

Pharmaceutical barcodes: the need for legislation

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Resources

GIRP (European Association of Pharmaceutical Full-Line Wholesalers)
W:girp.org

European Healthcare Initiative
W:www.ean-health.net

Press releases on single-dose labelling can be found at:
W:www.ean-health.net

There is a real need for harmonisation of the barcoding systems within the EU, and national systems should evolve toward an open standard, the EAN.UCC, Christian Hay advocates ...

The reasons why the European pharmaceutical market is fragmented into national markets include the diversity of languages spoken, cultural differences in the views on medication and reimbursement (or pricing) aspects. Because of this fragmentation and the history of pharmaceutical markets, governments have different attitudes towards the pharmaceutical market. Harmonisation within the EU mostly focuses on the way manufacturers are allowed to market the drugs they produce.¹ However, national authorities still have a certain level of independence in their management of the pharmaceutical market, such as considering its costs and risks for public health.

European harmonisation also addresses the wholesale market; wholesalers have to fulfil a certain number of requirements (Article 76 ff), including product traceability. Member States also have some independence in their legislative processes to achieve these requirements. At this stage, it is important to state that traceability can be achieved only if accurate product identification is available. It is therefore of interest to detail first how the problem of the identification of pharmaceuticals can be solved.

The development of fraud and counterfeiting has led several health authorities to adopt rules protecting their national health system and public health (it is estimated that the illegal drug market in Europe covers between 6% and 8% of the total market). This constitutes the third level of intervention that can impact on "pharmaceutical barcoding".

In this article, some characteristic trends to address these three objectives will be presented and an appeal to European-wide action for the benefit of health systems and patients will be made.

Identification of pharmaceuticals

Pharmaceuticals are commonly marketed according to appropriate authorisation from a national authority. This national authority adopts a rule forcing pharmaceutical manufacturers to print all compulsory information, including the administrative autho-

risation number, on packages. This is the case in countries such as Switzerland and France. In the former country, Swissmedic delivers an eight-digit registration number, which will then be embedded in an EAN.UCC barcode in accordance with the private foundation Refdata. In the latter country, the registration authority (AFSSAPS, or Agence Française de Sécurité Sanitaire des Produits de Santé) has passed an agreement with a private organisation, the Club Inter-Pharmaceutique (CIP), which ensures that manufacturers print the administrative number in a specific barcode. However, the Swiss market uses an international identification system (EAN.UCC), whereas the French one uses a national system. Recognising that national systems are not appropriate in an open market, CIP is implementing changes so that the barcode system can evolve towards the international standard.

Some countries, such as Greece, Italy and Belgium, have adopted laws to secure the identification of pharmaceutical products. In Italy and Belgium, in particular, the governments have adopted a law stating that, for a pharmaceutical product to be marketed, the details of the barcode (symbology and content) must be printed on the product itself.

In countries such as Ireland and the UK, it is the manufacturers who need to find an appropriate way to identify pharmaceutical products (most drugs carry an EAN.UCC identification).

Traceability of pharmaceuticals

Traceability is one of the Good Manufacturing Practices (GMP) promulgated by the US FDA; this means that manufacturers have to trace their products from source to first delivery (wholesaler or hospital). To achieve this, manufacturers have developed solutions that are highly effective, provided that the products are in their own "sphere of influence". Thus, in addition to their identification number, products have to carry a lot number and an expiry date.

Traceability is also part of the Good Distribution Practices (GDP), which wholesalers have to respect.

There is, as far as we are aware, no imposed solution (such as the use of a specific barcode) to achieve this. This means that international wholesalers have to adapt their procedures to national specifications and to the information available from the suppliers. A recent survey from the GIRP (see Resources) demonstrates that it is currently almost impossible to enhance the level of traceability at the wholesaler level, because boxes are not labelled in a standardised way – the survey shows wide variability in the information reported, and, when barcodes are available, symbology and data content are not appropriate for data management. Wholesalers are currently trying to register manually the information that is required to secure the traceability of incoming deliveries. Many hospitals do not have the necessary resources to capture systematically the data for full traceability and, therefore, have to limit their registries to the most “sensitive” drugs.

The traceability of pharmaceuticals – from manufacturer to patient – is not yet achieved. In Ireland, the Ministry of Health will launch in April 2004 a project to secure the traceability of factor concentrates for haemophilia patients by using the international standard EAN.UCC. This project may be extended to other countries or to other areas of the market, such as vaccines, for which the need for traceability is crucial and cannot be solved with the manually processed documents currently available.

Serialisation

The development of fraud and counterfeiting in the drug market has been an incentive for some governments, such as the Italian² and Belgian³ governments, to adopt regulations forcing manufacturers to allocate a precise serial number to any unit-of-sales of a given drug. In addition to the existing regulation to identify drugs, these two governments have developed a national system that consists of allocating a unique number (or serial number) to each unit-of-sales. The Italian and the Belgian approaches are different from each other. In Italy, identification and serial numbers are labelled with two different symbologies (code 39 for identification, code interleave 2/5 for the serial number), and the serial number has to be stored in a central database, currently in development. In Belgium, the identification and serial numbers are concatenated in a single barcode (code 128). These two examples illustrate the difficulties encountered for international pharmaceutical trade in Europe.

Barcoding of single doses

At the end of February 2004, and after months of consultations, the FDA released a rule for the labelling of pharmaceuticals and biological products

at the single-dose level with a linear barcode. Major pharmaceutical manufacturers have already begun to label their units of use with the EAN.UCC new symbology, the “Reduced Space Symbology”. In addition, some manufacturers have published press releases explaining that their efforts in barcoding with international standards benefit the patient’s safety. Others are currently adapting their manufacturing processes to deliver products with the appropriate labelling as soon as possible.

The FDA focuses on enhancing drug identification to reduce medication errors, and manufacturers can integrate lot number and expiry date into the product identification. By doing this, manufacturers allow hospitals to implement and store detailed information about medication in the electronic patient file by scanning a single label. All manufacturers recently contacted have chosen to label drug identification as well as lot number and expiry date (see Resources). This will benefit the patient both in the hospital environment and when receiving vaccines or other “sensitive” medications from a practitioner.

A pan-European solution is required

Although the political trend is to promote the free movement of goods across the EU, the European pharmaceutical market still has strong national components. National systems to identify marketed drugs at each package level need to evolve towards an open standard, the EAN.UCC system, because of its efficiency and large-scale use.

The EAN.UCC system, which is managed by not-for-profit organisations in each European country that implements it, has been in place for more than 20 years and has demonstrated its efficiency by expanding outside Europe. Its large-scale use is important for hospitals, as these are real “hubs”, receiving deliveries from an incredible variety of suppliers, most of whom are familiar with the EAN.UCC system.

A second argument in favour of the EAN.UCC system is that it includes concepts and solutions to identify drugs at each package level (from pallet to single dose), as well other tools that contribute to a better supply chain and logistics, such as electronic message structure for ordering or catalogues.

Representatives of full-line wholesalers, manufacturers, hospitals and retail pharmacists have started a joint initiative with EAN International and its European Healthcare Initiative (see Resources) to develop and implement tools to enhance the supply chain at the European level. The appropriate legal frame exists in most countries; in countries that have implemented a national system, intensive information has to be provided to give them an incentive to join the EAN.UCC system. ■

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