Impact on wholesalers

Introduction

With the adoption of the European Falsified Medicines Directive, the pharmaceutical sector is at a critical point in the development of coding and serialisation systems in Europe. While the main force of the Directive is very much welcomed by GIRP, the umbrella organisation of pharmaceutical full-line wholesalers in Europe, some aspects of the brand new legislation need to be defined further as they present significant concerns to the sector and could have an adverse impact on the current speed of delivery of medicines to Europe's pharmacies.

Harmonised pan-European safety features

The Directive on Falsified Medicines introduces mandatory, harmonised pan-European safety features in the form of tamper evident packaging and a unique identifier to be applied to all prescription medicines, subject to possible exclusions based on a risk assessment.

The European Commission is tasked with defining, in Delegated Acts, the mechanics of how this system will work. First consultations are expected to be launched at the beginning of 2012 with adoption scheduled for 2014. The Delegated Acts will define the characteristics and technical specifications of the "unique identifier" allowing identification of individual packs, and the accessibility of national product databases or repositories that allow verification of each dispensed pack.

GIRP believes that the information content as well as the data carrier needs to be harmonised at European level. In the light of the very limited space on a one dimensional code and the high costs and relatively low reliability of RFID tags on medicinal products, GIRP opts for the adoption of a 2 dimensional matrix code which as a minimum includes the national identification number, the batch number and the expiry date in addition to the randomised serial number.

In partnership with other pharmaceutical supply chain stakeholder organisations – the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Group of the European Union (PGEU), GIRP is working to jointly promote the development of an efficient, workable and cost effective product verification system that is to be run by stakeholder organisations on a non-profit basis.

The system proposed by the stakeholders is composed of a European central hub connected to a series of national or regional data repositories that serve as the verification platforms which pharmacies and other registered users including an interface for wholesale distributors to check a product's authenticity.

Impact for wholesale distributor

The new Directive insists, "wholesale distributors must verify that the products (**Figure 1**) they have received are not falsified by checking the safety features on the outer packaging". Whereas the detailed procedure on how this requirement should be fulfilled in practice will only be covered in the "Delegated Acts" it causes a lot of concern as it can potentially have major negative implications, not only for wholesale distributors but also for manufacturers, pharmacies and patients. If significant individual pack scanning is involved it presents major practical and costly challenges to the smooth operation of the distribution chain and will severely impact the speed of delivery of vital medicinal products to pharmacies and ultimately to patients. Today, the average European delivery time is 2-4 hours and we do not think it is necessary to let patients wait longer through unnecessary procedures.

For this reason GIRP urges the European Commission when drafting the Delegated Acts to take account of the need for proportionate, pragmatic and workable solutions for all stakeholders concerned. In particular, rather than a systematic process of checking all medicinal products received by wholesale distributors, GIRP proposes the 'selective, risk based' verification of the authenticity of medicines in forwards logistics. This would be the case for medicinal products obtained by wholesale distributors from sources other than the marketing authorisation holder or a person who is authorised by the marketing authorisation holder to supply these products. Concerning backwards logistics wholesale distributors should verify the authenticity of all returned medicines before putting them back to saleable stock.

GIRP strongly believes that a point of dispense verification system with a wholesalers interface to verify the authenticity of medicines in case of doubt is the most efficient and cost effective way to protect patients from receiving falsified medicinal products. It is also the most proportionate solution for meeting the requirements of the Directive as it does not compromise the delivery process of medicinal products and most importantly it ensures that patients can trust that they receive only genuine products through the legal supply chain.

Ongoing and next steps

A stakeholder-developed proposal for complying with the terms of the Directive by a result orientated process should

be welcomed by the European Commission. GIRP together with its stakeholder partners will propose to the European Commission a system that ensures verification of product authenticity by professionals at the point of dispense and provide a modern technology solution that will ensure patient safety.

To this effect 10 key principles have been developed between the stakeholder associations and we are currently working on getting all involved stakeholders on board as well as on conceptualising the framework for the stakeholder led organisation for governing the proposed system.

Ten core principles to protect patients from falsified medicines.

EFPIA/PGEU/GIRP Joint Position Paper, March 2011.

1. Combining tamper-evident packaging with a unique serial number:

- EFPIA, PGEU and GIRP support the requirement in the falsified medicines directive that the safety features should consist of a unique serial number placed on each pack together with packaging that would reveal if a pack has been opened or tampered with.
- Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispensing is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system.
- EFPIA and PGEU consider that safety features should be applied to all prescription medicines to ensure the same level of security. Therefore if a risk-based approach for prescription medicines is pursued, exemptions should be based on therapeutic categories, narrowly defined (e.g. ATC 4 level), rather than individual products to minimise the risk to patient safety.

2. Guaranteeing continuity of protection throughout the entire supply chain:

- As regards the obligations on the repackager to replace mandatory safety features, the original pack serial number should be cancelled in the database by the repackager and a new number provided. The original and new numbers must be linked in the database to enable the product to be tracked in case of recalls or other safety issues.

3. Ensuring a single coding and identification system on each pack across the EU:

- Given the movement of medicines across national borders, any effective coding and identification system must be able to exchange information between Member States. There should therefore be a harmonised standard coding system across the EU.
- In order to ensure that the coding system facilitates other functionalities such as reimbursement, the EU harmonised standards should allow for the incorporation of relevant national codes.
- EFPIA and GIRP propose using a two-dimensional code12 containing a unique serial number to encode all selected products. This code can be verified against a database. This means that pharmacists can rapidly verify the status of each pack before dispensing it to the patient. As well as the serial number, the code would store the expiry date along with product identification (including national code) and batch numbers, providing additional patient safety enhancements.

4. Ensuring product verification database systems can work together across the EU:

- In addition to using a common standard for pack identification in Europe, all national database systems must also be able to work together and exchange information in order to allow any pharmacist, and wholesaler where deemed necessary, in any Member State to check whether the pack has been dispensed before, irrespective of its country of origin.
- There should be sufficient flexibility to implement national or regional solutions within an overall EU technical framework.
- National database systems should meet equivalent quality assurance requirements.
- Without this interoperability, counterfeiters would be able to exploit gaps between national systems to insert falsified medicines into the legitimate supply chain.

5. Verifying every serialised pack at pharmacy level:

- It is everyone's responsibility in the supply chain to ensure that medicines delivered to patients are safe and genuine.
- Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust and cost-effective way to improve patient protection.
- However, unless every individual serialised pack is verified at the point of dispensing, patients will not

benefit fully from the safety features. The unique serial number can only provide protection against counterfeits if it is routinely checked against a central database and the status changed on the database to 'dispensed' when the product is handed to the patient.

- Systems should be configured so that pharmacists can undertake checks when medicines enter pharmacy stock, as well as at point of dispensing. Since the technical challenges of point of dispensing verification vary across the EU, pharmacists may initially adopt a system of verification when medicines enter the pharmacy, until such time as any technical issues with regard to point of dispensing verification have been resolved.
- The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and the avoidance of delays. In order to ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software. The process of verification at the wholesale level should allow products to be checked during forward logistics as well as for returning medicines and without changing the status on the database.
- Stakeholders shall work together to define standard procedures for exceptional events such as verification failure, system failure etc.

6. Maximising all the potential benefits of mass serialisation:

- Using mass serialisation provides benefits over and above improved counterfeiting prevention. Maximising these should help to encourage widespread use of identification systems and assist all stakeholders.
  1 Data matrix ECC 200
  2 PGEU does not endorse a particular technology at this stage
- The coding system enables the pharmacist to automatically read the batch number, serial number and expiry date, significantly enhancing patient safety and improving product recall procedures.
- The system may also facilitate the provision of additional services to patients by pharmacists.

7. Focusing on securing patient safety and protecting patient privacy:

- Verification systems are for preventing counterfeits, not for accessing individual pharmacy data.
- Manufacturers do not seek, and will not have access to, individual patient/prescribing profile information.
- Transactional data belongs to the pharmacist, or in relation to wholesaler verification, to the wholesaler. However, relevant stakeholders will need to see certain data to help investigate when there is a verification failure, a product recall or a level of unusual activity related to a specific serial number, in accordance with national circumstances.
- Any additional use of transactional data would need to be agreed between the stakeholders in accordance with national circumstances.

8. Using safety features that are simple, robust and cost-effective:

- The product verification solution proposed should meet the criteria of being practical, affordable and accessible. Unnecessarily complex and costly solutions should be avoided.

9. Working Together in the Interests of Patient Safety:

- As key stakeholders in the verification process, we are committed to working together to establish an efficient, viable and effective system to protect patients against the threat of counterfeit medicines.
- The establishment and management of product verification systems should be undertaken by relevant stakeholders. For the governance of product verification systems, EFPIA, PGEU and GIRP favour the setting up of independent non-profit organisations to be jointly managed by relevant stakeholders, building on the current coding environment in the various countries and meeting the needs of patients and all players in the supply chain.
- Each stakeholder will be severally responsible for the system.

10. Involving other stakeholders

- EFPIA, PGEU and GIRP welcome the involvement of other relevant stakeholder organisations which play an active role in the pharmaceutical supply chain in the further elaboration of the product verification system at point of dispensing. Together we can ensure a strong and comprehensive system to take forward the fight against counterfeiters.

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