



EUROPEAN FEDERATION
OF PHARMACEUTICAL
INDUSTRIES AND ASSOCIATIONS
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POSITION PAPER

IDENTIFICATION AND CODING OF PHARMACEUTICAL PRODUCTS IN EUROPE

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 30 national associations and 44 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,100 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

Introduction

The pharmaceutical supply chain in Europe is complex, with millions of medicine packs moving around the EU each year. Its fragmentation as well as the overwhelming growth of wholesaler intermediaries and traders involved in the European flow of medicines are resulting on a decrease of transparency of the supply chain, and an increase in the difficulties to track and trace medicines. Furthermore, the growing problem of counterfeiting, particularly in some third markets, raises a significant threat within the current supply chain system.

The standardised and unique coding of medicines can lead to opportunities to improve patient safety and enhance the security and efficiency of the medicines supply chain, with better traceability of medicines in Europe and worldwide.

Instead, the integrity of the medicines supply chain is continuing to fracture, with different coding solutions implemented in different Member States, each with its own objectives and motivation (see attachment). Opportunities to improve patient safety at a European level and enhance the control of the supply chain are being lost, while the multiplication of systems adds incremental production costs for manufacturing and increase further both the complexity and differentiation across the European market.

Towards a European/global solution

Against this background, EFPIA has carefully assessed the current solutions being implemented in Europe and the possibility of harmonising the system at the European level, taking into account several objectives and principles including:

- Primary needs (e.g. patients, authorities, stakeholders) have to be clearly identified
- Any solution has to be workable and easy to implement in order to be effective (i.e. a code system, could be effective but it might be too costly or too sophisticated and therefore impossible to implement)
- Any solution has to be applicable at both European and global level
- Short/medium term solutions should focus on technology currently available

Further to this assessment **EFPIA has concluded that for the time being, a standardised coding of medicines could offer a more secure, effective and efficient supply chain, with a better control on the medicine's location. This would ensure patient safety benefits and cost savings:**

1. By providing greater security in the supply chain, including:
Greater protection against fraud and counterfeits entering the legitimate supply chain.
2. By reducing medication errors (certification of product). Evidence also suggests coding could lead to an enhancement in compliance of tracking and the ability to alert possible interactions.

What technology to opt for?

From all possible technologies, RFID is one of the options that could better respond to the needs identified by the industry, while offering also some flexibility to adapt to future developments and needs. However, experience within the pharmaceutical industry (pilot projects) and other sectors show that the technology is not mature enough and is not able to meet all expectations of the industry for the time being. According to experts, it may not be fully available for at least another 10 years. Furthermore, the high costs associated with this technology make it difficult for it to implement by all stakeholders.

Any technology used with medicines has to be fully reliable and applicable. EFPIA has therefore identified other solutions that could help to improve the coding of medicines, such as:

- EAN 13: Can identify name, company and country
- EAN 128: Can identify name, company, country and around 10 more parameters. The main problem is that it takes a lot of space in the package
- 2D (i.e. Data matrix): Can cover multiple information and does not take almost any space in the package

The following table summarises how the technologies available would respond to needs identified:

	Info required	How identify/ comments	2D	Barcode EAN 128	One Barcode EAN 13
Reimbursement Fraud	Unique Product Serial Number	Database (DB)	Yes	Yes	No
Patient Safety					
(I) Counterfeit	Batch identification or Serial Number	Connect to DB and pharmacy/dispensing check	Yes	Yes	No
(II) Authentication	Batch identification or Serial Number	Connect to DB and pharmacy/dispensing check	Yes	Yes	No
(III) Track and trade all the supply chain	Batch identification at minimum	Link to other DB	Yes	Yes	No
Lot number			Yes	Yes or in DB	No
Expiry			Yes	Yes or in DB	No
Automation			Yes	Yes	Yes
Size and application			Smaller size for equivalent info	Same size (EAN 13) if use DB. Larger if all data on barcode	Yes
Label supplied by Government			Same	Same	
Pre-print			No	No	Yes

Following this assessment, EAN 128 and 2D seem to be the best options available in order to cover current needs. While costs of applying a new technology are significant, advantages indicated above are important mainly for patients, but also for the authorities and the industry.

Recommendations and proposals for implementing a unique authentication technology at EU level

1. Any change in the coding technology should be affordable to acquire as well as to put into place, and should lead to an improvement of the current situation. While

EAN 13 seems to be the cheapest option, it does not provide a solution to the main needs identified and is therefore not a good option for the future.

2. Both EAN 128 and 2D respond well to needs identified. While 2D is slightly more expensive, it provides significant advantages as it can include more information in a smaller area and provides more flexibility to incorporate future needs.
3. **EFPIA therefore recommends a 2D (2 Dimension Data Matrix) Bar Code system** to be introduced across Europe. This mechanism would include the use of unique serialisation numbers for each secondary packaging unit distributed and sold across Europe. It would enable the identification and verification across the entire supply chain, therefore improving transparency and patient safety, and helping fight serious problems like counterfeiting.
4. The new system can be adopted progressively (e.g. first at a batch level, secondly, at a product level) without requiring a radical change of all European coding systems, but leading to a smooth and progressive harmonisation of the technologies used in Europe and worldwide.
5. **The adoption of a 2D system does not prevent the adoption of an RFID system at a latter stage nor does it represent a double cost. Experience has shown that RFID technology is not workable at present but would certainly be a natural progression of the system.**
6. EFPIA wishes to address this issue urgently in order to prevent the continued fragmentation of coding standards across the EU, the fracturing of the supply chain, and in order to realise the patient safety benefits. With respect to lines of action, EFPIA will:
 - Engage with current European initiatives to put across a common Industry standard;
 - Promote the recommended system towards relevant EU bodies;
 - Work to highlight compliance and patient safety issues associated with lack of adoption of the recommended system.

EFPIA
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Attachment

EU Coding Initiatives Snapshot:

Italy – the Pharmaceutical Industry has to buy the peelable labels (bollini) for all products (OTC included) from the Italian Government (Poligrafico dello Stato). The manufacturers have to stick the labels on each sales pack and each label reports two bar-codes: the former incorporates the Italian product licence number, the latter the sequential number. This second code is primarily intended to prevent reimbursement fraud. The intention is that in the future the manufacturer and all distributors (wholesalers, pharmacists, hospitals, etc.) will be connected with a central data bank and each of them shall record and pass on the sequential number of all packs dispatched for a full tracking of all products placed on the market.

As far as the List A products (reimbursed by NHS) are concerned, the pharmacists shall take the top part of the peelable labels off, stick it onto the prescription and send the prescription to NHS.

The Ministerial Decree published on January 4th 2005, and enforced on January 19th 2005, provides for obligation to gather data, concerning handling medicines, and to pass them on to a central Data Bank (at AIFA level). Different steps for implementing the system have been planned, although there are still several unsolved technical problems.

Belgium - has sequentially numbered labels that must be applied to each medicine pack. The code uses EAN-128, and contains the licensing number for the product and a random sequential number. The manufacturer must buy the non-peelable labels from a printer, stick onto each sales pack, and tell the Government the range of numbers used.

France – Two bar codes must be applied on each medicine pack:

- The first one is a code 3/9 which contains the product's marketing authorisation number ("CIP code" with 7 numbers)
- The second one is a code 128, pre-printed on the vignette sticker used for reimbursement. This code of 14 numeric characters contains notably the marketing authorisation number, the reimbursement rate and the price

The AFSSAPS (the French Health Products Safety Agency) has decided to modify the coding system of pharmaceutical products, as part of the strengthening of the regulation on traceability of pharmaceutical products.

A new regulatory disposal will set a systematic marking of the batch number on pharmaceutical products. The barcodes used with EAN data structure should allow a total traceability of pharmaceutical products through each pharmaceutical operation. The technology chosen to include the batch number and the expiry date is Data Matrix.

Portugal – the bar codes are pre-printed on the Carton, using Code 39.

Spain – Codes are pre-printed on the carton on a perforated panel, which can then be pushed out and used for reimbursement purposes.

The Netherlands – Currently using HIBC code, but moving towards EAN

Greece and Germany – currently discussing what coding types to apply.