# European legislation could result in "enormous" supply delays

Falsified medicines legislation that is being brought in across Europe contains wording that is of major concern to wholesalers and could result in enormous supply delays, the European Association of Pharmaceutical Full-line Wholesalers (GIRP) has warned.

GIRP's director general Monika Derecque-Pois says that the Directive — which was adopted by the Council of the European Union last month — requires wholesalers to verify that all medicines they receive are not falsified, which would present "insurmountable challenges" to the distribution chain.

Speaking yesterday (7 June 2011) at the annual general meeting of GIRP in Tallinn, Estonia, Ms Derecque-Pois said it will be up to the commission to define how the requirement should be met, and GIRP has suggested a definition whereby wholesalers will only need to check medicines that have been put at risk of falsification.

"We believe that delivery units should be checked by our members unless they are delivered directly by the marketing authorisation holder or a person responsible to the MA holder, and we would also verify returns.

"But otherwise we cannot scan all packs of medicines because then we would not be able to deliver [them] any more to the pharmacies — it would lead to enormous delays," she said.

She renewed GIRP's call for verification to be carried out by pharmacists before handing drugs to patients (PJ, 12 June 2010, p572), saying this "end-to-end" approach "is the safest, most proportionate and cost-effective system, and most importantly it really protects the patient".

GIRP's director general Monika Derecque-Pois predicts enormous supply delays if wholesalers are required to verify every medicine

GIRP is working closely with the Pharmaceutical Group of the European Union and the European Federation of Pharmaceutical Industries and Associations to find a common position on how the Falsified Medicines Directive should be implemented. It is also welcoming the views of other European stakeholders, such as parallel traders and hospital and generic drug associations.

The organisations are holding an initial meeting with the EC on 21 June 2011 to set out their views, which Ms Derecque-Pois hopes will be welcomed by the commission as it begins evaluating the various safety and technical options for implementing the Directive.

The Directive covers the safety and traceability of medicines, the regulation of internet pharmacies and sanctions against counterfeiters. Earlier this year, it was described by UK pharmacy organisations as one of the most significant EU Directives to affect community pharmacy. Member states have 18 months to make changes to their national legislation.