Supply Chain Trends in Europe
Martin FitzGerald, Deputy Director General, GIRP
Agenda

- Introduction
- IPF study on “Distribution profile and efficiency of the full-line pharmaceutical wholesale industry sector”
- Falsified Medicines Directive and Delegated Regulation
- Good Distribution Practice Guidelines
- Shortages of medicinal products
The core activity of pharmaceutical wholesale distributors consists of:

- purchase and sale;
- warehousing storage; order preparation;
- and delivery of medicines.

Pharmaceutical full-line wholesalers carry and distribute the full assortment of products (in range and depth) to meet the needs of those with whom they have normal business relations and to deliver all medicines needed, in their geographical area of activity, within a very short period of time. Unlike the

Pharmaceutical full-line wholesalers are an indispensable partner for a Europe-wide, reliable, sustainable and secure medicines supply.
752 pharmaceutical full-line wholesalers ensured the fast, continuous and cost-effective supply of medicines and medical products to over 180,743 retail pharmacies, hospitals and dispensing doctors throughout the European Union plus Norway and Switzerland in 2015. They served over 520 million people.

1) National and regional wholesalers;
2) Pharmacies, hospital pharmacies and dispensing doctors

* EU-28 without Malta and Cyprus
** DE, ES, FR, IT, NL, UK

Source: IPF research 2016
More than 94% of all medicinal products distributed by pharmaceutical full-line wholesalers are sold to retail pharmacies, followed by hospital pharmacies with only 4%.

Percentage of medicinal products (quantity) distributed by pharmaceutical full-line 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: IPF research 2016
THE NEGATIVE EFFECT OF PRICE CHANGES ON WHOLESALERS’ MARGIN

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.

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

Source: IPF research 2016
PHARMACEUTICAL FULL-LINE WHOLESALING

- Over **795.6 million** transactions between pharmaceutical full-line wholesalers, pharmacies and manufacturers take place every year in the 6 key European markets (France, Germany, Italy, Spain, the Netherlands and the United Kingdom).
- **Without pharmaceutical full-line wholesalers**, the number of transactions would increase to **99.4 billion** transactions per year.

**Direct distribution**

~ **100 bn transactions**

**Full-line wholesaler distribution**

~ **800 moi transactions**

Source: IPF research 2016
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NEW GIRP-IPF Study “Distribution profile and efficiency of the full-line pharmaceutical wholesale industry” available at www.girp.eu/publications

- **4 main efficiency indicators:**
  - Full supply and stock-keeping function
  - Immediate medicines availability and delivery function
  - Bundling function
  - Pre-financing function
  - Value-added services

- **Pharmacists’ perception survey**
  - Satisfaction with distribution system
  - Satisfaction with delivery time and frequency
FULL SUPPLY AND STOCK-KEEPING FUNCTION

Facts and figures
Items on stock held by pharmaceutical full-line wholesalers: **18,650 – 100,000** (depending on the size of the market and the number of products authorized to be marketed).

Source: IPF research 2016
Delivery times & frequency

- Pharmaceutical full-line wholesalers ensures deliveries within **4.6 hours** (on average) and deliver **16.02 times per week** to pharmacies (including remote areas).

- Short-line wholesalers deliver their products within **20.05 hours** and only **4.34 times** per week.

- Direct deliveries from manufacturers average **57.86 hours** and deliver **3.66 times** per week.

<table>
<thead>
<tr>
<th></th>
<th>Pharmaceutical full-wholesalers</th>
<th>Short-line wholesalers</th>
<th>Direct sales from manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average delivery</td>
<td>4.60</td>
<td>20.05</td>
<td>57.86</td>
</tr>
<tr>
<td>frequency (hours)</td>
<td>[image]</td>
<td>[image]</td>
<td>[image]</td>
</tr>
<tr>
<td>Average deliveries</td>
<td>16.02</td>
<td>4.34</td>
<td>3.66</td>
</tr>
<tr>
<td>per week</td>
<td>[image]</td>
<td>[image]</td>
<td>[image]</td>
</tr>
</tbody>
</table>

Source: IPF research 2016

GIRP: the vital link in healthcare
BUNDLING FUNCTION (pharmacy process cost)

- There is an average of **18.8 manufacturer products** in one delivery from pharmaceutical full-line wholesalers.
- The bundling of **18.8 deliveries** in one delivery from a pharmaceutical full-line wholesaler saves **€234.84**.

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**Order from pharmaceutical full-line wholesaler**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determination of order demand</td>
<td>€ 2,48</td>
</tr>
<tr>
<td>Transmission of order</td>
<td>€ 0,83</td>
</tr>
<tr>
<td>Receiving and storaging of delivery</td>
<td>€ 4,69</td>
</tr>
<tr>
<td>Checking the delivery note and bill</td>
<td>€ 1,10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>€ 9,11</strong></td>
</tr>
</tbody>
</table>

Source: IPF research 2016
BUNDLING FUNCTION (pharmacy process costs)

➢ Pharmacies in the 6 key markets receive ~ **16 deliveries/week**:
➢ Without the pooling of orders through the pharmaceutical full-line wholesaling channel, the cost increase would be from **€7,590** to **€55,796 / year** per pharmacy, if only 25% of the full-line wholesaling deliveries were replaced by direct deliveries from manufacturers.
➢ If 50% of the wholesale deliveries were replaced by direct deliveries from manufacturers the process costs incurred by a pharmacy would increase by **€115,398 /year**.
➢ Without pharmaceutical full-line wholesalers and at the same frequency of deliveries provided by other operators the process costs per pharmacy would increase by **€210,814 / year**.

Source: IPF research 2016
Pharmaceutical full-line wholesalers assume a major financing function towards manufacturers and pharmacies.

Pharmaceutical full-line wholesalers guarantee the continuous supply of all medicinal products and also secures the cash flow of the social insurers.

The financing function can be expressed in terms of working capital.

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

Compared to the findings of the previous study, financing volume increased in all six selected countries by 2.3 bn and the financing period increased by 5 days from 2011 to 2015.
ADDED VALUE SERVICES OFFERED BY PHARMACEUTICAL FULL-LINE WHOLESALERS

Manufacturers
- Market access services
- Market intelligence, sales reports and statistics
- Marketing and promotion
- Warehousing and transportation
- Inventory and stock management
- Direct deliveries and special handling
- Product serialization and track & trace
- Product recalls and reverse logistics
- Pre-wholesaling/pre-financing
- Waste management services
- Product quality and professional services
- Aggregated ordering
- Clinical trial logistics

Pharmacies
- Warehousing and storage
- Stock management
- Automated order processing
- Guaranteed availability and accessibility to medicines
- Just-in-time delivery
- Micrologistics
- Financial service, sales and purchase analysis
- Marketing support
- Product recalls
- Education and awareness programmes
- Medicine adherence programmes and eHealth tools
- Product-specific training
- IT management systems
- Medical devices delivery

Patients
- Guaranteed product quality
- Guaranteed availability and accessibility to medicines
- Patient self-diagnostics and self-management
- Individual patient packaging (blistering)
- Patient training and education
- Patient compliance and adherence
- Patient monitoring
- Homecare, nursing and home delivery services
- Pharmacovigilance services
- eHealth and communication services
- Appointment and refill reminders
- Repeat prescription services

Society
- Guaranteed product quality
- Guaranteed availability and accessibility to medicines
- Patient self-diagnostics and self-management
- Individual patient packaging (blistering)
- Patient training and education
- Patient compliance and adherence
- Patient monitoring
- Homecare, nursing and home delivery services
- Pharmacovigilance services
- eHealth and communication services
- Appointment and refill reminders
- Repeat prescription services

Source: IPF research 2016
88% of pharmacists were satisfied with the full-line wholesale model
61% were satisfied with the delivery service offered by short-liners
57% of pharmacists were satisfied with deliveries coming directly from pharmaceutical manufacturers; 22% were not satisfied with deliveries from pharmaceutical manufacturers and 21% were neutral
PHARMACISTS’ SURVEY

PHARMACISTS’ SATISFACTION WITH THE DELIVERY TIME

➢ **94%** of pharmacists were satisfied with the delivery time offered by pharmaceutical full-line wholesalers
➢ **69%** of pharmacists were satisfied with the delivery time offered by short-line wholesalers
➢ **33%** were not satisfied with the delivery time offered by pharmaceutical manufacturers (attention: 33% are neutral answers!) and **only 34%** of the responding pharmacists are satisfied

Source: IPF research 2016
Based on answers from DE, ES, FR, IT, NL, UK
➢ 70% of pharmacists chose wholesalers to buy innovative medicines
➢ 75% of pharmacists chose wholesalers to buy other branded medicines
➢ 74% of pharmacists chose wholesalers to buy generics
➢ 61% of pharmacists chose wholesalers to buy OTC products

*Wholesalers: pharmaceutical full-line wholesaler and pharmaceutical non full-line wholesalers

Source: IPF research 2016
Based on answers from DE, ES, FR, IT, NL, UK
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Falsified Medicines Directive and Delegated Regulation

Good Distribution Practice Guidelines

Shortages of medicinal products
Falsified Medicines Directive (FMD) 2011/62/EU

- **Directive published 1 July 2011**
- **Entered into force 1 January 2013**
- **Contains measures to increase security of the medicinal supply chain in Europe**

1. **Strengthen Good Manufacturing and Good Distribution Practices including the sourcing of active ingredients**

2. **Improve supervision of actors in the distribution chain (e.g. wholesalers, parallel distributors...)**

3. **Ensure product integrity and authentication of medicines (safety features and product serialisation)**
Delegated Regulation to the FMD

- Adopted on 2nd October 2015
- Published on 9th February 2016
- Enacting terms:
  1. Characteristics and technical specifications of the unique identifier
  2. Modalities for the verification of the safety features
  3. Establishment, management and accessibility of the repository systems
  4. List of RX medicines exempted from carrying the safety features
  5. Notification procedure for exceptions by Member States
  6. Procedure for rapid assessment of notifications
Implementation of the Delegated Regulation – Required in Member States 3 years after publication

**Objective:** Protection of patients from falsified medicines in the legal distribution chain

**Content:** Pan-European system to verify the authenticity of medicinal products

- **2011:**
  - July 2011: Publication of FMD

- **2013:**
  - Jan 2013: FMD except Safety Features implemented

- **2016:**
  - 9 February 2016: Publication of Delegated Regulation

- **2019:**
  - 36 Mon.

*Italy, Belgium, Greece have 6 years longer for implementation

**Non-compliance puts sales at risk**
### Fundamental principles for medicines verification in the EU

<table>
<thead>
<tr>
<th>SAFETY FEATURES</th>
<th>System Design</th>
</tr>
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</table>
| • Unique identifier with randomised serial number  
• Check of pack’s authenticity at point of dispense |
| • Flexible to implement national solutions within an EU technical framework (according to User Requirement Specifications)  
• Interoperable between different national systems through European Hub |

<table>
<thead>
<tr>
<th>DATA</th>
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</table>
| • Transactional data belongs to stakeholder that generated it, e.g. pharmacists for dispensing data  
• No access to data of other stakeholders except for verification purposes |

<table>
<thead>
<tr>
<th>GOVERNANCE</th>
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| • Systems governed by non-profit organisations, established and managed by relevant stakeholders  
• Systems supervised by EU and/or national authorities  
• Quality supervision by EDQM (tbd) |
Common basic concept: Unique Identifier

- **Data-Matrix code, developed to ISO-standards**
- **Key data elements:**
  - Product code (GTIN/NTIN or PPN)
  - Randomised unique serial number
  - Expiry date
  - Batch number
  - National health number (where necessary)

<table>
<thead>
<tr>
<th>Product #</th>
<th>09876543210982</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch</td>
<td>A1C2E3G4I5</td>
</tr>
<tr>
<td>Expiry</td>
<td>140531</td>
</tr>
<tr>
<td>S/N</td>
<td>12345AZRQF1234567890</td>
</tr>
</tbody>
</table>

Required by Delegated Regulation
Common basic concept: Point of Dispense Verification

Required by Delegated Regulation
Pan-European Structure

European Hub

- National System
- National System
- National System
- National System

Pharmaceutical Manufacturer

Parallel Distributor

Required by Delegated Regulation

Pharmacy

Wholesaler

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IMPLEMENTATION OF THE GDP GUIDELINES…
STILL SOME FOOD FOR THOUGHT…..
Temperature control during transport

- wholesalers’ responsibility:

  protect medicinal products against breakage, adulteration and theft

  to ensure that temperature conditions are maintained within “acceptable limits” during transport

- storage conditions for medicinal products should be maintained during transportation within the defined limits as described by the manufacturers or on the outer packaging

- temperature excursion or product damage has to be reported (procedure for investigating and handling temperature excursions)

- risk assessment of delivery routes: to determine where temperature controls are required
TEMPERATURE CONTROL DURING TRANSPORTATION

„As described by the manufacturers or on the outer packaging“


No information

One delivery comprises on average 35 products from 19 manufacturers. Deliveries for 15 pharmacies on average in a van

More than 60 temperature combinations for RX medicines storage conditions in one country.
Different solutions are needed → different types of vehicles are used.
Attempts for a pragmatic, workable approach from our members

Proposed changes in the Austrian Transport Codex because of the GDP

• You have to define under which conditions you allow a deviation from the standard to between 2-30° = „global deviation“
  – E.g. permanent door openings within tours
  – E.g. loading phases
  – E.g. unloading phases
  – E.g. on real unusual hot and cold days
• That means: standard is 15-25° but you are allowed to have some defined risk based deviations within 2-30°
• Temperature control via control samples because of high amount of totes and because temperature within totes is different to temperature within vans
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Shortages of medicinal products
Medicine shortages have various causes

Bottlenecks can occur with all types of medicines. In principle, however, the following applies: the fewer manufacturers there are for a drug, the more vulnerable is the delivery security in the event that one of these manufacturers fails. One of the most important aspects for a sustainable and secure distribution is therefore the maintenance of supplier diversity.

**ECONOMIC**
- Small market size:
  - Low prices
  - Low volumes
- External price referencing
- Tendering
- Delays in payment

**MANUFACTURING**
- Just-in-time supply chain
- Active pharmaceutical ingredient (API) sources/regulation
- (Natural) disasters
- GMP issues

**RISING REGULATORY REQUIREMENTS**
- Regulatory inefficiency
- Desentralised reporting
- PSO + Article 81(2)
EU Supply Chain Round table Views on Shortages

**Key objective:** ensure enforcement of existing regulatory obligations to improve the integrity and transparency of the supply chain and work towards prevention of drug shortages

**Rationale:** regulatory enforcement, improved understanding and management of the supply chain would go a long way in improving access to medicines

**GIRP position:**
- No need for specific EU legislative initiative
- Better reporting of shortages (for whatever reason)
- Better enforcement of existing regulatory obligations (verification at each stage of the supply chain to ensure that medicines are received from and supplied by duly authorized players that fulfil their respective regulatory obligations)
- Greater transparency across the supply chain
- Emergency intervention as last resort to ensure security of supply

**Next steps:**
- Agree a consensus definition among stakeholders
- Develop a EU reporting mechanism involving all supply chain stakeholders
Questions?
Thank you!

European Healthcare Distribution Association

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