

72%

Satisfied Neutral Dissatisfied

Figure 19: Overall satisfaction with the distribution system

Wholesaler*: incl. RWA; Direct deliveries from Manufacturer**: incl. DTP

Source: IPF research 2016, Pharmacist survey

83% of pharmacists were satisfied with the delivery time offered by their wholesalers. Compared with the results from 2011, where 76% were satisfied with the delivery time, the overall level of satisfaction increased over the last years.

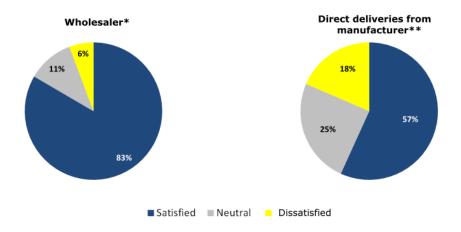


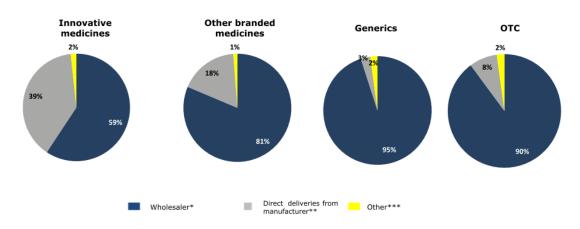
Figure 20: Satisfaction with the delivery time

 $\label{thm:manufacturer**: incl. RWA; Direct deliveries from Manufacturer**: incl. DTP$

Source: IPF research 2016, Pharmacist survey

As regards the product portfolio, almost 60% of respondents indicated that they obtained innovative medicines from wholesalers (including Reduced Wholesaler Agreements – RWA). 81% of pharmacists obtained other branded medicines via wholesalers, 95% purchased generic products, and 90% of pharmacists bought OTCs from wholesalers.

Figure 21: Distribution systems used by UK pharmacists for the following product categories



Wholesaler*: incl. RWA; Direct delieveries from Manufacturer**: incl. DTP

Other ***: quantum, special manufacturers, Wardles etc.

Source: IPF research 2016, Pharmacist survey

More than 85% of respondents felt that the level of service offered by pharmaceutical full-line wholesalers was adequate, however, only 35% agreed that they offered financial services. This response trend is similar to those observed for the other countries of the study and might therefore signal a new area for service-level improvement. Detailed results of each survey item can be found in Annex 2.

The results of the section 'Safety of medicines' show that the performance of wholesalers is considered to be high among pharmacists, especially as regards wholesalers' ability to respect the cold-chain, to protect against falsified medicines and to ensure the safety of medicines during transport. Detailed results of each survey item can be found in Annex 2.

5.2 Manufacturers' survey

As mentioned previously, the current study has a broader scope and includes new elements that were not included in the previous study. In particular, the new version includes additional supply chain partners, namely pharmaceutical manufacturers. This new dimension of the study was included to render the study more dynamic and the perspectives surrounding the quality, efficiency and reliability of the healthcare distribution sector more encompassing and comprehensive.

Since pharmaceutical companies pursue global strategies, the survey of pharmaceutical companies was disseminated globally and the results of the survey were not evaluated at the level of individual countries. The total number of manufacturers who participated in the survey was 123.

The participating manufacturers responded to the questionnaire on behalf of the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Israel, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the USA.

60% of the respondents indicated that their companies operated on an international level, 12% of the respondents have operations on the European level and 28% operated on the national level.

5.2.1 Distribution systems used by manufacturers

The majority of the responding manufacturers were satisfied with their supply chain. 78% were satisfied with the pharmaceutical full-line wholesale model in general, 19% were impartial, and only 3% of manufacturers were dissatisfied with the pharmaceutical full-line wholesale model. In general, 78% of manufacturers were satisfied with their third party logistics providers (3PLs) including the Direct-to-Pharmacy (DTP) model, 17% had a neutral attitude toward this distribution system and 5% were not satisfied with these models.

Full-line wholesaler

Short-line wholesaler

Short-line wholesaler

7%

7%

78%

Satisfied

Neutral

Dissatisfied

Figure 22: Satisfaction with the distribution system

Source: IPF research 2016, Manufacturer survey

Unlike the pharmacist questionnaire, the survey sent to the industry asked manufacturers to indicate their **reasons and motivations for using a certain distribution system.** The most commonly cited reasons for using a certain distribution system were the following are depicted in Figure 23:

^{*} Pre-wholesaling is included in 3 party logistic providers; a pre-wholesaler is an agent acting on behalf of a manufacturer and is responsible for the storage and distribution of the manufacturer's products to other wholesalers and to hospitals: manufacturer -> (pre-wholesaler) -> pharmaceutical full-line wholesaler -> public pharmacy -> patient

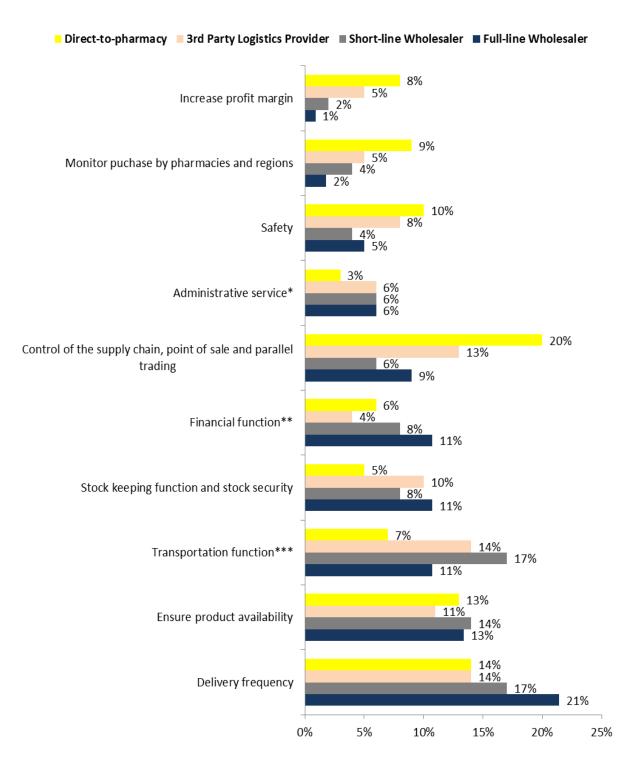


Figure 23: Motivation for selecting certain distribution models

*reduced contacts, easier accounting

Source: IPF research 2016, Manufacturer survey

^{**} the costs and financial risks are transferred – the pharmaceuticals are paid by the wholesaler and the financial risk of the goods has transferred to the wholesaler

 $[\]ensuremath{^{***}}$ from the industry to the wholesaler

According to the findings, 21% of respondents selected the pharmaceutical full-line wholesale model because of the delivery frequency and 13% due to their ability to ensure product availability. 17% of pharmaceutical manufacturers preferred short-line wholesalers because of the delivery frequency. 20% of respondents indicated that they preferred to use the direct-to-pharmacy model because it affords greater control of the supply chain and point of sale.

As only pharmaceutical full- and short-liners offer added-value services, respondents also cited the following as reasons for using these distribution routes to market their products.



Figure 24: Importance of added-value service

ste.g. Time to market, Opening sale channels

Source: IPF research 2016, Manufacturer survey

For 25% of the respondents, pharmaceutical full-line wholesalers' assistance with product recalls was of highest importance and for 19% of pharmaceutical manufacturers short-liners' support in launching a product was important.

With regard to the **service level** and potential areas for improvement, the results of the survey show that 81% of manufacturers wished to see improvements in pharmaceutical full-line wholesalers' stock level transparency. 63% of pharmaceutical manufacturers wished to see improvements in the quantity of ordered products (order quantity) and the order system. 52% of manufacturers agreed that there is room for improvement in terms of late payment services offered by pharmaceutical full-line wholesalers. Responses suggest that manufacturers would prefer extended payment periods to improve their liquidity. This figure, however, is relativised by the fact that, together, more than 50% of manufacturers had a neutral attitude toward these survey questions.

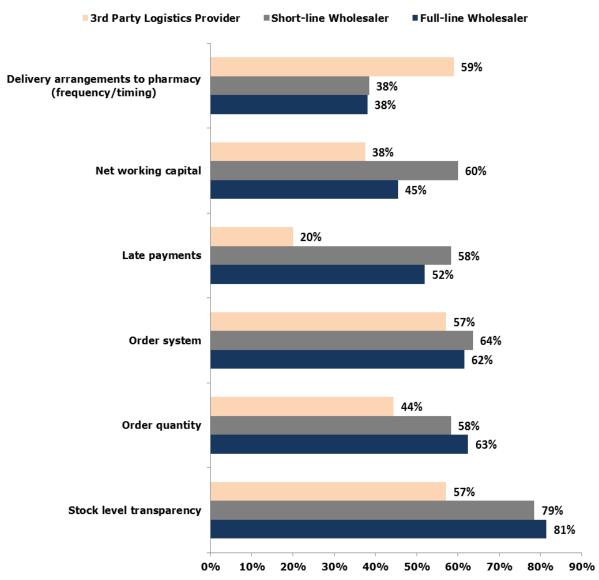


Figure 25: Service level - Desired improvements in the following areas

Source: IPF research 2016, Manufacturer survey

According to the results of the survey, pharmaceutical manufacturers believe that third party logistics providers should improve the frequency and timing of their deliveries to pharmacies. It may also be surmised that manufacturers feel that short-line wholesalers need to improve their net working capital, their order systems and their stock level transparency.

As regards pharmaceutical full-line wholesalers, pharmaceutical manufacturers see room for improvement in stock level transparency, in the order quantity and in improvements to the order system.

6 Efficiency of pharmaceutical full-line wholesaling

In order to better understand the essential role of pharmaceutical full-line wholesalers, it is worthwhile to examine how the sector achieves the complex task of distributing medicinal products whenever and wherever needed. The industry's performance, in general, is evaluated according to its ability to maintain a nation-wide, efficient, safe and continuous supply of medicinal products.

An efficient distribution system provides economic and social opportunities as well as benefits that result in positive multiplier effects, such as better accessibility to markets, employment and additional investments. When distribution systems are deficient, both in terms of capacity or reliability, they result in extra costs, missed opportunities and lower quality of life for patients.

6.1 Efficiency indicators

A variety of reliability indicators can be used to show the industry's efficiency. In this study, we will focus on indicators associated with the main functions of pharmaceutical full-line wholesalers, namely:

- (1) the full supply and stock-keeping function
- (2) the immediate medicines availability and delivery function
- (3) the bundling function
- (4) the quality assurance function
- (5) the financing function

These will be outlined in detail below.

6.1.1 Full supply function and stock keeping function

Pharmaceutical full-line wholesalers carry and distribute the complete assortment of products in range and depth within the framework set by the authorities and the market in order to meet the needs of those with whom they have normal business relations (Stern et al. 1992).

The number of items on stock can range up to 100,000 different products (Germany and Italy). The number of products carried by any given wholesaler depends on the size of the market and the number of products authorised on the market. Similarly, the share of medicinal products held on stock differs considerably from country to country depending on the number of medicinal products marketed.

Figure 26 gives an overview of the range of products held in France, Germany, Italy, the Netherlands, Spain and the UK. The average number of products on stock for the six listed countries is 57,176.

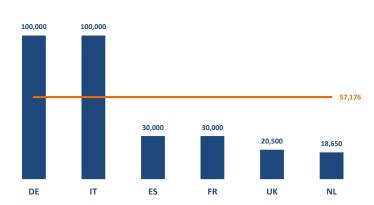


Figure 26: Items on stock held by pharmaceutical full-line wholesalers in DE, ES, FR, IT, NL, UK, 2015

Source: GIRP data 2015, IPF research 2016

The traditional logistics functions of bridging time and space are the core business functions of the pharmaceutical full-line wholesale sector. As a hub for healthcare distribution, they assume a quantity-based buffer function for healthcare providers, stocking medicinal products in sufficient quantities (oftentimes in bulk) for their geographic area of activity, and distribute them in adequate delivery sizes for further use by persons authorised to dispense medicinal products to the public. In so doing, and by applying procurement algorithms according to medicine consumption prognoses, pharmaceutical full-line wholesalers can bridge bottlenecks in peak demand times, such as during the flu season.

Since demand for specific medicinal products varies considerably and according to season, pharmaceutical full-line wholesalers manage complex flows of medicinal products. They hold a safety stock of medicines in order to meet unexpected peaks in normal demand patterns as well as unforeseen events, such as pandemics, that lead to increased demand in medicinal products.

To guarantee short-term availability of medicinal products, pharmaceutical full-line wholesalers rely on an 'optimised warehouse management' and efficient last mile delivery systems, which allow them to hold the full range of available products and to make

medicines available immediately, even in times of disruptions of supplies and unexpected demand (GIRP 2013).

On account of this ability, pharmaceutical full-line wholesalers in a number of Member States fulfil, either by law or on a voluntary basis, Public Service Obligations (PSO) that guarantee an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the entire area in question. Where such PSOs are in place, together with the legal right to be supplied³ (Belgium, France, Germany), pharmaceutical full-line wholesalers can help to pre-emptively combat or mitigate medicine shortages and to ensure continuous access to medicines. Pharmaceutical full-line wholesalers' ability to provide immediate access to medicines is an important and valued function amongst healthcare stakeholders.

Inventory turnover is a ratio showing how many times a pharmaceutical full-line wholesaler's inventory is sold and replaced over a given period. Inventory turnover differs according to the product, sometimes taking a month or only a few days, and is associated with seasonal changes.

In 2015, the inventory turnover was fastest in the UK and France, taking just 21 days on average, and slowest in Italy, taking 36 days on average. The average inventory turnover of the six considered countries amounts to 28.3 days, meaning that turnover of the total inventory takes place on average 13 times per year.



Figure 27: Inventory Turnover in DE, ES, FR, IT, NL, UK, 2015

Source: GIRP data 2015, IPF research 2016

³ In Belgium, France and Germany, manufacturers of medicinal products are required by law to supply pharmaceutical full-line wholesalers with sufficient products so as to avoid medicine shortages. Without this legal 'right to be supplied', pharmaceutical full-line wholesalers cannot adequately fulfil their public service obligation to guarantee an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a short time over the entire area in guestion.

Pharmaceutical full-line wholesalers carry and distribute the complete assortment of medicinal products in range and depth. They assume a quantity-based buffer function, stocking medicinal products in sufficient quantities for their geographic area of activity and are thus able to bridge bottlenecks in peak demand times.

6.1.2 Immediate availability and delivery of medicines

Optimal outcomes in citizens' health require access to innovative medicines, efficacious treatments and adherence. The latter implies that patients take medication properly, make and keep healthcare appointments, manage their own health and engage in behaviour that influences the course or prognosis of an illness. However, empirical studies have consistently shown that levels of patient compliance or adherence to medication or treatment plans are often far from optimal (WHO 2003).

The storage and delivery of medicinal products within a framework that ensures, above everything else, immediate availability, is of crucial importance.

One such study claims that 20%-30% of patients do not adhere to medication regimes that are curative or relieve symptoms, and 30%-40% fail to follow regimes designed to prevent health problems. When long-term medication is prescribed, 50% of patients fail to adhere to the prescribed treatment plan (CPME). In Europe, non-adherence to medicines and medication plans costs governments an estimated €125 billion and contributes to the premature deaths of nearly 200,000 Europeans a year (EFPIA).

While prescribing medicines is the first step towards safe and high quality pharmacotherapy, patients' timely access to medicines is the crucial next step to ensuring that medicines can be taken in accordance with the treatment plan. Therefore, it is essential that patients have access to the full spectrum of medicinal products, ranging from non-prescription to innovative medicines.

Pharmaceutical full-line wholesalers actively combat and mitigate medicine shortages to ensure continuous access to medicines. Pharmaceutical full-line wholesalers' ability to provide immediate access to vital medicines is an important and valued function amongst healthcare stakeholders.

The immediate availability and accessibility of vital medicines is essential in ensuring patient adherence to medicine and treatment schemes.

The **delivery function** involves getting the right medicines to the right patients at the right time in a safe and efficient manner. Every day, pharmaceutical full-line wholesalers

act as the vital link in the healthcare. They connect manufacturers to healthcare providers and patients along a complex supply chain. Medicinal products can only be used for therapy if they are available in time, therefore a prompt delivery of these medicines is essential. If medicinal products were not available within a few hours a large number of clinical guidelines would have to be revised, as they are based on the short-term availability of medicinal products (Wilke 2011). Currently only pharmaceutical full-line wholesalers achieve this delivery frequency and efficiency.

According to the *survey conducted among pharmacists* in the six observed countries, the average perceived delivery time of pharmaceutical full-line wholesalers is 4.6 hours, with an average of 16.02 perceived deliveries per week. These figures are based on deliveries received during pharmacies' regular opening hours, excluding weekends and out of hours, but including deliveries to pharmacies in remote areas (Figure 28).

The delivery time and frequency of deliveries per week *reported by pharmaceutical full-line wholesalers* are, with a delivery time of 2.56 hours and 15.88 deliveries per week on average, slightly lower than the pharmacists' perception. According to GIRP members' responses, German pharmaceutical full-line wholesalers deliver 3 times per day, French wholesalers deliver 2 times per day, Italian wholesalers deliver 3 times per day, Dutch wholesalers deliver once per day, Spanish wholesalers deliver 3 times per day and UK wholesalers deliver 2 times per day on average.

4.34
deliveries
per week

16.02
deliveries
per week

20.05 h

Pharmaceutical full-line
wholesaler

Short-line wholesaler
wholesaler

Direct sales from manufacturer

Figure 28: Delivery time in DE, ES, FR, IT, NL, UK, 2015

Data represents the weighted delivery time as well as the deliveries per week perceived by the responding pharmacists in the six target countries.

Source: Pharmacy questionnaire, IPF research 2016

According to the pharmacists surveyed for the study, pharmaceutical short-line wholesalers have an average delivery time of 20.05 hours with a delivery frequency of 4.34 times per week.

Deliveries coming directly from the manufacturer need, on average, 57.86 hours to reach the pharmacy and are delivered 3.66 times per week.

The time discrepancy of 53.26 hours between deliveries from pharmaceutical full-line wholesalers and direct sales from manufacturers can be explained by the use of divergent logistics models.

A further important indicator to evaluate the efficiency of pharmaceutical distribution is the order fill rate. This refers to pharmaceutical full-line wholesalers' ability to immediately execute orders received from pharmacies. According to the pharmacy survey, 97%-100% of pharmacists felt that pharmaceutical full-line wholesalers immediately follow-up on orders received from pharmacies.

6.1.3 The bundling function – creating significant efficiencies for pharmacies

When filling orders, pharmaceutical full-line wholesalers 'bundle' products from around 19 different manufacturers⁴ into one delivery to 'pool' multiple orders together in one delivery. This bundling function is of high value to pharmacies, as it reduces the time spent by an individual pharmacy on ordering, receiving and processing invoices from the various manufacturers whose products it sells. On a weighted average, pharmaceutical full-line wholesalers pool products from 18.8 different manufacturers per delivery. This figure has increased by 0.5 from 18.3 pooled products in 2011 to 18.8 in 2015. Pharmaceutical manufacturers are incapable of offering this delivery service, as they only hold their own products on stock and their warehouses are generally further away from pharmacies (IfH 2008).

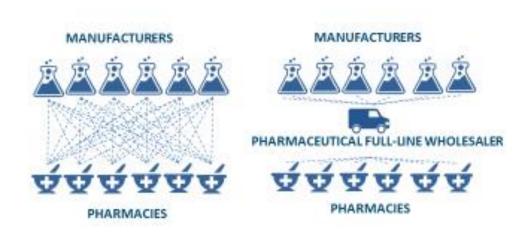
Practically speaking, if all medicinal products were supplied directly by manufacturers, pharmacies would have to contact each manufacturer individually in order to obtain a complete assortment of medicinal products. In the six countries observed, the continuous supply of medicinal products involved more than 795.6 million⁵ transactions between pharmacies, pharmaceutical full-line wholesalers and manufacturers in 2015. Without pharmaceutical full-line wholesalers this number would increase dramatically to 99.4 billion transactions per year (Figure 29)⁶.

⁴ According to responses obtained from the pharmacy survey, IPF Research 2016

⁵ Calculation based on national pharmaceutical full-line wholesalers

⁶These figures have significantly increased since 2011, when 703 million transactions occurred between healthcare stakeholders in the study's six target countries. Without pharmaceutical fullline wholesalers this number would have increased dramatically to 97.9 billion transactions per year

Figure 29: Distribution chain with and without intermediaries



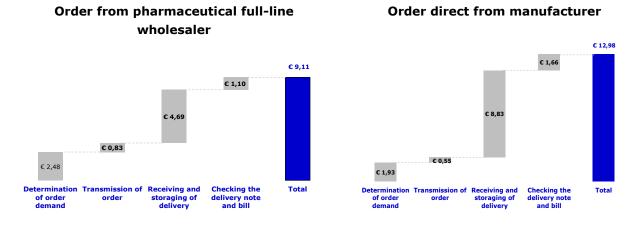
Approx. 100 billion transactions

Less than 800 million transactions

Source: Gümbel 1985, IPF research 2016

The average individual process steps in pharmacies include determining order demand, transmitting orders, receiving and storing deliveries, and checking the delivery note and invoice (IfH 2008). By comparing the process costs in pharmacies with the different supply routes, the difference in time expenditure and monetary cost (with respect to a single delivery) can be shown:

Figure 30: Pharmacy process and administration costs per order (pharmaceutical full-line wholesaler vs. direct sales from manufacturer) DE, ES, FR, IT, NL, UK, 2015



Source: EUROSTAT, IPAM 2006, Pharmacy questionnaire, IPF research 2016

- The cost difference of one direct delivery from a manufacturer to a pharmacy is
 €3.87 more expensive compared to one delivery from a pharmaceutical full-line wholesaler.
- The cost difference based on deliveries containing 18.8 products from different manufacturers is €234.84 compared to one delivery from a pharmaceutical full-line wholesaler.

Compared with the previous analysis carried out in 2011, costs of one delivery from a pharmaceutical full-line wholesaler have increased from €7.98 to €9.11 in the year 2015. The same development was observed for one delivery from a manufacturer to a pharmacy, which rose from €11.36 to €12.98. The overall cost difference therefore rose from €199.40 to €234.84.

Taking the average deliveries per week into account (15.88 times per week on average according to the pharmacy survey and 16.02 times per week according to pharmaceutical full-line wholesalers), the process costs accruing to pharmacies reveal the following figure:

Figure 31: Scenario: Impact on process costs per pharmacy per year (pharmaceutical fullline wholesalers vs. direct sales from manufacturers) in DE, ES, FR, IT, NL, UK, 2015



Source: EUROSTAT, Pharmacy questionnaire, IPF research 2016

- If 100% of the medicines ordered by pharmacies were supplied by pharmaceutical full-line wholesalers, then the pharmacy process costs would amount to €7,590 per year.
- When pharmacies order medicines from sources other than pharmaceutical full-line wholesalers, the pharmacy process costs increases significantly:

- If pharmacies were to order 25% of their supplies directly from the manufacturer, the pharmacy process costs would increase from €7,590 to a total of €55,796 per year (difference of €48,206 per year)
- If pharmacies were to order 50% of their medicines directly from the manufacturer, the pharmacy process costs would increase from €7,590 to €115,398 per year (difference of €107,808 per year)
- If pharmacies were to order 100% of their medicines directly from the manufacturer, the pharmacy process costs would increase from €7,590 to €210,814 per year (difference of €203,224 per year)
- Pharmaceutical full-line wholesalers' unique bundling function allows pharmacies to keep their process costs low

Replacement of deliveries from pharmaceutical full-line wholesalers with direct deliveries from manufacturers would entail significantly higher costs. Therefore, if there were no pharmaceutical full-line wholesalers, the process costs of an average pharmacy would increase from from $\[\in \]$ 7,590 to $\[\in \]$ 210,814 per year (difference of $\[\in \]$ 203,224 per year). For detailed information regarding the calculation, please see Annex 2. When compared with the process cost calculations conducted in 2011, process costs have increased by $\[\in \]$ 171,510.06 per year. The reason for this increase can be explained by higher salary costs and a slightly higher number of pooled products.

Through their bundling function pharmaceutical full-line wholesalers create significant efficiencies in the medicines supply chain. Without pharmaceutical full-line wholesalers, the additional costs associated with product distribution would have to be paid by manufacturers, pharmacies, health insurance funds and ultimately, by the patients.

6.1.4. Quality assurance

Pharmaceutical full-line wholesalers are actively involved in ensuring medicines safety and have established robust quality assurance systems as defined by various regulatory requirements and standards, such as the Good Distribution Practice Guidelines, ISO certifications and Standard Operating Procedures (SOPs).

According to the GDP Guidelines (2013/C343/01), for instance, distributors of healthcare products "must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities". The system for managing quality encompasses the procedures, processes and resources, as well as activities necessary to ensure confidence that the product delivered maintains its quality and integrity during storage and transportation. The quality system is overseen by a responsible person who fully documents and monitors its effectiveness. Quality systems also include quality risk management. In particular, pharmaceutical full-line wholesalers' quality assurance systems ensure that (1) medicinal products are procured, held, supplied or exported in a way that is compliant with the requirements of GDP; (2) management responsibilities are clearly specified; (3) products are delivered to the right recipients within a satisfactory time period; (4) records are made and kept contemporaneously; (5) all personnel involved

in wholesale distribution activities is continuously trained; (6) deviations from established procedures are documented and investigated; (7) appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct and prevent deviations in line with the principles of quality risk management.

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. Pharmaceutical full-line wholesalers apply quality risk management in order to ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. This is particularly relevant for medicinal products requiring special handling or having particular temperature requirements during transportation and storage. For example, procedures for handling products requiring special temperature storage and transportation (e.g. cold chain products) are routinely validated according to GDP requirements and the personnel involved in these activities receive additional training. An extra level of security is also foreseen for products requiring special handling (e.g. narcotics) which are completely segregated (both physically and electronically) during storage and transportation, and access to these products is severely restricted only to designated personnel.

Pharmaceutical full-line wholesalers are also obligated to ensure the quality of all outsourced or subcontracted activities, including procurement, holding, supply or export of medicinal products. In order to do so, pharmaceutical full-line wholesalers are vigilant about assessing the suitability and competence of the subcontractor and checking their authorisation status, if required, and monitoring the performance of subcontractors, including the identification and implementation of any required improvements on a regular basis.

Additionally, pharmaceutical full-line wholesalers have taken an active role in preventing falsified medicines from entering the legal supply chain. They are founding partners of EMVO, the European Medicines Verification Organisation, a European non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines. On account of new track and trace requirements and anti-tampering seals, pharmaceutical full-line wholesalers have been an essential partner in preventing counterfeit medicines from entering the pharmaceutical supply chain.

Pharmaceutical full-line wholesalers are actively involved in ensuring medicine safety and have established robust quality assurance systems that assess, control, communicate and review risks compromising the safety and quality of medicinal products.

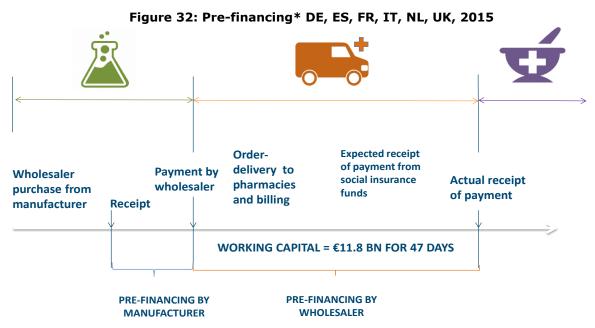
6.1.5 Pre-financing function

Pharmaceutical full-line wholesalers assume a pre-financing function towards manufacturers and pharmacies that is typically not offered by other distribution models. Pharmaceutical full-line wholesalers acquire ownership over the medicinal products when purchasing them from the manufacturers and pass on ownership to pharmacies when they are delivered. As payments made by pharmacies for their pharmaceutical supplies are usually effectuated significantly later than the delivery date, often until after reimbursement from the Statutory Health Insurance (SHI), pharmaceutical full-line wholesalers contribute significantly towards hedging healthcare system cash flows. As regards warehousing, pharmaceutical full-line wholesalers' commitment of capital also covers such risks as spoilage, breakage and loss (IfH 2008).

This function of pharmaceutical full-line wholesalers can best be expressed in terms of working capital. The working capital is affected by:

- The time frame within which incoming invoices are paid (pharmaceutical full-line wholesalers to manufacturers)
- The time frame within which the pharmaceutical full-line wholesalers' stock is financed
- The time frame within which outgoing invoices are paid

Pharmaceutical full-line wholesalers finance nearly the entire medicinal product market, guarantee the continuous supply of all medicinal products and secure the cash flow of pharmacies. Pharmacies depend on this pre-financing function for their economic sustainability; without it they are not able to afford to stock their shelves with all necessary medicines and medicinal products. Instead, they must rely on pharmaceutical full-line wholesalers to deliver the required products just in time. In France, Germany, Italy, Spain, the Netherlands and the UK alone, pharmaceutical full-line wholesalers prefinance on average €11.8 bn over a period of 47 days. In total, this sum is pre-financed approximately 7.8 times per year, and represents a total annual volume of €92 bn (figure 32).



^{*} As payment periods of pharmaceutical full-line wholesalers can claim to be representative for all wholesalers in the markets observed, the pre-financing calculation is based on the figures provided by national pharmaceutical full-line wholesalers.

Source: IPF research 2015

Compared to the findings of the previous study, the pre-financing volume increased in all six selected countries by 2.3 bn and the pre-financing period increased by 5 days from 2011 to 2015.

The funding and holding of buffer stocks, as well as the working capital and ownership that goes with wholesaling services, are vital for an effective and efficient functioning of the healthcare sector in Europe.

Pharmaceutical full-line wholesalers finance on average $\in 11.8$ bn over a period of 47 days. In total, this sum is financed approximately 7.8 times per year, and represents a total annual volume of $\in 92$ bn.

6.2 The advantages of pharmaceutical full-line wholesalers

As shown above, pharmaceutical full-line wholesalers offer many essential services to their clients which greatly contribute to the availability, accessibility and safety of medicines. The following section will examine the advantages and benefits of the full-line wholesaling model for each partner in the supply chain, namely, pharmaceutical manufacturers, pharmacies, patients and the public.

6.2.1 Services and benefits for pharmaceutical manufacturers

Pharmaceutical full-line wholesalers offer a number of essential services to pharmaceutical manufacturers, including, amongst others, purchase, storage, warehousing and delivery of medicines and healthcare products available in retail pharmacies.

Pharmaceutical full-line wholesalers purchase the full product range from manufacturers, including medical devices, in-vitro diagnostic medical devices, veterinarian medicinal products, food supplements, and other healthcare related products, and operate under strict legal frameworks to ensure the safe and continuous supply of medicinal products for all patients and citizens in Europe. In so doing, pharmaceutical full-line wholesalers act as important intermediaries between more than 3,500 manufacturers of medicinal and healthcare products on the one hand, and more than 180,000 retail pharmacies and healthcare professionals entitled to supply medicines to the public on the other hand. Without their vital role in the pharmaceutical supply chain, manufacturers could not operate sustainably, nor could the availability of approximately 100,000 different medicines be assured.

Pharmaceutical full-line wholesalers offer manufacturers a wide range of warehousing and storage services. Storage services comprise such activities as inventory management, pick-and-pack services, reverse logistics, such as returns and recalls management, as well as waste management and in some countries even pharmaceutical waste destruction services.

The delivery of medicines and healthcare products to pharmacies and other healthcare professionals entitled to dispense medicines to the public includes an array of high-end logistic services. These comprise temperature-adequate transport for all products, including risk assessment of delivery routes involving temperature-controlled transportation (ambient and cold chain products), and the transportation of medicines requiring special handling (e.g. "specialty" or orphan medicines).

Pharmaceutical wholesalers guarantee the quality and integrity of medicinal products by adhering to quality assurance standards (see section 3.1.4.) both during storage and transportation. Furthermore, they ensure that temperature indications are respected for cold chain or temperature-sensitive products, such as vaccines, blood plasma and biotechnology products, and assure continuous cold chain and temperature monitoring. Pharmaceutical full-line wholesalers also offer specialist delivery and care services for vaccines and biotech products.

Importantly, pharmaceutical manufacturers, regardless of their size, also benefit from pharmaceutical full-line wholesalers' vendor-neutrality in providing market access services.

6.2.2 Services and benefits for pharmacies

The biggest beneficiaries of pharmaceutical full-line wholesalers' services are pharmacies, as they can rely on a continuous supply of all medicinal products from one single source and in the shortest possible time at the lowest possible ordering expense.

As mentioned in chapter 3.1.3., pharmaceutical full-line wholesalers' bundling function, which regroups and combines products from many different manufacturers in one delivery, is of particular relevance to pharmacies, as it decreases pharmacies' overall transaction costs. Pharmacists can refer to pharmaceutical full-line wholesalers as a "one-stop-shop" and order a selection of products from the full range of medicines and healthcare products available on their respective markets and receive these in a single delivery. This allows orders of slow-moving, low-margin products to be pooled and delivered in exactly the same way and with the same speed and safety measures as fast-moving and high-margin products.

In addition thereto, pharmaceutical full-line wholesalers also offer stock management and automated order processing services, just-in-time delivery of products, returns management, product recalls and emergency services, and express deliveries

Most pharmacies are only able to stock a small number of medicinal products. In order to be able to distribute medicinal products whenever they are needed, pharmaceutical full-line wholesalers act as an external warehouse for their clients, reducing the pharmacies' inventory turnover. Based on their optimised warehousing network and coverage of even remote regions, pharmaceutical full-line wholesalers ensure the constant supply of medicinal products for all pharmacies in a cost-effective way (GIRP 2015).

Pharmaceutical full-line wholesalers therefore provide a significant financial service to pharmacies by pre-financing medicinal stocks and by hedging cash flows in the healthcare system. Without many of these services, pharmacies would operate far less efficiently and effectively.

Due to their high efficiency and quality of service, pharmaceutical full-line wholesalers' speed and efficiency in logistics processes remain unsurpassed: Pharmacies receive their ordered products within on average 2.56 hours after submitting their orders. These short delivery times give pharmaceutical full-line wholesalers a competitive advantage over other market players.

6.2.3 Services for patients and society

Pharmaceutical full-line wholesalers' timely and comprehensive distribution service is of paramount importance to physicians and patients. Given the broad range of medicinal products, patients receive exactly the medicines they need with almost no delay (GIRP 2013). Pharmaceutical full-line wholesalers even ensure that the most isolated patients can get highly specialised and orphan medicines just in-time.

In addition to benefitting directly from the efficient and low-cost network of pharmaceutical full-line wholesalers' distribution centres, which secure a fast and continuous supply of medicinal products (even of orphan and slow moving products) across Europe, patients also benefit from customised patient care. These services are further outlined under chapter 6.3.2. Added-value services for pharmacies and patients.

Pharmaceutical full-line wholesalers also render important public and security services to society at the national level. Due to their unique position in the supply chain, pharmaceutical full-line wholesalers are best placed to monitor medicine levels and to warn of impending medicine shortages, to partially safeguard or counteract shortages on account of their medicines stocks and supplies, and to monitor pandemics and disease fluctuations. Since pharmaceutical full-line wholesalers also offer to hold national security or emergency medicine stocks (e.g. for annual flu pandemics), they are also able to effectively engage in crisis management, if required. For instance, in several countries, wholesalers also hold stocks of iodine type medicines for pharmacies located near nuclear power plants and have emergency response and delivery plans in case of nuclear accidents.

Pharmaceutical full-line wholesalers offer their clients – manufacturers, pharmacists, patients and society – a broad spectrum of essential services. These reflect their legal and moral obligation to deliver medicinal products wherever and whenever they are needed.

The core services provided by pharmaceutical full-line wholesalers help their customers to focus exclusively on their core business: For the pharmaceutical manufacturers, this would be the development, production and marketing of medicinal products; for pharmacies, this would be the dispensing of medicines and the provision of advice to patients; and for doctors, this would be the diagnosing and prescribing of therapies to their patients (Clement et al. 2005).

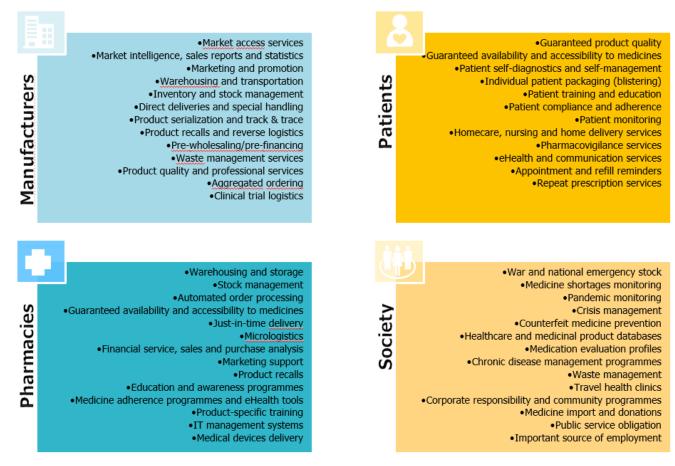
Having illustrated the many advantages of the pharmaceutical full-line wholesale model and its *core activities*, the next section will take a closer look at its *added-value services* and the benefits for the supply chain partners.

6.3 Added-value services

In response to the evolving needs and digital demands of the supply chain partners, and more significantly, in response to growing market and regulatory pressures, the role and function of pharmaceutical full-line wholesalers have evolved significantly. To ensure the sustainability of their public service activities, pharmaceutical full-line wholesalers have begun to offer a wide range of added-value services that extend far beyond their traditional core services to their supply chain partners (Clement et al. 2005).

Figure 33 depicts some of the added-value services that pharmaceutical full-line wholesalers offer to their suppliers and clients.

Figure 33: Added-value services offered by pharmaceutical full-line wholesalers⁷



⁷List of services is non-exhaustive

While services related to patients and society are normally performed by qualified pharmacists, they have been included here as services offered by wholesalers due to the fact that in some countries, pharmaceutical full-line wholesalers also operate pharmacies.

Source: GIRP 2016

6.3.1 Added-value services to pharmaceutical manufacturers

Many services that pharmaceutical full-line wholesalers provide to pharmaceutical manufacturers and pharmacies are invisible to the patient, but complement the distribution of medicines. Pharmaceutical full-line wholesalers therefore add value by undertaking services that are of tremendous benefit to their supply chain partners and that enable these to focus on the patient.

Added-value services offered by pharmaceutical full-line wholesalers to manufacturers range from clinical trial packing, specialised logistics, bio-sample repatriation and both clinical trial screening and recruitment, kit assembly, and (re)labelling and (re)packaging services according to market demand and country requirements.

Manufacturers placing products on a new market for the first time also make use of pharmaceutical full-line wholesalers' expertise of the local regulatory requirements. By using pharmaceutical full-line wholesalers' market registration services, manufacturers can navigate the matrix of product registration requirements at the national level in order to bring their products to market, faster, more easily and with full regulatory compliance.

In addition thereto, pharmaceutical full-line wholesalers also play an important role in providing market access/product (pre-)launch and marketing services such as providing consumer-driven brand plans, promotion and advertisement plans, and product placement with local media to profile brands. On account of their unique position in the medicines supply chain, they are also able to gather information, data and market intelligence pertaining to key target groups and countries, to provide expert knowledge of market dynamics and to therefore effectively handle promotional materials and samples.

Many pharmaceutical full-line wholesalers also offer a wide range of services to pharmaceutical manufacturers via pre-wholesaling subsidiaries. Pharmaceutical pre-wholesalers act as logistics and service partners for the manufacturers and are highly specialised providers of bulk deliveries (ranging from tens to thousands of pallets) of pharmaceutical, healthcare and consumer products to wholesalers, hospitals and pharmacies. This means that manufacturers do not have to use a wide range of service providers, thereby removing the need to invest in their own logistical network and having to put in place their own in-house operational infrastructure.

The distribution fleet for bulk transportation is GPS tracked and monitored for accurate placement of consignments, and covers the full range of temperature controlled requirements, resulting in reliable and temperature assured delivery.

While no two pharmaceutical pre-wholesalers are identical, they typically provide the services depicted in figure 34.

Figure 34: Services¹ provided by pre-wholesalers (acting as 3rd party logistic providers)

Warehousing	Warehouse Services	Transportation	
 cold chain monitoring inventory management packaging² returns management 	 order-to-cash VAT handling waste management destruction insurance 	 temperature controlled logistics, cold chain monitoring during transport cross border service emergency deliveries express delivery clinical trial packing² & logistics 	
Manufacturing ²	Information services		
 kitting (kit assembling) (re)labelling (re)packaging rework 	 documentation and scientific information pharmaceutical databases market access services marketing services 		

¹ Some of these services are subject to an additional fee. The services are carried out under GDP (Good Distribution Practice) unless indicated otherwise.

Source: GIRP 2016

6.3.2 Added-value services for pharmacies and patients

Pharmaceutical full-line wholesalers closely work together with pharmacies to develop new and innovative ways of ensuring patient safety and wellbeing.

Pharmacies can therefore benefit from a number of added-value services offered by pharmaceutical full-line wholesalers, including micro-logistics, sales and purchase analysis, as well as marketing support with specific products in some countries. In addition thereto, they also offer pharmacovigilance services that monitor the effects of medicines in order to identify and evaluate previously unreported adverse medicine reactions and interactions.

² Under GMP (Good Manufacturing Practice)

In recent times, pharmaceutical full-line wholesalers have begun to offer their pharmacy clients digital tools for their daily interactions with patients. In order to ensure that these products and tools are handled appropriately and effectively, pharmaceutical full-line wholesalers offer product-specific training and user education to pharmacists and pharmacy staff.

Digital advancements have also carried over to benefit the patient directly. Together with pharmacies, pharmaceutical full-line wholesalers have elaborated high-quality eHealth and mHealth communication services for patients, such as appointment and refill reminder services via call center's or digital applications. The aim of these efforts is to increase patient adherence to medicines and treatment plans and to empower chronic patients in attaining self-management of their disease(s).

In some countries, pharmaceutical full-line wholesalers cooperate with pharmacies in providing patient-specific blistering or individual patient packaging services, which repackage all medicines taken by a given patient into daily doses (blisters/pouches) in order to ascertain the patient's controlled and timely medicine intake and to avoid mismedication. Further to these services, pharmaceutical full-line wholesalers develop and offer patient-monitoring tools and programmes, patient self-diagnostics, self-management training and toolkits, as well as patient medicine and therapy adherence services oftentimes via homecare, nursing and home delivery services. Lastly, pharmaceutical full-line wholesalers also offer patients home and community-based medical care provided by fully trained, contracted nurses.

Added-value services are growing in importance, not only for the financial sustainability of the healthcare distribution sector, but also to fulfil the needs and demands of manufacturers, pharmacists, and patients in an ageing society.

6.4 The macroeconomic impact of pharmaceutical full-line wholesalers

This section provides an examination of the macroeconomic impact of the pharmaceutical wholesale industry in addition to the analysis of economic core indicators. The macroeconomic impact is measured in terms of value-added and jobs created by the industry in France, Germany, Italy, the Netherlands, Spain and the UK using Input-Output analysis by applying an extended Leontief-model.

The model is based on a national concept, e.g. the effects of imports and exports are not observed. It analyses economic effects generated on three different levels (Clement et al. 2005):

• Direct effects on value-added and employment – expressed in full-time-equivalents (FTE) – are created within the wholesale industry through its operations.

- To perform their tasks, pharmaceutical full-line wholesalers need electricity, conveyors, IT-services etc. and, of course, medicinal products. Due to the various interconnections between the wholesale sector and its supplying industries, pharmaceutical full-line wholesaling also generates jobs and value-added in these preliminary sectors. As these sectors are linked to other supplying industries (e.g. pharmaceutical manufacturers need chemicals, production facilities, etc.), value-added and jobs are also created. The sum of these economic effects is referred to as 'indirect effects'.
- The third kind of effects to be analysed are 'induced effects'. Induced effects, for instance, occur through employees' consumption and purchase of goods and services provided by the wholesale sector and its supplying industries, e.g. they spend their salaries to finance their living, buy clothes, food, etc. Consumption therefore helps generate value-added and jobs in business sectors apart from the wholesale industries, its suppliers and their suppliers. The second source of induced effects comes from investments made by pharmaceutical full-line wholesalers and preliminary industries (figure 35).

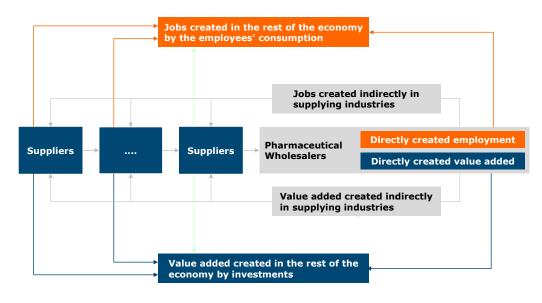


Figure 35: Macroeconomic Effects

Source: IPF research 2016

6.4.1 Multiplying effects

The use of multipliers helps to interpret the results of the previous section. Generally, the multiplier provides information on the overall value-added and number of jobs created by an industry as a whole for each invested unit of currency and for each job created in the sector (Clement et al. 2005).

Therefore, $\in 1$ invested in the pharmaceutical full-line wholesale sector generates on average $\in 2.01$ in the six countries observed. A detailed breakdown of the country multipliers reveals that the impact on the overall economy was the highest in the Netherlands and Italy (Table 4). The calculated cumulative multiplier is comparable with results from 2010.

Table 4: Multiplying effects on value-added and employment (FTE) in DE, ES, FR, IT, NL, UK, 2015

	DE	UK	FR	ES	IT	NL	
Multiplying effects on	2.01	1.93	2.10	1.87	2.15	2.29	
Value Added	2.01	1.95	2.10	1.07	2.15	2.29	
Total multiplying effects on	2.01						
Value Added							
Multiplying effects on	2.24	1.00	1.07	2.20	1.50	2 47	
Employment	2.24	1.80	1.87	2.20	1.56	2.17	
Total multiplying effects on	1,94						
Employment							

Source: EUROSTAT, GIRP data 2015, IPF research 2016

Each additional job offered by pharmaceutical full-line wholesalers generates 1.94 additional jobs in the economy as a whole (Figure 36). In Germany and Spain, the multiplying effect on employment is the highest. Compared with the findings from 2010, the multiplier is lower by 0.14.

Figure 36: Aggregated multiplying effects on employment (FTE) and value-added in DE, ES, FR, IT, NL, UK, 2015



Source: EUROSTAT, IPF research 2016

Many facets of pharmaceutical full-line wholesalers have now been observed, proving that they are not only an integral, but also a very valuable part of the medicines distribution chain.

The last chapter of this study will focus on future trends and developments in the healthcare distribution sector and how the changing demands of pharmacy and manufacturer clients, together with changing market conditions and technological progress, will impact the day-to-day business of pharmaceutical full-line wholesalers.

7 Future Trends and developments in the healthcare distribution

As evidenced by the results of the pharmacy and manufacturer surveys and the previous chapter on pharmaceutical full-line wholesalers' core and added-value services, pharmaceutical full-line wholesalers provide many essential services with added-value benefits for their clients, thus rendering them the vital link in the pharmaceutical supply chain. What, however, does the future hold for pharmaceutical full-line wholesalers and the healthcare distribution sector at large?

In the following chapter, we seek to explore some of the trends and developments in the healthcare distribution sector that will have an important financial and strategic impact on pharmaceutical full-line wholesalers' daily business in the future. These include:

- 1. An increasingly more difficult economic and regulatory environment
- 2. The growing importance of added-value services
- 3. The growing importance of digitalisation
- 4. Good corporate citizenship
- 5. Closer collaboration with supply chain partners

7.1 The regulatory and economic future of the healthcare distribution sector

The economic and regulatory challenges alluded to in the introductory section of this study will likely persist and increase in the foreseeable future. Pharmaceutical full-line wholesalers will continue to be confronted with growing product polarisation (a widening gap between low and high priced products), an increase in high-value medicines on the pharmaceutical market, a steady decline in wholesale margins, increasing financial and administrative burdens arising not only from the implementation of national and European legislation, but also from governmental cost-cutting measures to reduce healthcare expenditures and subsequently, increasing trends towards market consolidation.

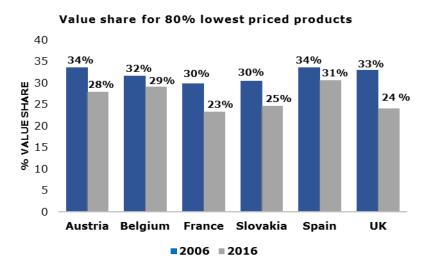
7.1.1 Product polarisation and the growing importance of high-value medicines

Advances in scientific research have given rise to a new generation of high-innovation, high-value, and high-priced or 'specialty' medicines that are used to treat complex or rare chronic conditions. These products comprise a fraction, in terms of volume, of the medicines market otherwise dominated by cost-effective or 'low priced' generic medicines.

Over the past decade, pharmaceutical full-line wholesalers have noticed an increasing polarisation between low-price, high-volume generics and high-price, low-volume innovative medicines in their product distribution portfolio. On average, generic medicines account for 70% of pharmaceutical full-line wholesalers' handled medicines volumes. At present, the value share of 80% of the least expensive products in terms of volume in Europe ranges from only 18% in the Netherlands to hardly 46% in Poland. In these two countries, the pack price identified at this level of the product range is not more than 7.94€ and 4.41€, respectively. Figure 37 illustrates how the value share in the retail market has declined over the last 10 years. In particular, the graph shows the cheapest 80% of volume for a selection of countries (QuintilesIMS, 2016).

Due to a steady increase in the volume to be handled for the same level of revenue, pharmaceutical full-line wholesalers have witnessed a progressive decline in their remuneration and overall earnings. The average price per pack of medicine has decreased substantially across a number of countries between 2011 and 2015.

Figure 37: Change in value share for the cheapest 80% in volume between 2006 and 2016 (retail market only)



Source: QuintilesIMS, 2016

At the other end of the spectrum, the price of high-value medicines has drastically increased. The below graph depicts the value-share that the most expensive 10% of medicines (in terms of volume) represented in June 2016 in the retail market in selected countries (Figure 38)."

Value share of the most expensive 10% of volume

70% 68% 67% 66%

60% 50%

40%

30%

20%

10%

Next representative that the strike test and the st

Figure 38: Value share of the most expensive 10% of medicines in terms of volume (2006-2016)

Source: QuintilesIMS, 2016

The distribution of high-value medicines shows a variegated picture across Europe. In a number of countries, these products are available in both pharmacies and hospitals and are delivered to these healthcare institutions by pharmaceutical full-line wholesalers. However, in numerous countries, most notably in southern Europe, many of these products are only available via the hospital and, due to the fact that hospitals oftentimes conclude direct sales agreements with manufacturers who use third party logistics providers (3PLs) for their deliveries⁸, circumventing the wholesale distribution and retail channels. In some countries, the dispensation of high-innovation products via hospitals is legally determined by the authorities.

Despite the fact that many high-value products, especially those in the form of tablets, subcutaneous injections and inhalers, could be dispensed directly to patients via pharmacies, a large number of these new products is not being considered for distribution via pharmacies for reasons as diverse as the control of medicine prescribing or the possibility of price negotiation (Figure 39). In some countries, high-value products are placed under the responsibility of the hospital despite the fact that the treatment is administered at home. This trend implies that the growth of the retail market is kept low,

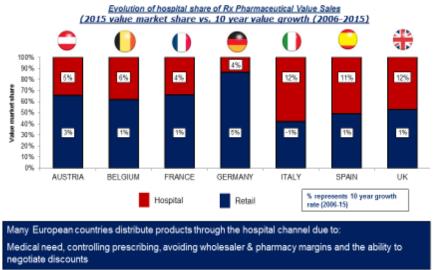
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Some manufacturers prefer to take direct control over the distribution of their products and also deliver directly to pharmacists

even reaching negative levels in several countries, while the hospital market sees an exceptional growth trend.

Figure 39: Evolution of the hospital share of Rx pharmaceutical Value Sales (2015 value market share vs. 10 year value growth) (2006-2015)

There is longer term shift to hospital in many markets



Source: QuintilesIMS, 2016

Where other distribution models for high-value medicines are applied, such as direct deliveries or third party logistics providers, the exclusion of pharmaceutical full-line wholesalers from this growing market and product segment, has important implications for the financial viability of the wholesale distribution model.

Figure 40: Distribution trends of high-value products reduce the size of the accessible market for full-line wholesalers



However, there are good reasons for placing high-value medicines in the pharmacy and wholesale distribution channels:

• **Patient access**: With approximately 165,000 community pharmacies across Europe (GIRP data, 2016), patients can more easily and more cost effectively access medicines via their local community pharmacy than via more infrequent and costlier hospitals (6,346) or hospital pharmacies (7,291). Especially for older and less mobile people, easy geographical access to local pharmacies to obtain their vital medicines is an important improvement in the quality of life.

Furthermore, with their efficient stock management and just-in-time delivery systems, pharmaceutical full-line wholesalers play an important role in providing timely access to high-innovation medicines even to patients in remote locations.

• Reduced burden on healthcare system: The administrative and financial costs associated with hospital care can place substantial strain on national healthcare systems. Since high-priced products are often dispensed exclusively through the hospital channel, such measures are in contradiction to the patient-centric approach and cost saving targets to which social security systems aspire across Europe. Treating a patient in a hospital, even in a one-day clinic or in ambulatory care, is significantly more expensive than a homecare treatment administered by a registered nurse or than dispensing products through a retail pharmacy with the support services of a nurse, where required.

Pharmacists, who receive comprehensive training in the provision of pharmaceutical care and understand biopharmaceutical technology, are experts in the provision of information and advice about how to administer a given treatment and how to best adhere to treatment schemes. As such, they can be considered to be competent partners in sharing some of the workload of doctors and nurses and in providing regular adherence and treatment monitoring services, thereby alleviating the financial burden of hospital dispensation and care. A move should be made towards reconciling medication information from primary and secondary care settings into a single patient record.

• Reduction of hospital inventory: Since pharmaceutical full-line wholesalers are already covering distribution at a national level, they can easily include the delivery of medicinal products to hospitals in their logistics planning. Hospitals could thus rely on them to act as conveniently placed external warehouses for their medicines, thereby reducing their on-site inventory and working capital (such as in Norway and Denmark). Lower on-site inventory can contribute to lower breakage risks, fewer incidences of theft and lower costs for hospitals. By relying on the services and advantages offered by pharmaceutical full-line wholesalers, hospitals can more effectively focus on their core activities: treating patients and administering care whereever and whenever needed.

• **Specialised care and handling**: Due to the fact that pharmaceutical full-line wholesalers comply with all required safety and quality assurance measures to ensure the integrity of the products during storage and delivery, they are experts in handling high-value products with special temperature or care requirements.

As both the volume and range of high-value medicines continue to increase in the future, payers and healthcare authorities must rethink the remuneration and distribution schemes associated very low-priced products as well as with high-value medicines in order to ensure their continued availability and the sustainability of the healthcare system, in general.

7.1.2 Remuneration for healthcare distribution services and wholesale margins

Although pharmaceutical full-line wholesalers deliver a broader range of medicines and healthcare products as well as a higher quality of service, remuneration for these services has reached an all-time low in many countries across Europe. In some countries, such as in Greece, Hungary, Italy and Poland, pharmaceutical full-line wholesalers deliver one package of medicines on the same day for less than $\{0.50\}$, which is far less than the cost of a postal stamp. This remuneration is not sufficient to cover daily operating costs, including pre-financing, risk, storage, picking and delivery.

In some countries, such as Austria, France and Germany, remuneration caps exist on the distribution of medicines. When placed on the distribution of slow-moving, high-priced products, such caps not only constrain pharmaceutical full-line wholesalers' financial opportunities, but also disincentivise pharmaceutical full-line wholesalers from carrying and distributing such products. In Austria, for instance, a pack of Sovaldi costs &13 690.41, however, wholesale remuneration is capped at &23.74 per pack. In a future likely to be characterised by the growth of the high-value medicines, remuneration models will have to be revised.

Several current remuneration and reimbursement models lack long term sustainability, however, developing new models is a lengthy and complex process. Until recently, percentage based compensation was deemed an acceptable form of remuneration. However, due to the fact that the average price of 'lower priced' medicines keeps declining while the share of these products in the wholesale portfolio continues to increase, the model is no longer sustainable. A first step in the right direction would be to apply a minimum fee-per-pack for low-priced medicines.

For high-value products, however, such a fixed fee will not be sufficient to uphold the breadth and depth of wholesale services. In order to cover the cost of financing, insurance, special and expensive logistic requirements and additional training and education will have to be covered by additional remuneration, either through a shift in risk or different financing models.

The margins of healthcare distributors make up only a small fraction of the costs of the medicine supply chain, but in most European countries, price reductions and margin squeezes are eroding their remuneration. To ensure the overall sustainability of the sector, healthcare distributors are already innovating in the provision of new and added-value services and adapting and responding to rising market trends. However, this must be matched by more secure remuneration models.

The sector must also reflect about the impact of new pricing and models on the remuneration of pharmaceutical full-line wholesaling, if there is no ex-factory price as base line. These include Managed Entry Agreements, Combinational Pricing, outcomesbased remuneration, as well as joint procurement, among others. In particular, a consensus has to be formed on the value of the availability of all medicines whenever and wherever they are needed.

It is critical for healthcare system to have a well-functioning distribution system. The pharmaceutical full-line wholesaling function can only be truly assured in the long term through an adequate remuneration regime.

7.1.3 The impact of regulation

In addition to an increasingly polarised market and progressive reductions in wholesaler margins and remuneration, pharmaceutical full-line wholesalers experience additional economic burdens arising from the implementation of legislative and regulatory measures issued at the national and European levels. Many of these will need to be implemented in the upcoming years. From an economic perspective, these new regulatory requirements have important financial implications on the day-to-day activities of pharmaceutical full-line wholesalers: Although new regulatory requirements aim to improve the quality and safety of the medicines supply chain, which are largely welcome, these legal obligations come at a cost and require investment in new technologies and processes.

Some of the new regulatory measures include the medical devices legislation, the implementation of the European Good Distribution Practice (GDP) guidelines and the implementation of the Falsified Medicines Directive and its supplementing Delegated Regulation on safety features. Especially the latter will require pharmaceutical full-line wholesalers to invest in new technology and processes in order to meet the terms of the new legislation.

7.1.4 Market consolidation

As pharmaceutical full-line wholesalers struggle with an increasingly difficult market and regulatory environment, consolidation will continue to fundamentally change the structure and dynamics of the sector. Consolidation is no longer a national or continental trend, but has reached global dimensions. Some examples of consolidation at the national level in recent years include the acquisition of Mediq Apotheken Nederland by Brocacef, a joint PHOENIX-Celesio venture in June of 2016, and the purchase of Belmedis

by Celesio in 2016. International mergers and deals include McKesson's acquisition of 75% of Celesio in 2015, and US-based Walgreens' purchase of internationally operating Alliance Boots in 2014, to name a few.

The combined effects of growing product polarisation, the increase in high-value medicines and the inaccessibility of these products to pharmaceutical full-line wholesalers in some countries, a steady decline in wholesale margins, increasing regulatory burdens and continued trends towards market consolidation, will continue to force pharmaceutical full-line wholesalers to think outside and beyond the box.

7.2 Added-value services

As outlined in the previous chapter, pharmaceutical full-line wholesalers have begun to offer an expanded range of added-value services in order to complement the full product range with a full range of services. Attesting to pharmaceutical full-line wholesalers' ability to innovate and to respond to market challenges in a flexible way, it is likely that such services will continue to grow in the future and will take on new directions and dimensions as technology and clients' needs evolve.

7.2.1 Services to pharmaceutical manufacturers

Pharmaceutical full-line wholesalers will continue to expand their range of services to manufacturers in the future. While pharmaceutical full-line wholesaling will be the core activity, services dedicated to supporting the pharmaceutical industry are regarded by some as a mean of future growth and development. In particular, services such as: bulk deliveries, storage and transportation of goods requiring special conditions (temperature controlled, cold chain, deep frozen products, clinical trials logistics, narcotics etc.), end-to-end supply chain management expertise, product packaging and labelling for national markets, product track and trace services (on-demand service for special products), reverse logistics services, market intelligence and data collection services, product launch, market access and marketing services, waste management services, quality and professional services and product registration support, will continue to evolve as demand grows.

In this context, to respond to the growth in direct sales, pre-wholesaling (3PL) services will play an ever greater role in medicines distribution, especially in bringing products to the market. 'To-market' services offered by pharmaceutical full-line wholesalers will become of increasing importance in the future and will be demanded especially by small and mid-size companies or for smaller markets.

As the medicines distribution chain becomes more globalised, effective collaboration with all supply chain stakeholders and partners must become a priority.

7.2.2 Services to pharmacies

As outlined in the previous chapter, pharmaceutical wholesalers clearly recognising and defending the indispensable duties and specialisation role of the pharmacist and pharmacy, pharmaceutical full-line wholesalers offer a wide range of core and added-value services to pharmacies. In the future, warehousing and storage services, stock management and automated order processing services, just-in-time delivery of products, assistance with product recalls, internal IT management systems and digital tools, trainings and education of campaigns for pharmacies as well as sales and purchase analysis, and marketing support for specific products will play an ever greater role in the services offered by pharmaceutical full-line wholesalers to pharmacies.

Personalised medicines are "medical models using characterisation of individuals" phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention". They allow tailor-made prevention and treatment strategies for individuals or groups of individuals suffering from a particular disease or its side-effects. Pharmacists and pharmacies will play an important role in the area of personalised medicines with full-line wholesalers providing all essential support.

The move towards personalised medicine is seen evolutionary process. While some personalised medicine approaches have already been introduced into practice in Europe, they are still at an early stage of implementation. In order to fully exploit the potentials of this innovative area, significant paradigm shifts will need to take place in medical research and healthcare. With the pharmacist at the centre of the process of the provision and supervision of the medicines, healthcare distributors will play an in increasing role in supporting the pharmacist and pharmacy deliver these new forms of treatment. Due to the fact that pharmacists across Europe already play an important role in the provision of pharmaceutical care, treatment monitoring and medicine information, they are ideally positioned to also dispense and monitor personalised medicines.

Pharmaceutical full-line wholesalers are advantageously positioned to jointly with pharmacies develop and implement patient adherence and monitoring programmes with pharmacies for the benefit of patients.

7.2.3 Patient services through pharmacies

As patient adherence initiatives and the evolution of treatment outcomes become more important on the political and healthcare agendas across Europe, pharmaceutical full-line wholesalers will likely be increasingly implicated in the development and implementation of new digital tools and programmes, such as eHealth and communication services for patients (appointment and refill reminder services as well as eDiagnostics with the

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⁸ Source: European Commission, 2016

support of an online doctor), and will increasingly offer services such as patient-specific blistering or packaging, patient self-diagnostics and self-management training and toolkits, pharmacovigilance services as well as patient medicine and therapy adherence services oftentimes via homecare, nursing and home delivery services. Available evidence proves that full-line wholesalers are in a perfect position to facilitate and support patient services in pharmacies, to help increase medicine adherence and to improve medication management.

7.3 The growing importance of digitalisation

Pharmaceutical full-line wholesalers recognise that the future is digital and are digitalising not only their internal operations and processes but also their services. Digitalisation in terms of connection between pharmaceutical full-line wholesalers and pharmacies is very well established (eg. EDI) however connection with the industry for ordering and invoice still remains at a low level (use of faxes) in several countries and therefore it is likely that the industry and wholesalers will increasingly look at digitalisation of their ordering and invoice interfaces.

Of particular interest and relevance to the healthcare sector in the upcoming years, will be the debates and discussions surrounding the potentials and challenges of big data. As big data becomes of increasing interest and relevance to the health sector and to outcome-based remuneration models, pharmaceutical full-line wholesalers are in a unique position to facilitate the collection and consolidation of data from different sources via digital apps and wearable devices, as well as patient records while respecting privacy and confidentiality concerns. Together with the other supply chain stakeholders and payers, pharmaceutical full-line wholesalers will play an important role in the analysis of big data in the eHealth and mHealth sectors.

eHealth is a relatively recent term for healthcare practice supported by electronic/digital processes in health. It can also include health applications and links on mobile phones, referred to as mHealth. Many healthcare distributors across Europe are capitalising on the potentials of digital health by developing platforms or services that bring together diverse healthcare professionals and stakeholders. Digital platforms link pharmacies and patients and enable them to jointly manage the patient's health via such services as appointment and prescription refill reminders, medication intake reminders, health tracking tools (e.g. weight loss, smoking cessation), immunization tracking, health measurement and progress tools (e.g. diabetes) and live chat tools to facilitate communication between patients and pharmacists.

As the populations across Europe age and the 'Silver Economy' expands, there will be many new potentials for the application of digital tools and processes in facilitating healthcare. These will evolve also in accordance with the need for better cyber-security and regulation, which will result in the need for these specialised resources to develop safer eHealth solutions.

7.4 Good corporate citizenship

Pharmaceutical full-line wholesalers have realised that good corporate conduct makes good business sense and are embedding social, environmental and economic responsibility, the so-called "triple bottom line" of people, planet and profit, into their core business strategies. Corporate responsibility increases the value of the company in the long term and promotes innovations that benefit society.

As consumers become more interested in their products and the origins of their products, they place higher demands and expectations on ethical standards, moral conduct and procedural and social correctness that respects the integrity and rights of customers, employees and suppliers. In order to meet these expectations, healthcare distributors increasingly focus on their local communities and education through local sponsorship or by supporting charities through financial, knowledge-based or material resource donations, others support young talent via partnerships with educational institutions.

In terms of environmental sustainability, pharmaceutical full-line wholesalers are committed to reducing excess and waste by encouraging efficient resource use both in their processes and services. In order to do so, pharmaceutical full-line wholesalers have implemented programmes to reduce resource consumption or obtain energy and materials from sustainable resources (e.g. paper from sustainably managed forests, energy from renewables). Going green will also imply installing eco-friendly and energy efficient machines and equipment with a lower CO2 output, and replacing fossil-fuel vehicles with electric or hybrid delivery fleets.

Lastly, pharmaceutical full-line wholesalers also have a responsibility to deliver value for shareholders and employees. Many do so by maximising economies of scale and capital efficiencies through internal fund mergers and other operational improvements while making a profit capable of financially supporting its employees.

As consumers' and clients' demands and needs change, and as new and more resource efficient technologies become available, pharmaceutical full-line wholesalers must react accordingly to meet the demands of the future. Since community and environmental responsibility extend to all players in a given geographic area or market, pharmaceutical full-line wholesalers will increasingly cooperate and collaborate with their supply chain partners to generate value for all involved stakeholders.

7.5 Closer collaboration with supply chain partners

As both the global dynamics of the healthcare distribution sector as well as the needs and information requirements of the healthcare stakeholders change, collaboration and cooperation will become of increasing importance. While such trends and tendencies have already been observed in other sectors (such as the automotive industry), the pharmaceutical market remains predominantly structured in non-interacting silos. In order to progress from this demarcated thinking of the past and to capitalise on the value of the broad and diversified expertise of the supply chain partners, pharmaceutical full-

line wholesalers are uniquely positioned to actively engage in and drive collaborations and partnerships between all supply chain stakeholders. Such collaborative efforts will become a priority in the provision of better services, adhering to compliance measures that effectively fulfil their intent, and in improving patient outcomes.

In order to do so, manufacturers and pharmaceutical full-line wholesalers will need to jointly develop and work towards synergised outcomes and to collaborate in tendering systems so as to better ensure the availability and affordability of vital medicines for patients. In order to develop and shape the future of healthcare distribution in Europe and to establish more effective distribution networks, pharmaceutical full-line wholesalers initiate partnerships with pharmaceutical manufacturers so as to help define product-specific storage and handling needs and to define corresponding distribution solutions. Product and process information transparency will need to be improved on both sides in order to advance both traceability and business intelligence solutions.

The increase of high-priced products on the market brings greater responsibilities for healthcare distributors regarding storage and transport. Remuneration of such products is however capped in many countries, typically at around at \in 30-32. This trend is undermining the profitability of the existing distribution model. Manufacturers will therefore need to find agreement on a new modus operandi to ensure the sustainability of the pharmaceutical full-line wholesaling and more broadly the healthcare distribution sector. By addressing remuneration needs both on a bilateral basis with manufacturers, but most importantly with healthcare authorities and payers, remuneration models for healthcare distribution, including remuneration for wholesalers' financing function and risk-insurance for high priced products, will need to be fundamentally rethought and redefined. This must take account of the expectations on healthcare distributors to provide their current high levels of service and of changing market conditions.

In a future marked by uncertainty, pharmaceutical full-line wholesalers will need to find new and novel solutions to tackle not only current but also future challenges. The sector has proven itself capable of innovation, flexibility, and adaptability in the past, but must engage in closer collaboration with its supply chain partners in order to ensure the sustainability and longevity of the sector.

7.6 Conclusion

This final concluding subchapter provides an overview of the core findings to each of the research questions addressed in previous sections of this study.

▶ What is the role of pharmaceutical full-line wholesalers in the European pharmaceutical distribution sector and how can this role be represented by core indicators?

In Europe, medicinal products are generally distributed via the following distribution path: manufacturer to (pre-wholesaler) to pharmaceutical full-line wholesaler to public pharmacy to patient. By ensuring the availability and continuity of the supply of all medicinal products to the citizens of Europe, pharmaceutical full-line wholesalers are the most essential link between Europe's pharmaceutical manufactures and dispensing points of medicinal products. Furthermore, the effective and efficient functioning of the healthcare sector in Europe is guaranteed, as pharmaceutical full-line wholesalers fund and hold stocks, therefore providing an important financing and public service function in addition to their logistics services. Such services, as well as the wide range of additional added-value services enable pharmaceutical full-line wholesalers to stand out from their competitors. Core indicators describing the efficiency of pharmaceutical full-line wholesalers are for example working capital, delivery time and process costs.

▶ What functions do pharmaceutical full-line wholesalers offer towards their supply chain partners and in which way do they contribute towards their efficiency?

Pharmaceutical full-line wholesalers provide functions, which are essential to the effective and efficient functioning of the healthcare sector in Europe, namely the full supply function, the immediate availability of medicinal products, the stock-keeping function, the delivery and recall function as well as the financing function.

Pharmaceutical full-line wholesalers' "full supply function" guarantees that they stock the complete assortment of products in range and depth, according to requirements which are set by the authorities and the market framework in each national context. In this way, the needs of the pharmacists and ultimately of patients can be met whenever and wherever needed. Pharmaceutical full-line whoalesalers' stock keeping function also makes it possible that large quantities of medicinal products are stocked and orders are delivered in the required amount. Even the most isolated patient can therefore receive specialised medicinal products via their pharmacists in a timely manner. For defective products, an effective recall system is in place. In addition thereto, pharmaceutical full-line wholesalers pre-finance nearly the entire medicinal product market, guarantee the continuous supply of all medicinal products and also secure the cash flow of the health system. Of all the currently existing distribution models in Europe, the pharmaceutical full-line wholesale model is the only one to offer these functions to manufacturers and pharmacies

▶ What services do pharmaceutical full-line wholesalers provide and what is the added value for stakeholders in the pharmaceutical supply chain and for the public?

The logistics function or "core service" of bridging time and space is the central business of the pharmaceutical wholesale industry. Through their quantity function, which consists of buying large quantities, breaking down the bulk and selling the products in small units, pharmaceutical full-line wholesalers improve the efficiency of the distribution chain. To secure the high quality standards of the products distributed pharmaceutical full-line wholesalers not only abide by a rigorous set of rules, practices and operating procedures (such as the Guidelines on Good Distribution Practice of Medicinal Products for Human Use, the Falsified Medicines Directive (Directive 2011/62/EU) and the Delegated Regulation on safety features (2016/161)) that ensure the quality and safety of medicines, but also provide additional added-value services for manufacturers, retailers and patients. These added-value services are the most important competitive factor in pharmaceutical wholesaling, enabling companies to stand out from their competitors.

▶ How have pharmaceutical full-line wholesalers been impacted by new regulations?

Pharmaceutical full-line wholesalers are experiencing additional economic burdens arising from the implementation of legislative and regulatory measures issued at the national and European levels. From an economic perspective, these new regulatory requirements have important financial implications for the day-to-day activities of pharmaceutical full-line wholesalers. Although new regulatory requirements aim to improve the quality and safety of the medicines supply chain, which are largely welcomed, these legal obligations come at a cost and require investment in new technologies and processes in order to meet the terms of the new legislations (e.g. medical devices legislation, the implementation of the European Good Distribution Practice (GDP) guidelines, the implementation of the Falsified Medicines Directive and its supplementing Delegated Regulation on safety features). The economic and regulatory challenges encountered by pharmaceutical full-line wholesalers over the past five years will likely persist and increase in the foreseeable future.

► How satisfied are the supply-chain partners (pharmacists and manufacturers) with the distribution systems they use?

A central issue of this study was to analyse the satisfaction of the supply chain partners, namely of pharmaceutical manufacturers and pharmacists, with the pharmaceutical distribution/supply system.

Overall, the findings show that there is a high level of satisfaction with pharmaceutical full-line wholesalers. 88% of pharmacists in the six target countries were satisfied with the pharmaceutical full-line wholesale model.

The fact that many pharmacists responded to the survey in a positive manner attests the importance of this distribution system to pharmacists.

With 80% a large majority of pharmaceutical manufacturers were satisfied with the pharmaceutical full-line wholesale model in general.

▶ Which service level do pharmacists consider as valuable and how do pharmacists classify the 'safety of medicines' delivered via pharmaceutical full-line wholesalers?

90% of pharmacists in all six target countries felt that the service level performance of pharmaceutical full-line wholesalers was very high. In particular, pharmacists felt that the delivery frequencies of pharmaceutical full-line wholesalers were sufficient (94%) and that their order systems were convenient (92%).

The above results demonstrate pharmacists' high levels of satisfaction with the pharmaceutical full-line wholesalers' "one-stop shop" services and just-in-time delivery of medicines in the right quantity and quality.

Results regarding the 'safety of medicines' also showed high levels of satisfaction with pharmaceutical full-line wholesalers: more than 90% of pharmacists answered that the safety of medicines during transportation was adequate, that the cold-chain was respected and that pharmaceutical full-line wholesalers offered protection against falsified medicines.

What is the motivation of pharmaceutical manufacturers for selecting certain distribution models?

Unlike the pharmacist questionnaire, the survey sent to the industry asked manufacturers to indicate their reasons and motivations for using a certain distribution system. The most commonly cited reasons for using the pharmaceutical full-line wholesale model were the delivery frequency and its ability to ensure product availability.

What is the pharmaceutical full-line wholesale sector's contribution to the overall economy – how much value-added and jobs are created by pharmaceutical fullline wholesalers?

Generally, multipliers provide information on the overall value-added and number of jobs created by an industry as a whole for each invested unit of currency and for each job created in the sector. Therefore, €1 invested in the pharmaceutical full-line wholesale sector generates on average €2.01 in the six countries observed (DE, UK, FR, ES, IT, NL). Each additional job offered by pharmaceutical full-line wholesalers generates 1.94 additional jobs in the economy as a whole.

What are the challenges faced by the pharmaceutical full-line wholesale sector and how could future trends affect the pharmaceutical distribution landscape? Due to the rise of new business models, the pharmaceutical wholesale sector was and still is heading for a period of radical transformations. Moreover, the interplay of different types of key stakeholders like manufacturers, wholesale distributors, retail pharmacies, hospitals or managed care organisations and insurance companies make the current situation more complex (Clement et al. 2005).

As pharmaceutical full-line wholesalers struggle with an increasingly difficult market and regulatory environment, consolidation will continue to change the structure and dynamics of the sector. Consolidation is no longer a national or continental trend, but has reached global dimensions.

The combined effects of growing product polarisation, the increase in high-value medicines and the inaccessibility of these products to pharmaceutical full-line wholesalers in some countries, a steady decline in wholesale margins, increasing regulatory burdens and continued trends towards market consolidation, will continue to force pharmaceutical full-line wholesalers to think outside and beyond the box.

In a future marked by uncertainty, pharmaceutical full-line wholesalers will need to find new and novel solutions to tackle not only current but also future challenges. The sector has proven itself capable of innovation, flexibility, and adaptability in the past, but must engage in closer collaboration with its supply chain partners in order to ensure the sustainability and longevity of the sector. (GIRP 2016)

Glossary

The following definitions are intended for a general understanding of the terms used in this study and should not be considered as a complete definition, since some are written in the simplest form to allow a general understanding of the terms listed.

Added value Added value is defined as an increase in the

> value of a product by adding an additional service. Usually by integrating the value with a customer's workflow, tailoring it to the customer's needs, making it more easily

accessible etc¹

Adherence Adherence is defined as the extent to which a

> person's behaviour corresponds with agreed recommendations from a healthcare specialist²

Asset is defined as an item of property (e.g. Asset

capital, money, a share in ownership)³

Average delivery time The time between the daily cut-off time and the

actual delivery¹³

Buffer stock The buffer stock is the stock held as a safety

measure to cope with unforeseen demand⁴

Business to Business (B2B) In our study the term business to business is

defined as the transactions between a business

and another business

Cash flow In finance the cash flow refers to the amount of

cash, which is received and spent by a business

during a defined time period³

Compliance Patient compliance describes the consistency

and accuracy with which a patient follows a recommended medical regimen, referring to a pharmacotherapeutic regime⁵

Core indicator In our study a core indicator is an indicator of

performance which is relevant for customers

and stakeholders

Cut-off time In our study the term cut-off time is defined as

a period for a deadline set by a supplier for the

acceptance of orders

Delivery time Delivery time is defined as the timeframe

between the placement of the order and the delivery through the customer (e.g.

pharmacist)⁶

Demand A demand is the quantity of a good or service

that a household or firm chooses to purchase at

a given price⁷

Direct salesIn case of direct sales the pharmaceutical

manufacturer or marketing authorisation holder sells its medicinal products directly to the pharmacist. In such scenarios, manufacturers or marketing authorisation holders may still opt to utilise the pharmaceutical full-line wholesaling

route¹³

Direct to Pharmacy (DTP)In the DTP distribution model pharmaceutical

manufacturers deliver their medicinal products directly to the pharmacies through one or more logistic service providers. In some cases pharmaceutical full-line wholesaler operate as

these logistic service providers¹³

Discount A discount is a price reduction which is granted

to specified purchasers under specific conditions

prior to purchase²

Dispensing doctors A dispensing doctor is a physician who is

authorised to dispense medicinal products to his

patients²

Distribution channel A distribution channel is defined as a system for

moving goods from producers to buyers, as well

as the people and organizations involved⁸

Distribution model In our study the term distribution model

describes the way how medicinal products are moved from the manufacturer to the pharmacist

EU 26 + 2 In our study this term is used for the European

Union without Malta and Cyprus but including

Norway and Switzerland

European Union

The European Union is a unique economic, political and social partnership between 28 independent European countries⁹

Falsified Medicines Directive

The proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source applies to medicinal products for human use intended to be placed on the market in the Member States¹⁰

Falsified medicinal product

A falsified medicinal product is defined as any medicinal product with a false representation of: its identity, including its packaging and labelling; its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

its source, including the manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder;

its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights⁸

Good distribution practice Guidelines (GDP)

GDPs are a set of rules that the European Commission has elaborated for the distribution of pharmaceutical wholesalers. According to these rules, pharmaceutical distributors must comply with the principles and guidelines of good distribution practice which include regulations about auality management, personnel, premises and equipment, documentation, deliveries to customers, returns, self inspections, etc¹¹

Hospital pharmacy

Hospital pharmacies are pharmacies that offer medicinal products to patients. Moreover, a hospital pharmacy is the healthcare service, which describes the art, practice, and profession of choosing, preparing, storing, compounding and dispensing medicines and medical devices, advising healthcare professionals and patients on their safe, effective and efficient use²

Hub

A central point which collects, sorts, transports and distributes goods for a particular area¹²

Liability

The present obligations of an enterprise, which arise from past events are defined as liabilities. Strictly speaking, a settlement which is expected to result in an outflow of resources from the enterprise, embodying economic benefits³

Macroeconomics

Macroeconomics considers the economy as a whole. Major aggregates are the household, business, and government sectors³

Margin

The percentage of the selling price that is profit. In the case of the pharmaceutical distribution, a wholesale or pharmacy margin is one type of remuneration awarded to distribution actors such as wholesalers and pharmacies for handling their services. The wholesale margin is the gross profit of wholesalers, expressed as a percentage of the wholesale price (pharmacy purchasing price). The pharmacy margin is the gross profit of pharmacies expressed as a percentage of the pharmacy retail price²

Medicinal product

The EC Directive on falsified medicines defines a medicinal product as follows:

- any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis⁸

Multi-channel system

A multi-channel system is a distribution system at the wholesale level. Medicinal products of different manufacturers are distributed and supplied in parallel via different wholesalers²

Multipliers

The quantity equilibrium output gains when the aggregate expenditures register shifts by a dollar⁷

One stop shop

All medicinal products used in the geographical

area, in which the wholesale distributor is active in are available from a single source¹³

Parallel trade

Parallel trade of medicinal products within the EU is a form of arbitrage in which medicinal products are acquired in one Member State, typically where the prices of the medicinal products are comparatively low, and sold in other Member States, where the prices are higher²

Peaks

A peak is the point in a business cycle where real output reaches its maximum level⁷

Pharmaceutical full-line wholesaling

pharmaceutical The activity of full-line wholesaling consists of the purchase, warehousing, storage, order preparation and delivery of medicines. Pharmaceutical full-line wholesalers carry and distribute the complete assortment of products in range and depth within the framework set by the authorities and the market to meet the needs of those with whom they have normal business relations. They deliver all medicines in their geographical area of activity on the same day/within less than 24 hours¹³

Pharmaceutical short-line wholesaling

The activity of pharmaceutical short-line wholesaling consists of the purchase, warehousing, storage, order preparation and delivery of only a selective assortment of medicinal products¹³

Pharmacist

A pharmacist is a person who has a university degree in pharmacy and who is licensed to practise pharmacy. Services provided by pharmacists include for e.g. the preparation of medicines according to prescriptions of medical and dental practitioners, or established formulae; checking prescriptions to ensure that recommended dosages are not exceeded, and that instructions are understood by patients²

Pooling (bundling)

In our study, pooling or bundling is a wholesale benefit, which involves the distribution of products from several manufacturers combined in one delivery

Pharmaceutical portfolio

A pharmaceutical portfolio is the collective of pharmaceuticals offered by a distributor¹³

Pharmaceutical prewholesaler

Pharmaceutical pre-wholesalers act as logistic service partners for pharmaceutical manufacturers and marketing authorization holders and are highly specialised in bulk deliveries of pharmaceutical, healthcare and consumer products to wholesalers, hospitals and pharmacies. They use their own storage facilities ranging from ambient (either monitored or controlled ambient), refrigerated, to other specialised high security products (clinical trial logistics, narcotics). In addition to their supply chain management and labelling for national markets. Pre-wholesalers are used for providing supplies to other wholesalers, as well as for carrying out direct deliveries to costumers¹³

Productivity

Productivity refers to the total output of goods and services in a defined period of time divided by work hours³

Product recall

A product-recall is the process of withdrawing or removing a pharmaceutical product from distribution channels if a problem arises with a medicinal product (e.g. product integrity concerns) and returning it to the manufacturer²

Public Service Obligation

The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question⁸

Purchasing

Purchasing is defined as the activity of buying materials, stock, equipment etc. that a company needs to produce goods or services⁹

Quotas

In the context of this study the term quotas is defined as limits on the quantity of ordered medicinal products

Reduced Wholesale Arrangement (RWA)

In the Reduced Wholesale Arrangement pharmaceutical manufacturers use only a small number of selected wholesalers in their

traditional manner to distribute medicinal

products¹³

Reimbursement Reimbursement relates to the percentage of the

reimbursed price (for a service or medicinal product) which is paid by a third-party payer

(e.g. Social insurance agency)²

Retail (community)

pharmacy

A retail pharmacy is a pharmacy which

dispenses medicinal products to patients²

RX products In our study RX products are defined as

Prescription only medicines

Safety stock A safety stock is defined as extra units of

inventory which is carried as protection against

possible stock outs⁴

Stakeholder Anyone who is affected by a company's

activities and/or performance⁴

Stock A stock refers to goods manufactured or bought

for re-sale by a business⁴

Stock (inventory) turnover The stock turnover is the number of times in a

trading year in which a firm sells the value of its

inventory⁴

Supply chain The supply chain is the system of organisations,

people, technology, activities, information and resources involved in shifting a product or

service from supplier to customer¹

Turnover The turnover is defined as the income of a

business over a period of time (usually a year)⁴

3rd Party Logistic Provider

(3PL)

A 3rd Party Logistics Provider is an entity that provides or coordinates warehousing or other

logistics services of a product on behalf of a manufacturer, marketing authorisation holder, wholesale distributor, or dispenser of a product, but does not take owhnership of the product, nor have responsibility to direct the sale or

disposition of the product ¹³

Value added The difference between the value of the output

and the value of the inputs purchased from other business companies is defined as the

IPF Institute for Pharmaeconomic Research

value added⁷

Vertical integration

The vertical integration is the combination of a parent firm and the suppliers of its raw materials or purchasers of its finished product⁴

Warehouse

A warehouse is a branch office which is often decentralized and which is used to store, consolidate, age, or mix stock³

Wholesale distribution of medicinal products

The wholesale distribution of medicinal products is based on all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned¹⁰

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ANNEX 1

The calculation of the quantitative efficiency indicators will be described in the following.

Working Capital

Working Capital Management can be used as an instrument to optimise a company's solvency and productivity. It focuses on analysing the problems which can arise in the course of planning, steering and regulating of the short-term working capital and liabilities and the interrelations between them (Hofmann et al. 2011).

Net Working Capital is a ratio of the Working Capital management and an efficiency indicator. Strictly speaking the Net Working Capital is defined as the difference between liabilities - from deliveries and performances and possible additionally current liabilities - and current assets (Hofmann et al. 2011).

Several ratios are needed to analyse and control the Net Working Capital:

	Days Sales Outstanding – DSO
	(capital commitment from accounts receivable)
	Days Inventory Outstanding - DIO
т	(capital commitment from stock)
	Days Payable Outstanding - DPO
-	(pre-financing from suppliers)
=	Net Working Capital Days

A concept to measure and control the effectiveness of the Working Capital Management is the concept of the Cash to Cash Cycle. Within the concept the Cash to Cash Cycle time is the essential ratio of the Cash to Cash Cycle and is defined as the time period from payment outflow for resources to suppliers up to payment inflow from the customer (Hofmann et al. 2011).

Input-Output Analysis

Input-output analysis focuses on the examination of the flow of goods and services between industries and its impact on overall demand for labour and capital within an economy.

Within the concept a distinction between final demand and intermediate demand has to be made. Final demand embraces goods and services sold to the final customers, whereas intermediate demand refers to inter-industry trading. Together, these two types of demand result in the total demand in various sectors of the economy.

Final demand directly creates value added and jobs in the specific industry. These effects are therefore called direct effects. Final demand also influences the level of intermediate-demand for goods and services provided by supplying industries, therefore stimulating investment and labour in these sectors. These effects are referred to as indirect effects. Direct and indirect effects only observe direct supplier-customer relations, but increase in employment also radiates in other sectors, due to consumption and investment (induced effects).

Value added is defined as the value of a company's output minus the value of the intermediate goods purchased from supplying industries. Therefore, the calculation of value added is closely related to the production value. For trading-industries, production value is computed as follows:

Turnover

- + Capitalized production
- Goods and services for resale
- +/- Changes in stocks of finished products and work in progress
 - = Production value

In a second step, value added at factor cost is calculated using the following top-down scheme:

- Production value
- Carriage forward
- Purchase of material for processing
- Operating cost
- Low value assets
- Taxes and fiscal charges
- + Subsidies
- = Value added at factor cost

Therefore, value added at factor cost embraces:

- Net operating surplus
- Wages and salaries
- Intermediate consumption
- Charges on production
- Depreciation

Leontief's input-output-model provides the methodological basis for the examination of the flow of goods and services between different sectors of the economy. The model is based on an economy with n sectors of the economy. The total production value x of sector i comprises goods and services supplied by sector i to sector j (intermediate goods) and goods and services provided by sector i for final consumption (y) (Pischner et al. 1976).

(1)
$$x_i = \sum_{i=1}^{n} x_{ij} + y_i$$

Equation (1) may also be expressed by the matrix

(2)
$$x = \sum_{i=1}^{n} x_{j} + y \quad with \ x_{j} = (x_{1j}, x_{2j}, ..., x_{nj})$$

The production functions of Leontief's model are given in equation:

(3)
$$x_{ij} = a_{ij} \cdot x_j \quad with \ i = 1, 2, ..., n$$

$$j = 1, 2, ..., n$$

$$a_{ij} \dots input - coefficient$$

The input-coefficients are put together in matrix A, resembling the cost-structure of the economy. Each element a_{ij} of matrix A displays the value of intermediate goods procured by sector j. Therefore, a_{ij} can be interpreted as direct effect of production generated in sector i by producing the quantities of intermediate goods demanded by sector j.

$$A \cdot x = \sum_{i=1}^{n} x_{i}^{i}$$

The Leontief-equation is obtained by substituting equation (4) in (2).

(5)
$$x = A \cdot x + y \quad with \ 0 \le a_{ii} \le 1$$

Given the constraint in equation (5) the solution to the model is

(6)
$$x = (E - A)^{-1} \cdot y$$
$$x = C \cdot y$$

E...Identity matrix

C...Leontief inverse

The Leontief-inverse C measures all production effects induced by final consumption. Any element c_{ij} shows how many units of intermediate goods of sector i need to be obtained to produce one unit in sector j.

By multiplying $(E-A)^{-1}$ with the vector of final consumption ΔC_0 the induced production ΔX_0 might be computed in addition.

$$\Delta X_0 = (E - A)^{-1} \cdot \Delta C_0$$

Baligh-Richartz Effect

By analysing vertical market structures Baligh and Richartz in the 1960s discovered a law, proving that the use of intermediaries is efficient even if they induce higher cost than a direct contact between manufacturers and retailers would (Gümbel 1985).

In an economy with m producers, n consumers and no intermediaries, the number of contacts is $m \cdot n$. Supposing that no matter how many producers and customers are in the market costs of contact are constant and equal 1, than total cost of contact is $C_T = m \cdot n$.

When introducing one intermediary in the distribution chain the number of transactions and costs are reduced to ${}^{C_T=m+n}$. In an economy with 8 producers and 8 customers, the number of contacts would therefore be 64 whereas the number of contacts is reduced to 16 by introducing a single intermediary. Therefore costs also are reduced by $(m \cdot n) - (m+n)$

Potential savings from the existence of intermediaries is growing dramatically with the number of producers and customers because of the multiplicative effects of direct distribution. Suggesting perfect competition, the benefits of introducing intermediaries are reduced with the installation of further middle-man until $m \cdot n = a \cdot (m+n)$ with a representing the number of traders. Therefore, with $a = \frac{m \cdot n}{m+n}$ companies in the market as much costs occur as if the goods were traded directly.

Process Costs

The analysis of the process costs in the pharmacy focuses on the evaluation of the costs of the different purchasing processes and the time required for ordering medicinal products.

The time required for the different process steps depends on the distribution system used. All necessary process steps for ordering medicinal products are realised by a pharmacy assistant.¹⁰

Although the determination of the order demand is predefined by the inventory management system and supported by the amount available, additional and mainly externally controlled manual activities have to be done. For example: several orders from the pharmaceutical full-line wholesalers are affected by the need of the customers for particular, not stocked medicinal products. The time required for the determination of order demand amounts to 9 minutes for the pharmaceutical full-line wholesale order versus 7 minutes for the order from the manufacturer (direct sale) (IfH 2008).

Normally, pharmaceutical full-line wholesalers recall the order data electronically from the inventory management system from their pharmacies. Furthermore, it is possible that pharmacies contact their pharmaceutical full-line wholesalers once or several times per day for reorder or to clarify open questions via phone. It takes the pharmacy assistant 3 minutes to transfer an order to the pharmaceutical full-line wholesaler and 2 minutes to transfer it to the manufacturer (IfH 2008). The reason for this time discrepancy is that in the case of a pharmaceutical full-line wholesale order, pharmacy assistants usually order a higher amount of medicinal products, which is mostly not the case when ordering through direct sales from manufacturer.

Receiving and storage of the delivery include the original inspection, the booking of the incoming goods and the storage and removing of the goods. 17 minutes are needed for a delivery from a pharmaceutical full-line wholesaler and 32 minutes for a delivery from direct sale from manufacturer. The longer time for a delivery from the manufacturer is caused by the accumulation of transactions (IfH 2008).

Due to the fact that pharmacies receive single invoices, they have an additional expense regarding book-keeping, the time to check the delivery note and bill of up to 6 minutes whereas it is 4 minutes for deliveries from pharmaceutical full-line wholesalers. According to IfH (2008) pharmacies receive bills from pharmaceutical full-line wholesalers every two weeks, respectively per month.

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¹⁰ The following data obtained from a study amongst selected pharmacies which took place between October 2005 and March 2006. The study was conducted by the "Institut für Pharmkoökonomie und Arzneimittellogistik" (IPAM) of the University of Wismar, Germany. The objective of this study was to find out which process costs are caused by the different distribution systems in different pharmacies. Therefore, five pharmacies which are different concerning their dimension and historical purchasing character but representative for the whole market, were selected. See Wilke T., Neumann K.: Großhandel, Überweisergeschäft oder Direkteinkauf?, in DAZ, 147. Jg. (2007), Nr. 41, S. 54-66. The calculations are based on the assumptions of the IfH. See Institut für Handelsforschung (IfH): Profil und Effizienz des vollversorgenden pharmazeutischen Großhandels, 2008.

Duo a agg stan	Delivery from pharmaceutical	Delivery from direct sales	
Process step	full-line wholesaler	from manufacturer	
Determination of order	Duration (min.): 9	Duration (min.): 7	
demand	Responsibility: pharmacy assistant	Responsibility: pharmacy assistant	
Transmission of order	Duration (min.): 3	Duration (min.): 2	
Transmission of order	Responsibility: pharmacy assistant	Responsibility: pharmacy assistant	
Receiving and storage of	Duration (min.): 17	Duration (min.): 32	
delivery	Responsibility: pharmacy assistant	Responsibility: pharmacy assistant	
Checking the delivery	Duration (min.): 4	Duration (min.): 6	
note and bill	Responsibility: pharmacy assistant	Responsibility: pharmacy assistant	

Based on the national gross salaries per minute in the six countries the process costs have been quantified and calculated.

	Gross salary per minute
	(in €)
DE	0.25
ES	0.26
FR	0.29
IT	0.31
NL	0.28
UK	0.27

Source: European Association of Pharmacy Technicians 2016, Eurostat 2016, IPF research 2016

Due to the fact that **pharmaceutical full-line wholesalers pool a number of medicinal products from different** manufacturers per order the process costs of a delivery from the manufacturer were multiplied with this number of different manufacturers to compensate the costs and to compare it with the costs per order from pharmaceutical full-line wholesalers.

To calculate the impact of process costs per year for pharmaceutical full-line wholesalers, the number of deliveries per week was multiplied with the process costs and 52 weeks.

ANNEX 2

Annex 2 includes tabular results referring to the pharmacists' and manufacturers' survey.

Pharmacist survey:

Table 5: Overall satisfaction with the distribution (DE, FR, IT, NL, ES, UK)

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	87,70%	5,99%	6,31%
Short-line Wholesaler	61,45%	31,93%	6,63%
Direct deliveries from manufacturer	57,04%	20,62%	22,34%

Source: IPF research 2016, Pharmacist survey

Table 6: Overall satisfaction with the delivery time (DE, FR, IT, NL, ES, UK)

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	93,91%	3,53%	2,56%
Short-line Wholesaler	68,55%	23,90%	7,55%
Direct deliveries from manufacturer	34,04%	33,33%	32,62%

Source: IPF research 2016, Pharmacist survey

Table 7: Service level - pharmacists' agreement (DE, FR, IT, NL, ES, UK)

	Full-line Wholesaler	Short-line Wholesaler	Direct deliveries from manufacturer
Frequency of delivery is sufficient	93,91%	63,00%	42,00%
Order service/system is convenient	91,64%	68,00%	50,00%
Delivery of intact goods (good condition) is appropriate	91,37%	75,00%	72,00%
In-time deliveries support a good patient service	90,51%	55,00%	29,00%
Delivery time is predictable	89,78%	55,00%	30,00%
Delivery arrangements are convenient	89,52%	62,00%	55,00%
Range of products is adequate	86,98%	52,00%	56,00%
Minimum orders are adequate	86,04%	62,00%	36,00%
Cut-off time is adequate	85,35%	61,00%	41,00%
Recall-time/Recall-service is adequate	79,74%	44,00%	36,00%
Financial support is provided (e.g. extended credit)	55,48%	24,00%	27,00%

Table 8: Safety on medicines – pharmacists' agreement (DE, FR, IT, NL, ES, UK)

	Full-line Wholesaler	Short-line Wholesaler	Direct deliveries from manufacturer
The cold-chain is respected	94,25%	69,46%	83,28%
Safety during transportation is adequate	92,33%	72,78%	80,69%
Protection against falsified medicines is adequate	91,40%	72,78%	87,85%

Individual country-level results:

France (FR)

Table 9: Satisfaction with the distribution system

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	95,16%	4,84%	0,00%
Non full-line wholesaler sources	52,78%	41,67%	5,56%
Direct deliveries from manufacturer	76,67%	16,67%	6,67%

Source: IPF research 2016, Pharmacist survey

Table 10: Satisfaction with the delivery time

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	100,00%	0,00%	0,00%
Non full-line wholesaler sources	47,06%	44,12%	8,82%
Direct deliveries from manufacturer	35,00%	40,00%	25,00%

Source: IPF research 2016, Pharmacist survey

Table 11: Distribution system used by French pharmacists for the following product categories:

	Innovative Medicines	Other branded Medicines	Generics	отс
Wholesaler	76,71%	69,89%	51,76%	15,38%
Direct deliveries from manufacturer	23,29%	23,66%	35,29%	70,51%
Other**	0,00%	6,45%	12,94%	14,10%

Table 12: Service level – pharmacists' agreement

	Full-line Wholesaler	Short-line Wholesaler	Direct deliveries from manufacturer
Delivery arrangements are convenient	96,67%	54,29%	56,90%
Order Service/System is convenient	95,08%	52,78%	55,93%
Frequency of delivery is sufficient	95,08%	37,29%	37,29%
Delivery time is predictable	95,00%	26,47%	22,03%
Delivery of intact goods (good condition) is appropriate	93,33%	54,29%	44,83%
Range of Products is adequate	90,16%	41,67%	62,71%
Minimum Orders are adequate	90,00%	30,56%	24,14%
In-time deliveries support a good patient service	88,52%	22,86%	10,17%
Recall-time/Recall Service is adequate	86,89%	17,14%	32,20%
Cut-off time is adequate	86,67%	35,29%	29,31%
Financial support is provided (e.g. extended credit)	55,74%	8,57%	6,90%

Table 13: Safety on medicines – pharmacists' agreement

	Full-line Wholesaler	Non full-line wholesaler sources	Direct deliveries from manufacturer
The cold-chain is respected	95,00%	48,57%	84,75%
Safety during transportation is adequate	93,33%	57,14%	67,80%
Protection against falsified medicines is adequate	90,16%	60,00%	88,14%

Source: IPF research 2016, Pharmacist survey

Germany (DE)

Table 14: Satisfaction with the distribution system

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	93,55%	3,23%	3,23%
Short-line Wholesaler	33,33%	50,00%	16,67%
Direct deliveries from manufacturer	67,80%	22,03%	10,17%

Table 15: Satisfaction with the delivery time

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	100,00%	0,00%	0,00%
Short-line Wholesaler	33,33%	53,33%	13,33%
Direct deliveries from manufacturer	58,62%	37,93%	3,45%

Table 16: Distribution system used by German pharmacists for the following product categories:

	Innovative Medicines	Other branded Medicines	Generics	отс
Full-line Wholesaler	66,67%	71,60%	64,44%	50,89%
Short-line Wholesaler	1,19%	3,70%	1,11%	1,79%
Direct deliveries from manufacturer	32,14%	22,22%	33,33%	44,64%
Other	0,00%	2,47%	1,11%	2,68%

Source: IPF research 2016, Pharmacist survey

Table 17: Service level – pharmacists' agreement

	Full-line Wholesaler	Short-line Wholesaler	Direct deliveries from manufacturer
Delivery of intact goods (good condition) is appropriate	100,00%	55,56%	91,23%
Delivery time is predictable	100,00%	44,44%	31,03%
Frequency of delivery is sufficient	100,00%	44,44%	50,88%
Order service/system is convenient	96,67%	44,44%	43,86%
Range of products is adequate	96,55%	16,67%	44,64%
In-time deliveries support a good patient service	95,00%	35,29%	17,86%
Cut-off time is adequate	94,92%	33,33%	46,30%
Minimum orders are adequate	93,22%	33,33%	34,48%
Recall-time/Recall-service is adequate	84,75%	29,63%	29,63%
Delivery arrangements are convenient	81,36%	58,62%	58,62%
Financial support is provided (e.g. extended credit)	66,10%	16,67%	36,21%

Table 18: Safety of medicines – pharmacists' agreement

	Full-line Wholesaler	Short-line Wholesaler	Direct deliveries from manufacturer
Safety during transportation is adequate	96,55%	47,06%	83,00%
Protection against falsified medicines is adequate	95,00%	47,06%	95,00%
The cold-chain is respected	95,00%	56,25%	87,00%

ITALY (IT)

Table 19: Satisfaction with the distribution system

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	98,04%	1,96%	0,00%
Direct deliveries from manufacturer	80,85%	14,89%	4,26%

Source: IPF research 2016, Pharmacist survey

Table 20: Satisfaction with the delivery time

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	93,75%	4,17%	2,08%
Direct deliveries from manufacturer	50,00%	30,43%	19,57%

Source: IPF research 2016, Pharmacy survey

Table 21: Distribution system used by Italian pharmacists for the following product categories:

	Innovative Medicines	Other branded medicines	Generics	отс
Full-line Wholesaler	75,47%	61,84%	74,60%	64,71%
Direct deliveries from manufacturer	22,64%	35,53%	23,81%	35,29%
Other	1,89%	2,63%	1,59%	0,00%

Table 22: Service level – pharmacists' agreement

	Full-line Wholesaler	Direct deliveries from manufacturer
Order Service/System is convenient	100,00%	61,70%
Delivery arrangements are convenient	98,00%	63,83%
In-time deliveries support a good patient service	96,00%	44,44%
Delivery time is predictable	95,92%	47,83%
Cut-off time is adequate	94,00%	48,89%
Frequency of delivery is sufficient	93,88%	55,56%
Delivery of intact goods (good condition) is appropriate	87,50%	82,98%
Recall-time/Recall Service is adequate	87,50%	52,27%
Minimum Orders are adequate	85,11%	47,83%
Range of Products is adequate	82,00%	80,00%
Financial support is provided (e.g. extended credit)	56,82%	47,62%

Table 23: Safety of medicines - pharmacists' agreement

	Full-line Wholesaler	Direct deliveries from manufacturer
Protection against falsified medicines is adequate	96,00%	96,00%
Safety during transportation is adequate	92,00%	94,00%
The cold-chain is respected	91,84%	91,00%

Source: IPF research 2016, Pharmacy survey

UNITED KINGDOM (UK)

Table 24: Satisfaction with the distribution system

	Satisfide	Neutral	Dissatisfied
Wholesaler	71,65%	17,01%	11,34%
Direct deliveries from manufacturer	55,06%	22,47%	22,47%

Source: IPF research 2016, Pharmacy survey

Table 25: Satisfaction with the delivery time

	Satisfide	Neutral	Dissatisfied
Wholesaler	83,42%	10,88%	5,70%
Direct deliveries from manufacturer	56,79%	24,69%	18,52%

Table 26: Distribution system used by UK pharmacists for the following product categories:

	Innovative Medicines	Other branded medicines	Generics	отс
Wholesaler	59,32%	81,33%	95,04%	89,86%
Direct deliveries from manufacturer	38,98%	17,47%	2,84%	7,97%
Other	1,69%	1,20%	2,13%	2,17%

Table 27: Service level - pharmacists' agreement

	Wholesaler	Direct deliveries from manufacturer
Delivery of intact goods (good condition) is appropriate	85,64%	68,24%
Frequency of delivery is sufficient	82,81%	33,73%
Minimum orders are adequate	79,69%	43,53%
Order service/system is convenient	79,58%	41,18%
In-time deliveries support a good patient service	78,87%	42,86%
Delivery arrangements are convenient	74,87%	42,17%
Range of products is adequate	73,98%	48,24%
Cut-off time is adequate	73,85%	38,55%
Delivery time is predictable	71,00%	26,51%
Recall-time/Recall-service is adequate	63,00%	38,10%
Financial support is provided (e.g. extended credit)	32,24%	17,28%

Source: IPF research 2016, Pharmacy survey

Table 28: Safety of medicines – pharmacists' agreement

	Wholesaler	Direct deliveries from manufacturer
Safety during transportation is adequate	88,14%	81,40%
The cold-chain is respected	86,98%	82,35%
Protection against falsified medicines is adequate	85,57%	79,07%

Manufacturer survey:

Table 29: Satisfaction with the distribution system

	Satisfide	Neutral	Dissatisfied
Full-line Wholesaler	78,13%	18,75%	3,13%
Short-line Wholesaler	57,14%	35,71%	7,14%
3rd Party Logistics Provider +			
Direct-to-pharmacy	78,13%	17,19%	4,69%

Source: IPF research 2016, Manufacturer survey

Table 30: Motivation for selecting certain distribution models

			3rd Party	
	Full-line	Short-line	Logistics	Direct-to-
	Wholesaler	Wholesaler	Provider	pharmacy
Delivery frequency	21,43%	17,00%	14,00%	14,00%
Ensure product availability	13,39%	14,00%	11,00%	13,00%
Transportation function	10,71%	17,00%	14,00%	7,00%
Stock keeping function and stock security	10,71%	8,00%	10,00%	5,00%
Financial function	10,71%	8,00%	4,00%	6,00%
Control of the supply chain, point of sale				
and parallel trading	9,00%	6,00%	13,00%	20,00%
Administrative service	6,00%	6,00%	6,00%	3,00%
Safety	5,00%	4,00%	8,00%	10,00%
Monitor puchase by pharmacies				
and regions	1,79%	4,00%	5,00%	9,00%
Increase profit margin	0,89%	2,00%	5,00%	8,00%

Source: IPF research 2016, Manufacturer survey

Table 31: Importance of added-value service

	Full-line Wholesaler	Short-line Wholesaler
Product recalls	25,00%	16,00%
Support in product launch	20,83%	19,00%
Sales reports and services	19,44%	16,00%
Quality assurance services	10,00%	10,00%
Track and trace	6,94%	13,00%
Marketing and promotion	5,56%	13,00%
Waste collection and destruction management	5,56%	3,00%
Repackaging	4,17%	3,00%
Other	3,00%	3,00%

Source: IPF research 2016, Manufacturer survey

Table 32: Service level-desired improvements in the following area

	Full-line Wholesaler	Short-line Wholesaler	3rd Party Logistics Provider
Stock level transparency	81,48%	78,57%	57,14%
Order quantity	62,50%	58,33%	44,44%
Order system	61,54%	63,64%	57,14%
Late payments	52,00%	58,33%	20,00%
Net working capital	45,45%	60,00%	37,50%
Delivery arrangements to pharmacy (frequency/timing)	38,10%	38,46%	59,09%

Source: IPF research 2016, Manufacturer survey

ANNEX 3

Questionnaire for pharmacists:

NOTE:

We kindly request that the following questionnaire be completed by the chief pharmacist in the pharmacy

Introduction

The Institute for Pharmaeconomic Research (IPF), a scientific research institute based in Vienna, Austria, is conducting a study on the role of medicines distribution in Europe.

This study seeks to collect and compare data on various medicines distribution channels to pharmacies in six European countries. By comparing pharmaceutical full-line wholesaling to other distribution channels in providing access to medicines, this study seeks to assess the role of full-line pharmaceutical wholesaling for the healthcare system from a macroeconomic and microeconomic point of view.

For this purpose, the IPF has created a short questionnaire to examine potential challenges arising from the different distribution channels (e.g. additional labor costs, limited product range, increased stock capacity requirements, etc.) from the perspective of the pharmacists.

We kindly ask that you devote 5 minutes of your time to complete the following questionnaire. We greatly appreciate your assistance and support!

Please note that the confidentiality of the information you provide as well as compliance with data protection regulations is guaranteed.

For further questions please do not hesitate to contact us:

Sandra Ressl, MA s.ressl@ipf-ac.at

Phone.: +43 1 513 20 07

www.ipf-ac.at

Thank you for your cooperation!

Α.	Gene	ral Data							
1.	In wh	nich area is y	our ph	arma	cy loca	ted?			
		Wales	Engla	nd		Sco	otland		Northern Ireland
2.	Inhal	oitants of the	e city/e	distric	t wher	e yo	ur pharm	nacy is l	ocated:
		0-5,000		5,001	1-20,00	0		20,001	-100,000
		>100,000		> 1 N	∕lio.				
В.	Distri	ibution syste	m						
3.	s. From which source/distributor do you buy Rx and Gx medicines (Σ								
	100%	6)?							
_							1		
Sou	irce/D	istributor					In volum	ne	In value (£)
							(packs)		

%

%

%

%

100 %

%

%

%

%

100 %

4. From which source/distributor do you buy the following products?

Full-line wholesaler (including DTP)

Short-line wholesaler

Other:

Total:

Manufacturer (direct sales)

	Innovative drugs	Other branded medicines	Generics	отс
Full-line wholesaler (incl. DTP)				
Short-line wholesaler				
Manufacturer (direct sales)				
Other:				

C. Satisfaction

5.		general, how satisfi stem/s?	ed are yo	u with your pha	rmaceu	tical supply
		I-line wholesaler (in very satisfied very dissatisfied	ncluding I satisfied	DTP)		dissatisfied
	She	very dissatisfied very dissatisfied	satisfied	☐ neutral		dissatisfied
	Ma □	nufacturer very satisfied very dissatisfied	satisfied	☐ neutral		dissatisfied
6.	On	average, how many		-	e from y	our:
		Full-line wholes	ler (incit	iding DIP) :		
		Per week				
		Short-line whole	esaler:			
		Per day				
		Per week				
		Direct deliveries	from ma	nufacturers :		
		Per day				
		Per week				

7.		is the average de	-	e (i.e	. the time	between p	olacing an order
	receiv	ving the delivery) fr	om your :				
		Full-line wholes	aler (inclu	ding	DTP) :		
		Average delivery	y time in h	ours			
				OR	<u>'</u>		
		Average deliver	y time in d	ays			
		Short-line whole	esaler:				
		Average delivery	y time in h	ours			
				OR			
		Average deliver	y time in d	ays			
		Direct deliveries	from mar	oufaci	turers :		
		Average delivery			uieis .		
		Attenage denter	,	OR			
		Average delivery	y time in d				
				<u>-</u>			
8.	How	satisfied are you	with the a	verac	ıe deliver	v time?	
.					,	,	
	Full-l	ine wholesaler (i	ncluding D	TP)			
	□ v	ery satisfied 🗌	satisfied		neutral		dissatisfied
	□ v	ery dissatisfied					
	Shor	t-line wholesaler					
	□ v	ery satisfied 🗌	satisfied		neutral		dissatisfied
	□ v	ery dissatisfied					
	Direc	t deliveries from	manufactı	urers			
	□ v	ery satisfied 🗌	satisfied		neutral		dissatisfied
	□ v	ery dissatisfied					

and

9.	Please provide the average number of manufacturers, whose products are
	combined/bundled in a single delivery from your:

Full line wholesaler (including DTP):	
Short line wholesaler:	
Direct deliveries from manufacturer:	

D. Service level

10. Please provide feedback on the following services:

Full-line wholesaler (including DTP)

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Order service/system is convenient, accessible,					
friendly and competent					
Range of products is adequate					
Minimum orders are adequate					
Delivery of intact goods (e.g. in good condition) is appropriate					
Delivery arrangements are convenient					
Cut-off time is adequate					
Delivery time is predictable					
Frequency of delivery is sufficient					
In-time deliveries support a good patient service					
Recall-time/Recall-Service is adequate					
Financial support is provided (e.g. loan guarantee, extended credit)					

Short-line wholesaler

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Order service/system is convenient, accessible, friendly and competent					
Range of products is adequate					
Minimum orders are adequate					
Delivery of intact goods (e.g. in good condition) is appropriate					

The European Pharmaceutical Wholesale Sector

Delivery arrangements are convenient			
Cut-off time is adequate			
Delivery time is predictable			
Frequency of delivery is sufficient			
In-time deliveries support a good patient service			
Recall-time/Recall-Service is adequate			
Financial support is provided (e.g. loan guarantee, extended credit)			

Direct deliveries from manufacturers

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Order service/system is convenient, accessible,					
friendly and competent Range of products is adequate					
Minimum orders are adequate					
Delivery of intact goods (e.g. in good condition) is appropriate					
Delivery arrangements are convenient					
Cut-off time is adequate					
Delivery time is predictable					
Frequency of delivery is sufficient					
In-time deliveries support a good patient service					
Recall-time/Recall-Service is adequate					
Financial support is provided (e.g. loan guarantee, extended credit)					

E. Safety

11.Regarding the safety of medicines, please provide your feedback on the following elements:

Full-line wholesaler (including DTP)

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Protecting against falsified medicines is adequate					
Safety of transportation is adequate					
The cold-chain is respected					

Short-line wholesaler

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Protecting against falsified medicines is adequate					
Safety of transportation is adequate					
The cold-chain is respected					

Direct deliveries from manufacturers

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Protecting against falsified medicines is adequate					
Safety of transportation is adequate					
The cold-chain is respected					

Comments:			

F. Future trends

G. In which area do you expect future trends i.e. chances and risks of the distribution system in general and special distribution models in particular?

Definitions:

Average delivery time: The time between the daily cut-off time and the actual delivery.

Bundling: The combining of products from different manufacturers in the same delivery tote/crate.

Cut-off time: The time limit at which pharmacies must place an order so that it can be delivered on time.

Direct to Pharmacy (DTP) or Reduced Wholesale Agreement (RWA):

A pharmaceutical manufacturer delivers its medicines directly to the pharmacies through one or more logistics service providers, who are paid a delivery fee per pack (unlike wholesalers, logistics service providers do not acquire ownership of the medicines, have no stockholding responsibility and deliver according to the service level paid for by the manufacturer). Where ever DTP is indicated in the questionnaire, we are referring to both DTP and RWA. While the wholesaler in the RWA model takes ownership of the stock, unlike in the DTP model, we are combining the two models here in order to reduce complexity for the respondent.

ANNEX 4

Questionnaire for pharmaceutical manufacturers

Introduction

On behalf of the European Association of Pharmaceutical Full-line Wholesalers (GIRP), the Institute for Pharmaeconomic Research (IPF), a scientific research institute based in Vienna, is conducting a study on the role of pharmaceutical full-line wholesaling in Europe.

In the course of this study, data on pharmaceutical distribution will be collected and to thereby assess its role for the healthcare system from a macroeconomic and microeconomic point of view.

For this purpose, the IPF has created a short questionnaire to elicit potential problems with the different distribution channels.

We hope to enlist your expertise in support of this study and would kindly like to ask you to devote 4-6 minutes of your valuable time to complete the following questionnaire. We are very grateful for your contributions.

For further information on the activities of our institute, we would like to refer you to our website www.ipf-ac.at.

The confidentiality of the information you provide is guaranteed, as is compliance with data protection regulations. The IPF thanks for your cooperation and would kindly like to refer you again to the following questionnaire.

For further questions please do not hesitate to contact us:

Ms. Sandra Ressl: s.ressl@ipf-ac.at

Phone.: +43 1 513 20 07-12

www.ipf-ac.at

The IPF thanks for your cooperation!

A. Company profile

1. For which country(ies) are you filling in this questionnaire?

□Austria	☐Belgium	□Bulgaria
☐ Croatia	☐ Cyprus	☐Czech Republic
□Denmark	□Estonia	☐Finland
France	☐Germany	□Greece
Hungary	☐Ireland	□Italy
Latvia	□Lithuania	Luxembourg
□Malta	□Netherlands	□Norway
□Poland	□Portugal	Romania
□Slovakia	□Slovenia	□Spain
Sweden	Switzerland	☐United Kingdom
■United States	Other	
2. Is your com	pany operating on:	
□National level □European level □ International level		

3. Your product portfolio is comprised of:

	Share
☐Patented products	%
☐Generics	%
□отс	%
☐ Medical Devices	%
Biosimilars	%
Parapharmaceuticals	%
□Diagnostics	%

^{*}In case of an overlap between the categories, please nevertheless provide the full percentage per category.

4. Your product portfolio requires:

☐Ambient temperature
☐Cold chain
☐Below 0°C handling
■Narcotics control

1. Do you supply the country from your own warehouse? Yes No 2. Is the warehouse located in the country or elsewhere? In the country elsewhere: 3. Do you use outsourced supply chain services? Yes No If yes, Do you use these services for the distribution of country stock (pre-

4. Which distribution system is your company using?

 \square Do you use these services for direct sales to

	Innovative drugs	Generics	отс	Cold chain	Frozen	Narcotics
Full-line wholesalers						
Short-line wholesalers						
3 rd Party Logistics provider						
DTP (direct-to- pharmacy) or RWA (reduced wholesale agreement)						
Other						

^{*}Please mark all boxes that apply.

B. Distribution system

wholesale)?

pharmacies/hospitals?

C. Satisfaction

1. How satisfied are you with your pharmaceutical distribution system/s in general?

	Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied
Full-line wholesaler					
Short-line wholesaler					
3 rd Party Logistics provider					
DTP (direct-to-pharmacy) or RWA (reduced wholesale agreement)					
Other					
Additional remarks/reasoning:					

C.1 Full-line Wholesaler

1. What is your motivation for choosing the full-line wholesale model as your distribution system?

7041 4104112441011 270401111	
Ordering process (logistic service)	
Delivery frequency / product availability	
Financial function*	
Safety	
Bundling of orders	
Stock keeping function and stock security	
Transportation function**	
Administrative service***	
Control of the supply chain and point of sale	
To monitor purchases by pharmacies and regions	
Increase profit margin	
Control parallel trading	
Ensure product availability	
Other	

^{*} The costs and financial risks are transferred – the pharmaceuticals are paid for by the wholesaler and the financial risk of the goods has transferred to the wholesaler

^{*} If you marked "Neutral", please provide explanations in the space below:

^{**} From the industry to the wholesaler

^{***} Reduced contacts, easier accounting

2. Which added-value services provided by full-line wholesalers are important to your company?

Added-value service	
Product recalls	
Support in product launch*	
Repackaging	
Track and trace	
Quality assurance services	
Sales reports and statistics	
Marketing and promotion	
Waste collection & destruction management	
Other	

^{*}e.g. time to market, opening sale channels

C.2 Short-line Wholesaler

1. What is your motivation for choosing a short-line wholesaler?

Ordering process (logistic service)	
Delivery frequency / product availability	
Financial function*	
Safety	
Bundling of orders	
Stock keeping function and stock security	
Transportation function**	
Administrative service***	
Control of the supply chain and point of sale	
To monitor purchases by pharmacies and regions	
Increase profit margin	
Control parallel trading	
Ensure product availability	
Other	

^{*} The costs and financial risks are transferred – the pharmaceuticals are paid for by the wholesaler and the financial risk of the goods has transferred to the wholesaler

^{**} From the industry to the wholesaler

^{***} Reduced contacts, easier accounting

2. Which added-value services provided by short-line wholesalers are important to your company?

Added value service	
Product recalls	
Support in product launch*	
Repackaging	
Track and trace	
Quality assurance services	
Sales reports and statistics	
Marketing and promotion	
Waste collection &	
destruction management	
Other	

^{*}e.g. time to market, opening sale channels

C.3 3rd Party Logistics provider

1. What is your motivation for choosing a 3rd Party Logistics provider (3PL)?

provider (SLE):	
Ordering process (logistic service)	
Delivery frequency / product availability	
Financial function*	
Safety	
Bundling of orders	
Stock keeping function and stock security	
Transportation function**	
Administrative service***	
Control of the supply chain and point of sale	
Monitor purchases by pharmacies and regions	
Increase profit margin	
Control parallel trading	
Ensure product availability	
Other	

C.4 DTP (Direct to Pharmacy) or RWA (Reduced Wholesale Agreement)

1. What is your motivation for choosing the DTP or RWA distribution model?

Ordering process (logistic service)	
Delivery frequency / product availability	
Financial function*	
Safety	
Bundling of orders	
Stock keeping function and stock security	
Transportation function**	
Administrative service***	
Control of the supply chain and point of sale	
Monitor purchases by pharmacies and regions	
Increase profit margin	
Control parallel trading	
Ensure product availability	
Other	

D. Service level

1. In which areas would you like to see improvements?

D.1 Full-line wholesaler

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Late payments					
Order system					
Delivery arrangements to pharmacies (frequency/timing)					
Order quantity					
Net working capital					
Stock level transparency					

^{*} If you marked "Neutral", please provide explanations in the space below:

D.2 Short-line wholesaler

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Late payments					
Order system					
Delivery arrangements to pharmacies (frequency/timing)					
Order quantity					
Net working capital					
Stock level transparency					

^{*} If you marked "Neutral", please provide explanations in the space below:

D.3 3PL or pre-wholesaler (only relevant if you use a 3PL or prewholesaler for direct sales, DTP and RWA)

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Late payments					
Order system					
Delivery arrangements to pharmacies (frequency/timing)					
Order quantity					
Net working capital					
Stock level transparency					

^{*} If you marked "Neutral", please provide explanations in the space below:

E. Future trends

- 1. In which areas do you expect future trends, i.e. chances and risks of the distribution system in general and special distribution models in particular?
- 2. What do you expect/want from full-line wholesalers?
- 3. Any additional suggestions:
- 4. Please provide the name of your company unless you wish to stay anonymous.

Thank you for your participation!

Annex – definitions:

Direct to Pharmacy (DTP): In the DTP distribution model pharmaceutical manufacturers deliver their medicinal products directly to the pharmacies through one or more logistic service providers.

Direct sales: In the case of direct sales, the pharmaceutical manufacturer sells its medicinal products directly to the pharmacist. In such scenarios, manufacturers may still opt to utilise the pharmaceutical full-line wholesaling route.

Pharmaceutical full-line wholesaling: The activity of pharmaceutical full-line wholesaling consists of the purchase, warehousing, storage, order preparation and delivery of medicines. Pharmaceutical full-line wholesalers carry and distribute the complete assortment of products, both in terms of range and depth, within the framework set by the authorities and the market in order to meet the needs of those with whom they have normal business relations. They deliver all medicines in their geographical area of activity on the same day/within less than 24 hours.

Pharmaceutical short-line wholesaling: The activity of pharmaceutical short-line wholesaling consists of the purchase, warehousing, storage, order preparation and delivery of medicinal products. Pharmaceutical short-line wholesalers carry and distribute only a selective assortment of products.

Pharmaceutical pre-wholesaler: Pharmaceutical pre-wholesalers act as logistic service partners for pharmaceutical manufacturers and are highly specialised providers of bulk deliveries of pharmaceutical, healthcare and consumer products to wholesalers, hospitals and pharmacies. They use their own storage facilities ranging from ambient (either monitored or controlled ambient), refrigerated, to other specialised high security products (clinical trial logistics, narcotics). In addition to their supply chain management expertise, pharmaceutical pre-wholesalers provide additional value-added services such as product packaging and labelling for national markets. Pre-wholesalers are used for providing supplies to other wholesalers, as well as for carrying out direct deliveries to customers. A pre-wholesaler usually acts as a 3rd Party Logistic Provider (3PL).

Reduced Wholesale Arrangement (RWA): In the Reduced Wholesale Arrangement pharmaceutical manufacturers use only a small number of selected wholesalers to distribute medicinal products.

3rd Party Logistics Provider (3PL): A 3rd Party Logistics Provider is an entity that provides or coordinates warehousing or other logistics services of a product on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

This study was prepared by the Institute for Pharmaeconomic Research (IPF) Vienna for the European Association of Pharmaceutical Full-line Wholesalers (GIRP). The information in this study was compiled with the utmost care. However, IPF cannot be held responsible for the consequences of errors arising from the use of the study.

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