Press Release

GIRP responds to the European Commission consultation on the Delegated Act of the Falsified Medicines Directive

Budapest, Hungary, 27th April 2012 – GIRP, the European Association of Pharmaceutical Full-line Wholesalers, is pleased to announce it has submitted its response to the European Commission public consultation on the Delegated Act on the detailed rules for a unique identifier for medicinal products for human use, and its verification.

In its extensive response to the policy options presented by the Commission in the concept document, GIRP raised the following key points:

1. Concerning the code structure, GIRP insists that the batch number and expiry date be included in and be available in a machine-readable format on each pack of medicines requiring the safety features. Without this information being available in a machine-readable format, wholesale distributors will not be in a position to effectively meet its obligations within the Falsified Medicines Directive to record the batch number of each product supplied.

2. Systematic verification at the point of dispensing is the most cost-effective and proportionate approach to achieve supply chain and patient safety and implement the Falsified Medicines Directive. However, product verification at the point of dispensing with random (using risk-based determinants) checks at the level of the wholesale distributor adds an additional layer of security to the system. For this reason GIRP supports policy option n°2/2 of consultation topic n°2 on the modalities for verifying the safety features which is estimated to cost the wholesale distribution sector alone around 36 million EUR.

3. GIRP members distribute 75% of all medicines dispensed by pharmacies, hospitals and other authorised points of dispensing. The 25% balance is distributed largely through direct sales by manufactures. While 75% throughput represents huge volumes of medicines, the current remuneration mechanisms for wholesale distributors are very tightly squeezed to such an extent that the costs of policy option n°2/3 of consultation topic n°2 on the modalities for verifying the safety features (which would necessitate wholesale distributors systematically scanning all medicines carrying safety features) would make wholesaling not viable any longer in several European countries. This policy option would cost the wholesale distribution sector alone an estimated 636 million EUR.

GIRP fully supports the joint submission by of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Pharmaceutical Group of the European Union (PGEU), the European Association of Euro Pharmaceutical Companies (EAEPC) and GIRP, which are the currently involved organisation in the European Stakeholder Model (ESM) that proposes a pan-European medicines verification system.

The main objective of the Delegated Act is to lay the foundation for the development of a harmonised system across the EU and EEA areas 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 leading stakeholder organisations of the ESM are already moving to transform the project concept into reality and today the national members of the involved European stakeholders are gathering in Budapest, Hungary at a regional meeting instigated by GIRP to facilitate an initial discussion among

manufactures, parallel traders, wholesale distributors, pharmacists and national authorities on the national approach to the ESM in Hungary and other countries within the region.

The event is part of a series of other events currently being held by stakeholders at national level right across Europe.

The GIRP submission and the joint response can be found on the GIRP website.
www.girp.org

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About the European Stakeholder Model

The solution proposed under the European Stakeholder Model ("ESM") is an end-to-end, point-of-dispense 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 (in addition to the batch number and expiry date). The ESM solution provides an efficient and cost-effective method to meet the requirements for pack identification put forth in the recently adopted Falsified Medicines Directive and has been presented to the European Commission in joint response to the consultation on the Delegated Acts.

The system is composed of 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. The system will be interoperable between the various countries and will allow for the reconciliation of parallel distributed products through the European Hub. The European Hub will also allow the performance of key tasks such as the proper handling of multi-country packs. Specifically, the system will constitute an end-to-end, real-time verification tool enabling manufactures to upload serial data; healthcare professionals throughout the supply chain (i.e. wholesalers, pharmacists or hospital pharmacists, dispensing doctors and parallel distributors) to verify that a product is genuine, for parallel distributors to decommission individual codes and upload new codes (linking the new code to the old code at batch level), and dispensing pharmacists, doctors and hospital pharmacists to decommission individual codes. The proposed system should accommodate different needs in different regions, but be based on common principles to ensure mandatory coding and verification of products in line with a harmonised coding system.

The European Hub will be established and managed by a not-for-profit stakeholder organisation referred to as the European Medicines Verification Organisation ("EMVO"). The stakeholders have elaborated and have reached working-level agreement on a Memorandum of Understanding ("MoU") which outlines the proposed solution and steps for implementation including:

- Unique Identifier for medicinal products;
- Modalities for verifying the safety features;
- Provisions on the establishment, management and accessibility of the repositories system;
- Lists of products to be covered by the safety features.

The ESM is currently discussing with national stakeholders on the roll out of the systems at national level.

About GIRP

GIRP is the European umbrella organisation of pharmaceutical full-line wholesalers. Pharmaceutical full- line wholesalers ensure the safe, efficient and timely delivery of all medicines whenever and wherever they are needed. GIRP and its members play a vital role in the healthcare supply chain, by supplying about 170,000 retail pharmacies as well as hospitals and other healthcare professionals with more than 100,000 different medicinal products.

About EFPIA

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 35 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,000 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

About EAEPC

EAEPC regroups the European licensed parallel distribution industry. Through national associations and individual company membership, it encompasses over 70 firms from 20 countries in the European Economic Area (EEA). All products handled by EAEPC members have national or EU regulatory approval and are exclusively sourced from and sold to EEA countries using authorised trade channels.

About PGEU

The Pharmaceutical Group of the European Union (PGEU) is the European association representing more than 400,000 community pharmacists. PGEU's members are the national associations and professional bodies of pharmacists.

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