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Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Ref: 12.03.16E 02PR

PRESS RELEASE

16 March 2012

Best Initiative of the Year in Pharmacy awarded to EFPIA-GIRP-PGEU for their Core Principles on European Medicines Verification

For Immediate Release

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 in 31 European countries, including EU Member States, EEA/EFTA members and EU applicant countries.

For more information, please visit the PGEU website www.pgeu.eu or contact Ms Giovanna Giacomuzzi, PGEU Communications and Policy Officer (tel. +32 2 238 08 18).

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Representatives from three European associations (EFPIA,GIRP and PGEU) received on the 12 March 2012 in Madrid, Spain, the awards for the "2011 Best Pharmacy Initiatives of the Year". The awards were given out by the Spanish newspaper Correo Farmaceutico in recognition of the EFPIA/GIRP/PGEU ten core principles for their vision for a stakeholder-led European Medicines Verification Systems ("EMVS").

EFPIA, GIRP and PGEU are jointly working on a European medicines verification project with the aim of preventing falsified medicines from entering the European supply chain and improve patient safety. More recently, EAEPC, the association representing parallel distributors joined the project.

The award was received by **John Chave, PGEU Secretary General,** who thanked the *Correo Farmaceutico* newspaper for the vote of confidence in their approach and commented: "Timely, secure and cost-effective implementation of a product verification system is best assured with a system that is designed and run by those who will use it day-to-day, such as pharmaceutical manufacturers, pharmacists, wholesalers as well as parallel distributors".

EFPIA Director General Richard Bergström added "This award is an important mile stone for our joint efforts and demonstrates clear recognition of the distinct advantages of the European pharmaceutical supply chain stakeholder model. The stakeholders vision is to develop a harmonised system that provides a high level of security for patients, while being cost effective and integrating into existing structures in the distribution chain".

"ESM which is under development by the four organisations represents a practical means of implementing the requirements of the EU Falsified Medicines Directive and is the least burdensome solution available for all parties involved" adds **Monika Derecque, Director General of GIRP.**

"We are pleased that the three founding organisations have been publically recognised for their efforts to date and it is extremely encouraging to see the initiative is already the winning approach", **Richard Freudenberg , Secretary General of the EAEPC** said on hearing the news of the awards.

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About the project

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 2D data matrix barcode, which contains a unique serial number. 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 will be presented to the European Commission in the consultation on the Delegated Acts.

The system is composed of a European central 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 central hub. The European central 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 central 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 tentatively agreed 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 MoU, currently awaiting official approval by the four organisations, is based on a joint "10 core principles" document for which the award is being given.

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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.

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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.

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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.