« View of the pharmaceutical full-line wholesalers »

GIRP – The European Association of Pharmaceutical Full-line Wholesalers

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1. What is pharmaceutical full-line wholesaling?
Pharmaceutical full-line wholesalers...
- handle full range of medicines
  - with recall and emergency procedures
- guarantee continuous availability
  - 24 hours a day, 365 days a year, 2-4 hrs average delivery time
- follow public service obligations
- are the owners of the products they distribute!
What is GIRP?

- Umbrella organisation of European pharmaceutical full-line wholesalers

- The Members* of GIRP
  - employ about **140,000 people**
  - hold products on stock from over **3,500 manufacturers**
  - supply more than **100,000 medicines**
  - distribute medicines throughout the whole continent to more than **133,000 pharmacies**
  - deliver in a timely, safe and efficient way
  - guarantee access to all medicines for patients throughout Europe

Technical Committee

- **Aims:**
  - create a better market position for pharmaceutical wholesalers by applying modern and the most feasible technologies

- **Main issues:**
  - Guidelines of Good Distribution Practice 94/C 63/03
  - Numbering and Labelling Systems

- **Means:**
  - discussion forums
  - position papers

- **Organisation:**
  - several meetings a year
  - “Technical Conference” as open forum approx. once a year
2. What do pharmaceutical full-line wholesalers need?
What we offer – what we need

What we offer:
- apply the most appropriate technologies, in order
- to reach the ultimate aim of delivering
  the right medicines to the right place at the right time!

What we need:
- adopt practical and logical solutions, which means
- to weigh the application of new technologies
  against their benefits in the practical implementation!

Conclusion:

! New Technologies = Advantages + Disadvantages !
Warehousing

- Pharmaceutical full-line wholesalers’ warehouse operations:
  - receiving, un-packing, checking, storing
  - order booking, order picking, checking, invoicing
  - route planning, loading, delivering

- For a better identification and traceability of products, we aim at:
  - harmonising and standardising of product identification for medicines,
  - according to the needs of the supply chain partners,
  - seamlessly using standards throughout the whole supply chain.

- Selection criteria for GIRP
  - safety & reliability
  - maturity & costs

Visit of the Phoenix warehouse on Thursday, 1st February
The plant utilisation of a wholesaler

- Pharmaceutical full-line wholesalers provide the continuous availability of medicines
  - 24 hours a day - 365 days a year
  - European average delivery time 2-4 hours, 4-5 times a day

Example:
- 115,000 pieces per day
- 4 pieces per second*
- 5,000 totes per day

2 hours

46,000 pieces
2,000 totes

46,000 pieces
2,000 totes

2 hours

* Calculated with a working day of 8hrs
3. Where do we stand today?
What GIRP did so far since 2005

- Study “Packaging and Labelling”
  - defined a minimum set of information requirements, necessary to efficiently manage products in the supply chain

- Definition of a “wish list” referring to
  - contents
  - data structure
  - optical carrier

- Analysis of different technologies in order to find out the most feasible
  - OCR vs. bar coding vs. 2D coding vs. RFID
Current situation

- No common technology to read the product information by means of technical equipment
  - No homogeneity (neither from manufacturer to manufacturer, nor from country to country)

- Pharmaceutical full-line wholesalers must have machine readable data in order to track & trace products

- Therefore it is absolutely essential to have
  - National product identification
  - Expiry date AND
  - Batch number

... in a machine readable format!
GIRP'S Technical Committee has examined the different technologies.
# Automatic product identification (II)

## Review of possible data carriers

With respect to the content which is required: **product ID, batch number and expiry date**

<table>
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<tr>
<th>Content</th>
<th>Space</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>X 1D-Code</td>
<td>either not complete or too big</td>
<td></td>
</tr>
<tr>
<td>✓ 2D-Code</td>
<td>complete</td>
<td>OK</td>
</tr>
<tr>
<td>X RFID</td>
<td>complete</td>
<td>?</td>
</tr>
</tbody>
</table>

- Additional information for the industry can be saved.
- Not yet a mature technology.
Automatic product identification (III)

Having assessed the impact of all technologies, GIRP and its members want to implement

- as data structure: GS1 numbering system and
- as data carrier: 1D or 2D code

  - data matrix code is preferred, as it allows for further content expansion and it may cover additional needs of manufacturers,
  - whereas RFID is a future technology only.

**GIRP and its Members want to remain as up to date as possible, which involves finding a balance between advancing technologies and practical solutions!**
Automatic product identification (IV)

Benefits of the GS1 numbering system for the whole supply chain of medicines in the sense of a co-existing model:

- **GS1 Application Identifiers** (standardised data elements):
  - GLN (Global Location Number)
  - GTIN (Global Trade Item Number)
  - Batch number
  - Expiry date

- **GS1 change request**
  - Pharmaceutical article number (international level)
    - ISO country code
    - Pharmaceutical article number (9 digits, national level)
4. Excursus: Problems of RFID and Serial number
Problems with RFID tags

- **Overall:**
  - data protection not readily discussed

- **High Frequency (13.56 MHz):**
  - accuracy of reading not given: no mature technology
    - liquids, aluminium and glass will lead to error rates > 30%

- **Ultra High Frequency (2.45 GHz):**
  - accuracy of reading is improved, however:
    - no norm up to day
    - higher costs of multi-read-tags
    - possible harms to the molecular structure of medicines
Problems with the Serial number

Problems with respect to the exclusive use of a serial number:

– missing data – which are needed on an ad-hoc basis, e.g.
  - identification
  - batch number
  - expiry date

– data would come from a database, but there are many unsolved questions:
  - Who is in charge of the database?
  - Who owns the data?
  - Who pays for the costs of the database?
  - Who organises the data transfer?
  - Who is guaranteeing the continuous availability and performance within the supply chain?
Conclusion (I)

- Always take into account criteria such as
  - maturity degree
  - costs as well as
  - safety and reliability of the technology.
- Solutions must be suitable for the pharmaceutical supply chain
  - smooth integration of national product identification, expiry date and batch number
  - speed of delivery
  - European wide technological harmonisation and
  - competitive costs of implementation

*Delivering right medicines at the right time to the right place = need to apply best technological processes!*
Conclusion (II)

Every decision in order to be effective must comprise ALL partners in the Supply Chain!
Thank you very much for your attention!

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