Press Release

European pharmaceutical full-line wholesalers approve Memorandum of Understanding between supply chain partners on medicines authentication

Lisbon, Portugal, 4th June 2012 – On the occasion of its Annual Meeting, the European Association of Pharmaceutical Full-line Wholesalers (GIRP) approved a Memorandum of Understanding with the supply chain stakeholders, the European Federation of Pharmaceutical Industries and Association (EFPIA), the Pharmaceutical Group of the European Union (PGEU) and the European Association of Euro Pharmaceutical Companies (EAEPC). The adopted document sets out core principles for a European Medicines Verification System (EMVS) which is to be run through a European Stakeholder Model (EMS) – a coalition of the involved supply chain stakeholders.

The Memorandum of Understanding has been in principle endorsed by the all stakeholder partners. The document details the possible legal, practical and technical aspects of the planned EMVS, and forms the basis of the discussions between the involved partners and with the European Commission in the months ahead as the preparation of the Delegated Acts evolves.

EFPIA, GIRP, EAEPC and PGEU are jointly working on the European Stakeholder Model (ESM), a European medicines verification project with the aim of preventing falsified medicines from entering the European supply chain and ensuring patient safety.

GIRP President Mr. Rene Jenny states that "GIRP's endorsement shows how deeply committed our sector is to the development of a practical and cost-effective system that will meet the key objective of protecting patients from falsified medicines. Stakeholders such as those involved in the EMVS' development must be the key drivers in any authentication system as demanded by the Falsified Medicines Directive. Together with our main supply chain stakeholder partners we have the depth of expertise and knowledge to bring the concept to reality."

GIRP Director General Ms. Monika Derecque-Pois: "We are confident that the great collaboration between the stakeholders in the development of this vision and concept will stand the test of time".

As a partner of the ESM, our overriding objective is to develop a system that provides security for patients while being cost-effective and integrating it effectively into existing structures and practices in the pharmaceutical supply chain. This includes:

- Safe access for patients to high quality medicines across the EU;
- A straightforward, cost-efficient system embedded in routine processes of involved stakeholders;
- Close collaboration amongst all stakeholders to further and continuously improve the system in a joint effort in countering the threat of falsified medicines.

The adoption on July 1, 2011 of the EU "Falsified Medicines Directive" is an important step in better protecting patients from counterfeit medicines.

The directive introduces mandatory, harmonised pan-European safety features in the form of tamper-evident packaging and a "unique identifier" or serial number that will be applied to medicines, subject to possible exclusions based on risk assessment. The European Commission will define the mechanics of how this system will work in Delegated Acts that are to be adopted by 2014. In such they will define the characteristics and technical specifications of the "unique identifier", which will enable identification of individual packs, and the accessibility of product databases or repositories to verify each dispensed pack.

GIRP AISBL – 10th floor, Rue de la loi, 26 - B-1040 Brussels
Tel: +32 2 777 99 77 - Fax: +32 2 770 36 01
girp@girp.org - www.girp.eu

GIRP supports this legislation and is pleased to work with stakeholder groups and the European Commission in establishing an effective system in the interests of patient safety.

To this end the partners have developed a concrete proposal for a system for the verification of pharmaceutical products in Europe that is designed and governed by the stakeholders who will use it day-to-day. The aim is to set up a cost-effective and scalable European product verification system to meet the requirements of the Directive that is to be run by stakeholder organisations on a non-profit basis. The members of this European coalition stand ready to work in partnership with national regulators and Governments to ensure optimum implementation of the European Stakeholder Model (ESM) at the national level.

The ESM approach also incorporates the best approach to product verification at the wholesale distribution level.

- Concerning the code structure of the safety feature, GIRP insists that the batch number and expiry date be included in a machine-readable format (2D matrix code). If not, wholesale distributors will not be in a position to effectively meet their obligations within the Falsified Medicines Directive to record the batch number of each product supplied.
- The ESM approach foresees the systematic verification at the point of dispensing as the most cost-effective and proportionate approach to achieve patients' 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 supply chain at a cost of EUR 36 million compared to the exorbitantly high costs of EUR 636 million for systematic product verification at the level of the wholesale distributor.

"While GIRP welcomes the additional layers of security for the safe supply of medicines, the cost implications of a systematic product verification would endanger the economic viability of our sector", GIRP President Mr. Rene Jenny emphasised.

"The numbers speak for themselves and a logical understanding of operations at the wholesale distribution level proves the disproportionate, costly and ineffective approach of systematic product verification at the level of the wholesale distributor", GIRP Director General Ms. Monika Derecque-Pois underlined.

The adopted Memorandum of Understanding is available on the GIRP website www.girp.eu.

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