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## **EU wholesalers, pharma and pharmacists still concerned over plans to secure supply chain**

by Nick Smith

TALLINN, June 8 (APM) - European wholesalers' body, GIRP, has warned it is impossible for its members to check every individual pack of medicines for authenticity as part of Europe's plans to protect patients from counterfeit drugs.

Although the European Union in theory finalised its counterfeit medicines legislation in May (APMHE 23724), even then pharmacists, wholesalers and pharma raised concerns about the lack of detail and closer examination has not reduced this fear, it emerged at GIRP's annual conference in Tallinn.

GIRP's new warning comes after the final drafting of Europe's directive on falsified medicines contained the clause: "wholesale distributors must verify that the products they have received are not falsified by checking the safety features on the outer packaging."

Speaking to the press at the meeting on Monday, GIRP director general, Monika Derecque-Pois said GIRP was expecting the directive to be qualified with the word "selective" or similar, allowing wholesalers to make checks of products which were more likely to be at risk of being counterfeit.

Under Europe's plan, packs of drugs will carry a unique identifier which will be machine read to ensure the pack is genuine.

While approving of this as an approach, individual checking of millions of packs of medicines was an insurmountable task that could only lead to delays in getting medicines to patients, she added.

GIRP now wants the European Commission to act to specify exactly what is required and effectively remove any compulsion to examine drugs delivered directly from the marketing authorisation holder or its agent.

GIRP indicated this is perhaps 99% of medicines being handled by its members, which are all full-line wholesalers committing to stocking all drugs required by pharmacists.

GIRP argues that routine verification should be at the beginning of the process with the manufacturer and the end of the process when the pharmacist hands the drugs to the patient.

### **EGA ALONE**

GIRP was not the only body to sound an alarm at its meeting, but according to speakers at GIRP on Tuesday, wholesalers continue to enjoy the support of pharmacists and innovative pharma in their thinking.

John Chave, secretary general of the Pharmaceutical Group of the European Union described the plans as "incredibly vague".

Chave said PGEU members, community pharmacists, were prepared to accept some expense

as part of their desire to make the system more secure but wanted a pragmatic approach.

"We do not want a gold-plated system (we want) an optimal system in terms of patient safety ... not the most expensive system," he said.

Chave added that securing the EU medicines supply chain offered pharmacist, wholesaler and manufactures a "unique opportunity to present a common front before the public" and it would be serious mistake to miss this chance.

Hugh Pullen, a director of product integrity for Eli Lilly, was not alone in noting that a 'white list' of prescription medicines which would be exempt from security coding and a 'black list' of over-the-counter drugs which would need to carry the coding was possibly unworkable.

In addition, he said his best estimate was that it would be 2016 before the system was implemented.

In a tri-partite undertaking, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the PGEU and GIRP have been working together to direct Brussels in a direction that suits them in terms of counterfeit medicine for around three years.

Speaking to APM, GIRP delegates at the conference have said this close co-operation has helped to bolster relations between wholesalers and industry hit by pharma companies looking to cut out wholesalers and deliver direct to pharmacists.

During his presentation, head of EFPIA, Richard Bergstrom held out the prospect of more co-working with wholesalers (APMHE 23873). He did not mention direct-to-pharmacy delivery and was not asked about it by wholesalers.

In this case it was the European Generics Association (EGA) which continues to find itself the outsider due to its insistence that measures applied to branded drugs do not need to be applied to generics.

EGA representative Hugo Carradinha stressed, "there are no examples of generic medicines being counterfeited."

All arguments or appeals against this stance by the other speakers were met with the same argument.

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