27 April 2012

European wholesalers set out their demands on anti-counterfeiting

BRUSSELS, April 27 (APM) - The European association of pharmaceutical full-line wholesalers, GIRP, has made clear its own priorities on the way the European Union's new anti-counterfeiting measures should work.

GIRP is part of the consortium with manufacturers, pharmacists and parallel importers that is setting up what is known as "the European Stakeholder Model", their preferred solution to meeting the requirements under the recently adopted Falsified Medicines Directive.

But it has particular demands of its own over the way the new system should work, which it outlined in a statement on Friday.

In particular, it wants the unique identifier for medicines subject to the new rules to be coded in such as to allow for wholesaler verification in an efficient fashion.

MACHINE READABLE DATA

In its reply to a consultation by the European Commission, GIRP insists that the code structure should include the batch number and expiry date in a machine-readable format on each pack of medicines requiring the safety features.

If this information was not machine-readable, wholesalers could not meet their obligations under the directive to record the batch number of each product supplied, GIRP points out in the paper it submitted to the commission today.

The wholesalers support systematic verification at the point of dispensing. This, they say, is the most cost-effective and proportionate approach to achieving safety in the supply chain and for patients.

However, they also favour backing this up with random checks at the level of the wholesale distributor using risk-based determinants.

This, they say, will provide an additional layer of security - although GIRP recognises that this could cost the wholesale distribution sector alone around 36 million euros.

But the alternative suggested by the commission - of wholesale distributors systematically scanning all medicines carrying safety features - would be even more expensive. Such an approach would cost the wholesale distribution sector 636 million euros, GIRP estimates.

The GIRP position underlines that "the current remuneration mechanisms for wholesale distributors are very tightly squeezed" - to such an extent that universal verification would make wholesaling unviable in some European countries.

Its members distribute 75% of all medicines dispensed by pharmacies, hospitals and other authorised points of dispensing (with the remaining 25% largely going through direct sales by manufacturers). This throughput "represents huge volumes of medicines", it points out.

COMMON VIEWS

In other respects, GIRP fully supports the joint submission by of the European Federation of Pharmaceutical Industries and Associations, the Pharmaceutical Group of the European Union, and the European Association of Euro Pharmaceutical Companies, the current backers of the European Stakeholder Model.

The commission has been seeking views on the secondary legislation (known in EU jargon as 'delegated acts') that it must adopt to put the falsified medicines rules into effect.

The European Stakeholder Model is intended to lay the foundation for the development of a harmonised system across the EU, as well as Norway, Iceland and Liechtenstein, based on international standards that provide a high level of security for patients while being cost-effective and capable of being integrated in existing structures across the supply chain.

The lead organisations in the project met in Budapest on April 27 with national manufactures, parallel traders, wholesale distributors, pharmacists and authorities, for discussions on how their planned European system could mesh with national approaches.

What is planned is an end-to-end, point-of-dispensing coding and serialisation system, which allows pharmacists and other dispensing professionals to check a unique identification code on each individual pack when it is dispensed to the patient.

The codes are generated and applied by manufacturers using a data matrix barcode, which contains a unique serial number (and - as GIRP is insisting - the batch number and expiry date).

The system is designed with a European hub connected to a series of national or regional data repositories that serve as the verification platforms that pharmacies and other authorised parties can use to check a product's authenticity.

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[28994] 27/04/2012 14:09 GMT