

Improving Patients' Safety Using Machine Readable Codes for Product Identification GIRP Position Paper

1. Introduction

GIRP, "Groupement International de la Répartition Pharmaceutique Européenne", is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. Founded in 1960, GIRP represents the national associations of over 600 pharmaceutical full-line wholesalers serving 31 European countries, including major pan-European pharmaceutical wholesaling companies. GIRP members employ about 140.000 people and distribute medicines with an annual value of around 100 billion Euro.

GIRP members carry the full range of medicines and are the vital link in healthcare towards European citizens, as GIRP members ensure the continuous product availability to patients within a matter of hours, while maintaining quality standards that guarantee the safety and integrity of medicines. Pharmaceutical full-line wholesalers have the most complex distribution channels in the world as they are responsible for the distribution of over 100.000 products to about 160.000 pharmacies throughout Europe. Each GIRP member has a network of warehouses providing several daily and overnight deliveries to hospitals and retail pharmacies. GIRP members employ state-of-the-art information technology and physical infrastructure to undertake these services with a high level of intensity, sophistication, quality and efficiency.

As the greatest concern of GIRP members is to protect patients' health by the safety of the medicines handled throughout Europe, this paper outlines the possibilities as well as the technological requirements and constraints for pharmaceutical wholesalers to adopt product identification mechanisms. With respect to safeguarding the health of patients throughout Europe, some national governments of the European Union's Member States reflect upon adopting technical measures to secure the supply of medicines.

2. The current situation

Following the strict legal requirements of the Community Code 2001/83/EC relating to medicinal products for human use, as amended by Directive 2004/27/EC, and the Guidelines of Good Distribution Practices 94/C 63/03, and in light of the European Commission's 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, pharmaceutical full-line wholesalers operate quality systems which ensure proper storage conditions of medicinal products and the safe and secure distribution of medicines within the pharmaceutical supply chain. Additionally, these quality systems guarantee that the right products are delivered to the right addressee in a safe, efficient and

continuous manner. However, today there is no uniform approach on how to identify the flow of medicines throughout Europe, due to the lack of a harmonised product codification system & machine readable information on the medicines implemented throughout the EU Member States. Today pharmaceutical wholesalers are unable to operate fully automated reading systems to control the products' flow, which are a pre-requisite to maintain the delivery frequency and to supply medicines in a timely manner.

Some Member States have already put or have reflected to put a respective legislation in place. Hence it is crucial to consider all elements a legislative approach has to comprise, for providing all necessary information to the supply chain partners in order to set up the coding and subsequent identification of products, as well as to avoid unnecessary delays in the delivery of medicines.

3. Delivery times

The enormous and very complex throughput in wholesalers' warehouses (commissioning of around 12 packs per second in peak times with an average order fulfilment time of less than an hour) requires a high speed of action with respect to the delivery of products. Wholesalers fear a dramatic decrease in the speed of commissioning and delivery in the warehouse, which would be related to the reading of every single package throughout the goods flow. This means that with the current technologies, wholesalers are still facing the unresolved issue of having to read every single pack code, before the product is distributed. GIRP strongly encourages all involved actors to join pharmaceutical full-line wholesalers in their efforts to find technological solutions for maintaining the speed in the delivery of medicines, in order to guarantee the continuous and timely delivery of medicines.

4. Information requirements of pharmaceutical wholesalers

The key objective for pharmaceutical full-line wholesalers is to have harmonised, machine readable data on every pack of medicine. These harmonised, machine readable data are essential to automatically and securely capture the relevant product information within the workflow in the warehouse.

Pharmaceutical full-line wholesalers require the

- national product identification number,
- serial number (if required),
- expiry date and
- batch number

in a machine readable format on every pack of every medicine as a pre-requisite for product identification. This is a necessity for any technical solution, which must be the result of close collaboration between all partners of the pharmaceutical supply chain.

5. The approach towards a solution

The basic requirements for an efficient product identification system within the pharmaceutical supply chain are, amongst others, all-embracing and standardised infrastructure and communication systems. In order to safeguard public health, it is essential to find a common solution on standards in agreement with all partners of the supply chain. Therefore, GIRP strongly advocates a solution, which is applied by all partners in the pharmaceutical supply chain. GIRP thereby emphasises that a functioning and workable system can only be developed in close collaboration with all supply chain partners! Standardisation and automation aligning all supply chain parties will increase patients' safety and data accuracy. It is very important that all data on product identification are kept available throughout the whole pharmaceutical supply chain. For all supply chain partners it is of paramount importance to be able to immediately access at all times all relevant product information (expiry date, batch number, national identification number and the serial number if required), which therefore must be available on the package itself. The necessary data for product identification needs to be processed and stored in a way that every wholesaler is in a position to identify the medicines going through its warehouse.

6. Technological solutions

The technologies currently on the market enable wholesalers to differentiate between:

- the data structure and
- the carrier of the data.

The data carrier could be a 1 Dimension or 2 Dimension code. However, in respect to the carrier, GIRP would like to stress that there are label technologies which wholesalers cannot readily use (which includes Code 13) and which therefore should be excluded from reflections on a harmonised European solution.

In the future, Radio Frequency Identification technology and its tags as carriers, may allow wholesalers to automatically identify products. However, even though RFID could bring significant advantages to the identification of medicines in the future, it has presently proved not to be a technology mature enough to be embraced on the short run. Due to possible improvements of the technology, GIRP considers RFID to be a solution for the future.

GIRP believes that for the present the best possible choice with regards to code labelling is:

- 2D which allows content expansion on smaller space and may also cover additional information needs of manufacturers.

GIRP supports any initiative on coding and identification of pharmaceutical products which consists of the harmonisation of pharmaceutical products' codification throughout Europe as well as harmonised coding systems on secondary packaging of all products sold in Europe including product code, national identification number, batch number, expiry date & serial number (if required) and the verification of pharmaceutical products at their point of dispensing. However GIRP would like to stress the importance of the wholesaling sector being fully involved in the development of a harmonised coding system, the data base structure and its accessibility and security as well as in the identification process itself. Wholesalers need to be able to verify products in the forwards logistics in case of doubts and in backwards logistics for the returns from pharmacies, enabling the verification of returns and recalled products.



the vital link in healthcare

7. Conclusion

A decision for the adoption of product identification technology of medicines throughout the supply chain must take into account criteria such as the maturity degree, costs as well as aspects such as safety and reliability of the technology. The members of GIRP require a solution which is suitable for the pharmaceutical supply chain, allowing:

- smooth integration of national product identification, serial number (if applicable), expiry date, batch number
- speed of delivery
- European wide technological harmonisation and
- low costs of implementation in order to not increase distribution costs

GIRP faces the need to adopt practical and logical solutions to reach the ultimate aim of delivering the right medicines at the right time to the right place and the need of applying best technological processes in an ever evolving pharmaceutical environment. GIRP and its members are fully committed to actively contribute to any initiative, which furthers coding and identification of medicines and involves all stakeholders. The members of GIRP will embrace new technological solutions as soon as they are workable and economically viable.

GIRP

*The European Association of Pharmaceutical Full-line Wholesalers
Brussels, January 2010*