Press Release

European Commission urged to take a pragmatic and proportionate approach to further defining the scope of the recently adopted Falsified Medicines Directive

Brussels, Belgium 6th June 2011 – 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 and its members, some aspects of the brand new legislation still present significant concerns and could have an adverse impact on the current pace and speed of the delivery of medicines to Europe's pharmacies.

"GIRP continues to have concerns about the proportionality of the measures contained in the Directive", GIRP Director General, Ms. Monika Derecque-Pois stressed when speaking to members of the press today in the context of the associations' Annual General Meeting currently underway in Tallinn, Estonia.

The new Directive insists that "wholesale distributors must verify that the products they have received are not falsified by checking the safety features on the outer packaging". According to the head of the association this new requirement has "major practical implications for full-line wholesalers as if individual pack scanning is involved it presents insurmountable challenges to the smooth operation of the distribution chain". On this topic, she calls on the European Commission through the delegated act to further specify "proportionate, pragmatic and workable solutions" under the authority given to the institution in the Directive in order to further specify parts of the measures in a delegated act in a feasible and proportionate manner.

Explaining GIRP's position in further detail, the Director General stated that GIRP proposes and supports 'selective' checking of the safety features for verification purposes especially for those medicinal products obtained by wholesale distributors from other sources than the marketing authorization holder or a person who is authorized by the marketing authorization holder to supply these products as well as for products returned by pharmacies. The members of GIRP are firmly committed to checking the safety features when any degree of doubt arises and in all circumstances when products are being returned.

Derecque-Pois emphasised that "GIRP stands by an end-to-end verification system at the point of dispense which is the most efficient and cost effective way to protect patients from receiving falsified medicinal products and therefore fulfils the aim of the Directive". She added that "an end-to-end verification system also is the most proportionate measure from the wholesale distributors' viewpoint as it does not compromise the delivery process of medicinal products".

In the context of the delegated act the Commission will decide within the next 18-24 months the specifications of the serial number allowing identification/ authentication of

individual packs and will set out the provisions on the establishment, management and accessibility of the databases.

"A stakeholder developed proposal for complying with the terms of the Directive should be welcomed by the European Commission" she stated, as it is due to evaluate various measures, such as the characteristics and specifications of the safety features and the technical options for the repository systems, as part of the impact assessment to prepare the delegated acts.

GIRP is therefore actively collaborating with PGEU (European pharmacist association) and EFPIA (European pharmaceutical industry association) to find a common position on the implementation of the provisions of the Falsified Medicines Directive and hopes that the other stakeholders involved will still come on board. 10 key principles have been developed between the associations based on the verification of medicine packs at the point of dispensing with an interface for wholesalers as the most robust and cost-effective way to fulfil the new requirements and protect patients.

Photos of the conference will be available from:
http://flic.kr/s/aHsjuYUVsm

For further information contact:

Monika Derecque-Pois
GIRP Director General
European Association of Pharmaceutical Full-line Wholesalers
Rue de la Loi, 26, 10th floor - B-1040 Brussels, Belgium
T: +32 (0) 2 777 99 77 F: +32 (0) 2 770 36 01
E: girp@girp.org