Possible Regulations of Supply Modes of OTC Medicines into “PHARMACY ONLY MEDICINES” and “GENERAL SALES MEDICINES”

The Distributors’ View

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# About GIRP

<table>
<thead>
<tr>
<th><strong>750+</strong></th>
<th>safe and efficient supply to more than</th>
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<tbody>
<tr>
<td>pharmaceutical wholesalers</td>
<td>170,000 pharmacies and healthcare professionals</td>
</tr>
<tr>
<td>32 European countries</td>
<td>140,000 employees</td>
</tr>
<tr>
<td>100,000 products</td>
<td>3,500 manufacturers</td>
</tr>
</tbody>
</table>

The premier platform reaching across Europe and beyond with expertise and experience for our partners’ excellence

**quality, integrity, excellence**

GIRP members are trusted supply chain partners

**the vital link in healthcare**
Main points

Channels of OTC sales

GDP requirements for transportation, storage & safety of OTCs

Impact on healthcare costs

Sustainability of medicines distribution
Current channels of OTC sales

Countries where OTC products are sold only in pharmacies:
- Austria
- Belgium
- Cyprus
- Estonia
- Finland
- France
- Germany
- Greece
- Latvia
- Lithuania
- Romania
- Slovakia
- Spain

Countries where OTC products can also be sold outside pharmacies:
- Bulgaria
- Croatia
- Czech Republic
- Denmark
- Hungary
- Ireland
- Italy
- Netherlands
- Poland
- Portugal
- Sweden

1 with some exceptions
Main points

Channels of OTC sales

GDP requirements for transportation, storage & safety of OTCs

Impact on healthcare costs

Sustainability of medicines distribution
Good Distribution Practice ensured by wholesalers

Pharmaceutical full-line wholesalers follow the GDP guidelines, which ensure that the quality of medicinal products (including OTCs) is maintained throughout all stages of the supply chain from the site of manufacturer to the pharmacy or person authorised or entitled to supply medicinal products to the public.

Pharmacies follow good pharmacy practices, which are laid down on national level.
Comparison of GDP versions

Document 94/C 63/03
Published in 1994
4 pages
6 chapters

Document 2013/C 68/01
Published in 2013
14 pages
10 chapters

Old GDP

New GDP
Key new areas in GDP

Chapter 1: Quality Management
- Detailed quality and quality risk management system instead of standard operating procedures
- Corrective and preventive actions (CAPA)
- Change Management

Chapter 2: Personnel
- Responsible Person instead of Management Representative
- Staff trained in GDP
- Procedures for personnel’s’ hygiene

Chapter 3: Premises and equipment
- Broadened control of environmental conditions
- Temperature mapping
- (Electronic) segregation of medicines stock
- Qualification and validation of key equipment & computer systems incl. CAPA

Chapter 4: Documentation
- Extended documentation requirements
- Batch number recording for at least those products carrying safety features
- Version control procedures for documentation

Chapter 5: Operations
- Verify suppliers authorisations and GDP compliance (incl. Brokers)
- Verification that batches are released for sale
- Monitoring of sales patterns and investigation of irregularities
- Exporters need a wholesaling authorisation
- First Expired First out (FEFO) instead of FIFO
Key new areas in GDP

Chapter 6: Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

- 10 days acceptable time limit for returns
- Returns of cold chain products only possible if adequate storage conditions can be demonstrated
- Medicinal products should be unopened

Chapter 7: Contract operations

- Only contract-based outsourcing of activities
- Auditing of contract takers for GDP operations

Chapter 8: Self inspections

- Independent external audit is recommended
- CAPA to be applied for deficiencies

Chapter 9: Transportation

- No difference between “delivery” and “transport”
- Storage conditions = transport conditions as described by the manufacturers or on the outer packaging
- Risk assessments of delivery routes to identify when temperature control is needed
- Dedicated vehicles to be used where possible; procedures to cover use of non-dedicated vehicles
- Maintenance and calibration of temperature equipment
- Temperature excursions should be reported and investigated

Chapter 10: Specific Provisions for Brokers

- Quality management system
- Comply to GDP provisions as far as relevant
Delivery of OTC products... Who? How? Where?

If OTC is NOT delivered by pharmaceutical full-line wholesaler

Who will check:

GDP and safety regulations

Who will guarantee:

Storage and transport conditions

What are the limits concerning the location of OTC sales? Drugstores? Supermarkets? Gas stations? ... What comes next?
Recall of pharmaceutical products

- Pharmaceutical full-line wholesalers have an effective recall system in place in all European countries, to withdraw defective products from the market (class 1-3)
- Rapid alert procedures for emergency recalls
Pharmaceutical wholesalers involved in waste management process from pharmacies

**Waste collection and storage**
- Bulgaria
- Denmark
- France
- Hungary
- Lithuania
- Portugal
- Spain
- Slovenia

**Waste collection**
- Austria
- Greece
- Iceland
- Latvia
- Serbia
- Switzerland

**Not involved**
- Croatia
- Estonia
- Germany
- Italy
- Luxembourg
- Slovakia
- UK

*Pharmaceutical waste is transferred to official disposal company*
Main points

Channels of OTC sales

- GDP requirements for transportation, storage & safety of OTCs
- Impact on healthcare costs
- Sustainability of medicines distribution
Economic evaluation of the range of medicines

<table>
<thead>
<tr>
<th>Product Price</th>
<th>N° of products sold</th>
<th>High volume</th>
<th>Low volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>high price</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>low price</td>
<td>20% of revenue</td>
<td></td>
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- **Attractive Products:**
  - Good coverage of fixed costs
  - High margins
  - High stock rotation
  - Small risk
  - High turnover

- **Unattractive Products:**
  - Small margin
  - Low stock rotation - high risk
  - Small turnover - insufficient coverage of fixed costs

will increase the overall healthcare costs
Sale of other types of products in pharmacies

- Big variations in product types allowed to be sold in pharmacies due to limitations imposed:
  - Only \( \frac{2}{29} \) countries* allow beverages to be sold in pharmacies without restrictions.
  - In only \( \frac{5}{29} \) countries* food can be sold in pharmacies without restrictions.
  - In \( \frac{19}{29} \) countries* the sale of perfumes is allowed without restrictions.
- Restrictions are imposed on all these categories of products and at the same time, OTC products are to be sold outside the pharmacy.

Consequences?
This will endanger the sustainability of medicines supply

*Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK, Norway, Switzerland, Serbia
Impact on pharmaceutical wholesalers

- GIRP members believe that a decision to sell OTC medicines outside of pharmacies could endanger the safe, efficient and continuous supply of medicines to patients.
- In addition to the risk for patients, the sustainability of wholesalers and pharmacies is in danger if OTC medicines are distributed through other channels.
  - OTC medicines are a key element of the product basket that wholesalers and pharmacies distribute.
  - OTC products represent on average 10-15% of the turnover of a pharmaceutical wholesaler.
  - If OTC medicines leave the pharmaceutical channel, medicines availability could be endangered.
  - There may be a need to increase the remuneration for distribution of reimbursed medicines in order to maintain the sustainability of the system.