

Celesio Policy Position

Understanding the Value of Pharmaceutical Distribution

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Background

Pharmaceutical distributors are the backbone of national medicines supply, delivering swiftly the medicines that patients need. Their main activities include purchasing medicines from manufacturers, storing them securely and appropriately and distributing them safely to community pharmacies. With this support, pharmacies can maintain efficient stock levels and patients are assured of same or next day medicines supply. As a partner for pharmaceutical manufacturers and community pharmacies, pharmaceutical distributors relentlessly streamline delivery processes.

This paper outlines the frequently overlooked role of pharmaceutical distributors in the medicines supply chain and how this is evolving to provide a wider range of value services for the benefit of patients, healthcare systems and society. We call on policy makers and payors to recognise the contribution of pharmaceutical distributors and to support this vital sector of the medicines supply chain to ensure the safest and most cost-effective supply of medicines to our national healthcare systems.

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What is pharmaceutical distribution?

Pharmaceutical distributors play an essential role in the medicines supply chain through their medicine distribution centres and fleets of delivery vehicles. Each day they supply 62 million medical products and medicines – whether for minor illnesses or life-threatening diseases – to over 183,000 pharmacies across the European Union.¹ Thanks to pharmaceutical distributors, patients across Europe receive the medicines they need on time.

Because of the critical nature of the healthcare products they handle, pharmaceutical distributors are rightly subject to very stringent regulations for storage and delivery, in particular in relation to temperature control. EU legislation² imposes an obligation on pharmaceutical distributors to ‘ensure appropriate and continued supplies’ to pharmacies. Many countries also impose a national Public Service Obligation (PSO), for example to hold a wide portfolio of medicines in stock, to deliver within maximum times and to ensure a constant supply of medicines. These rules mean that pharmaceutical distributors have to conduct very complex operations. They are private companies and receive no state subsidies.

¹ GIRP Annual Report 2015-2016

² Article 81, Directive 2001/83/EC on the Community code relating to medicines for human use

Furthermore, pharmaceutical distributors have evolved to develop close working relationships with pharmacies, offering business support expertise and marketing tools, among other services.

What are the advantages of the current EU supply model?

The pharmaceutical distribution sector's highly regulated model ensures a reliable supply of medicines to patients. Pharmaceutical distributors' comprehensive product range includes many lesser-used medicines of which only a few packs might be ordered each month in any one country. Pharmaceutical distributors in six countries – France, Germany, Italy, the Netherlands, Spain and the UK (EU6) – stock an average of 57,000 medicines, with German pharmaceutical distributors providing 100,000.³

Pharmaceutical distributors are manufacturer-neutral and enable market access for smaller pharmaceutical companies. The beneficiaries of regular deliveries include not only community pharmacies but also hospitals and other places where healthcare professionals work, e.g. prisons, military bases etc. This network also covers remote areas with smaller populations.

By receiving payment in arrears, pharmaceutical distributors provide flexibility to community pharmacies, with supportive terms and conditions. In the EU6 in 2016, they provided medicines worth on average €11.8 billion over 47 days before receiving payment.⁴

Technological sophistication (e.g. electronic orders) and competition between pharmaceutical distributors helps to keep costs down. They also provide innovative/additional services to pharmacies such as support for medication reminder systems, self-diagnostics, customised drug delivery, monitoring services, nursing services, digital services (apps), repackaging into weekly doses and logistics innovations to support compliance, among others.⁵ They also provide additional services to manufacturers such as data services, patient adherence and product launch support services.

Threats to this critical medicines supply chain

In some countries, individual manufacturers deliver their medicines directly to the dispenser/pharmacy, by-passing existing distributors. Such a model, while sometimes cost-effective for manufacturers, does not offer the same comprehensive coverage for pharmacies and patients. Manufacturers can cherry-pick the most lucrative products, undermining the cross-subsidisation which enables pharmaceutical distributors to ensure that a full range of medicines is available to all customers. Moreover, through economies of scale, pharmaceutical distributors can supply all pharmacies and other points of dispensing – in 2015 they undertook over 796 million transactions to pharmacies in the EU6. Under direct delivery, manufacturers would have needed to conduct 99.4 billion transactions⁶ to ensure the same coverage. Inevitably under the direct delivery model, many pharmacies are not supplied.

Current challenges facing pharmaceutical distributors

The pharmaceutical distribution model is under pressure through several difficult challenges:

- **Remuneration:** Distribution costs and margins make up only a small fraction of medicine costs, but in most European countries, the sector's remuneration is eroding – on average by

Our key messages

Pharmaceutical distributors play a key role in the medicines supply chain.

Patients throughout Europe benefit from the huge range of medicines and wide geographical coverage offered by pharmaceutical distributors.

Other distribution models, e.g. from manufacturers, are not as comprehensive and do not offer the same advantages to pharmacies or patients.

In order to carry out their duties effectively, pharmaceutical distributors ask for secure remuneration, predictable and realistic regulation and a reliable supply from manufacturers.

³ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

⁴ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

⁵ GIRP: The Role of Pharmaceutical Full-line Wholesalers in Europe, August 2015

⁶ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

29.3% between 2001 and 2014.⁷ The volume of mid-value medicines is declining, while there is a growth of small-value medicines (which are poorly rewarded) and high-value medicines (whose storage and transport involve greater risks – remuneration is capped at a fixed amount in many countries). This trend is undermining the profitability of the existing pharmaceutical distribution model.

- **Inconsistent regulation:** The EU's Good Distribution Practice (GDP) guidelines, which form the basis of national rules for storage and distribution of medicines, rightly set high standards, often at considerable cost to pharmaceutical distributors. For example, to comply fully with the latest GDP Controlled Room Temperature rules during transport (15-25°C), a refurbishing of the entire current transportation fleet in Europe would cost €170 million, plus €107 million of yearly running costs.⁸ While all pharmaceutical distributors aspire to meet such obligations, this is however made difficult by inconsistent interpretation and application of regulations between, and sometimes even within, countries. This can mean uncertainty about how they should store medicines and how and where they can make deliveries.
- **Digitalisation:** The pharmaceutical distribution sector will witness a fundamental change transforming both existing supply chain models and the way patients order and receive their medication.
- **Additional regulatory obligations:** Pharmaceutical distributors face additional obligations such as the implementation of the Falsified Medicines Directive from 2019. This will oblige them to scan all medicines which they distribute to another party and any products which leave the supply chain and to report any products subject to tampering or suspected falsification.
- **Restrictive supplies:** Pharmaceutical distributors prefer to stock and deliver a full or nearly full range of medicines, and may indeed be legally obliged to do so – for example, in France, they must stock 90% of all the medicines on the market. Conversely, they are often faced with restrictions from certain manufacturers who have imposed quotas for the supply of certain medicines. This can make it impossible for pharmaceutical distributors to fulfil their obligations and lead to shortages on the market.

Our request to regulators and policy makers

As an owner of pharmaceutical distribution companies in eleven European countries,⁹ Celesio is asking regulators and healthcare policy makers to consider the following principles for our sector:

- **Secure remuneration** which takes account of the expectations on pharmaceutical distributors to provide their current service level and of changing market conditions to allow investments to be made to improve standards and quality
- **Consistency in the application and enforcement of regulations in the pharmaceutical distribution sector**
- **Recognition by payers that the digital agenda is changing the environment** – shifting traditional distribution models. This will require a new look at emerging cost pressures.
- **No regulations that impose more obligations on pharmaceutical distributors unless a demonstrable patient or safety benefit exists and following a full impact assessment**
- **Remove artificial barriers to supply from manufacturers** so that pharmaceutical distributors can carry out their deliveries effectively – this may only be possible through intervention by policy makers.

⁷ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

⁸ GIRP Annual Report 2015-2016

⁹ Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Norway, Portugal, Slovenia, UK

About Celesio

With around 36,000 employees, Celesio operates in 13 European countries. Every day, the group serves over 2 million customers – at more than 2,150 pharmacies of its own, at about 300 managed pharmacies and at over 5,500 participants in brand partnership schemes. With 109 pharmaceutical distribution branches, Celesio supplies more than 50,000 pharmacies and hospitals every day with up to 130,000 pharmaceutical products. This benefits a patient pool of about 15 million per day.



Celesio Markets in Europe

Facts and Figures

Please see our online Annex at <http://www.celesio.com/ag-en/company/external-affairs/position-papers/pharmaceutical-distribution/21244>

Celesio Policy Position

Understanding the Value of Pharmaceutical Distribution

Annex – Facts and Figures

Numbers served

EU6 (FR, DE, ES, IT, NL, UK)¹

- Yearly: 795.6 million transactions from pharmaceutical distributors to pharmacies – from manufacturers this would require 99.4 billion transactions
- Average deliveries per week per pharmacy: typically 16 from pharmaceutical distributors, versus 3.66 from manufacturers

EU 26 (EU minus Cyprus and Malta) + Switzerland, Norway, Serbia and Iceland²

- 2014: Wholesalers served 183,591 retail pharmacies, hospitals and dispensing doctors
- Wholesalers deliver an average of 62 million medicine packs per day

Country	Manufacturers	Pharmacies	Product lines	Boxes per day
France ³	260	21,772	30,000	4.2 million
Germany ⁴	1500	20,000	100,000	6 million

Delivery times

Average times

- EU6: Average total delivery time:⁵
 - 4.6 hours from pharmaceutical distributors,
 - 57.86 hours from manufacturers
- France: Average total delivery time = 2hrs 15 mins⁶
- Germany: Average time between receiving order and dispatch = 45 mins⁷

¹ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

² GIRP Annual Report 2015-2016

³ CSRP – La Répartition Pharmaceutique – L'essential 2016

⁴ PHAGRO – Fläckendeckende Vollversorgung, June 2016

⁵ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

⁶ CSRP – La Répartition Pharmaceutique – L'essential 2016

Pharmacists happy with delivery times, 2016⁸

- EU6: 94%
- France: 100%
- Italy: 98%
- Germany: 100%

Payment in arrears

Through delivering goods in advance of payment, pharmaceutical distributors provide important support to pharmacies. In the EU6 in 2014, this amounted to:

- An average of €11.8 billion over 47 days
- An annual total of €92 bn.⁹

Costs

EU6 2015¹⁰

- Cost per delivery = €9.11 from pharmaceutical distributor; €12.98 from manufacturer
- Additional process costs per pharmacy per year if medicines come directly from manufacturer:
 - If 25% come from manufacturer, €48,206
 - If 50% come from manufacturer, €107,808 per year
 - If 100% come from manufacturer, €203,224 per year

Public Service Obligation (PSO)

European countries which impose PSO on wholesalers¹¹

Belgium	Czech Republic	Finland	France
Greece	Hungary	Italy	Luxembourg
Latvia	Norway	Poland	Portugal
Romania	Slovenia	Slovakia	Spain

⁷ PHAGRO – Fläckendeckende Vollversorgung, June 2016

⁸ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

⁹ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

¹⁰ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

¹¹ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017; Celesio research

Examples of PSOs¹²

Country	Minimum stock	Delivery times
Belgium	<ul style="list-style-type: none"> At least two-thirds of pharmaceutical specialities, sera and vaccines With the average value of one month's turnover of the past year 	Within 24 hours
France	<ul style="list-style-type: none"> At least 90% of marketed products Two weeks supply for regular customers 	Within 24 hours
Germany	Two weeks supply for average demand	Within an appropriate time period on weekdays
Italy	At least 90 % of all essential Rx products	Within 12 hours
Norway	Full range of products (not further defined)	<ul style="list-style-type: none"> Within 24 hours Within 48 hours for areas with difficult communication Medicines Agency may make exemptions for special circumstances
Portugal	<ul style="list-style-type: none"> Medicines marketed for over 12 months: average stock level over last 12 months Medicines marketed for under 12 months: average stock level since market entry 	<ul style="list-style-type: none"> Within 12 hours for medicines that are not in the pharmacy but are available to distributors For medicines that are not available to distributors, wholesalers must maintain evidence of efforts to procure them from manufacturers

Remuneration

Decrease in margin in the EU, 2001-2016¹³

- Wholesale – from 100 to 71

Breakdown of medicine costs

Country	Wholesaler	Pharmacy	State	Industry
France ¹⁴	3%	21.5%	10%	65.5%
Germany ¹⁵	3.5%	15.3%	16%	65.2%
Italy ¹⁶	3%	30.35%	-	66.65%

¹² GIRP - Overview of public service obligation per country, 2012; Infarmed – Deliberação No. 021/CD/2011

¹³ GIRP – Distribution profile and efficiency of the European pharmaceutical full-line wholesaling sector, 2017

¹⁴ CSRP – La Répartition Pharmaceutique – L'essential 2016

¹⁵ PHAGRO – Fläckendeckende Vollversorgung, June 2016

¹⁶ ADF – Intermediate Distribution – Trade Margins

<http://www.adfsalute.it/index.php/la-distribuzione-intermedia-3/i-margini-commerciali>

France¹⁷

- 70% of all medicines distributed are generics
- Wholesaler margins fell 17.4 % between 2004 and 2015

Germany

- Wholesaler costs make up only 0.5% of the costs of the public sick funds (GVK)¹⁸

Good Distribution Practice Guidelines

The EU's Good Distribution Practice (GDP) Guidelines¹⁹ imposes obligations on wholesale medicine distributors, which they must follow under EU law.²⁰ They cover practices in ten areas:

1. Quality management
2. Personnel
3. Premises and Equipment
4. Documentation
5. Operations (including receipt of medicines and storage)
6. Complaints, returns, suspected falsified medicinal products and medicinal product recalls
7. Outsourced activities
8. Self-inspections
9. Transportation
10. Specific provisions for brokers

The Guidelines are supervised by authorities at national or regional level.

¹⁷ CSRP – La Répartition Pharmaceutique – L'essential 2016

¹⁸ PHAGRO – Fläckendeckende Vollversorgung, June 2016

¹⁹ European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use

²⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use