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Industries and Associations



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Press Release

EAEP-EPFIA-GIRP-PGEU working for better Patient Safety

Brussels, 26 January 2012: At the occasion of a workshop organized today in Strasbourg by the European Directorate for the Quality of Medicines & Healthcare (EDQM) to present its "eTact" coding system, EAEP, EPFIA, GIRP and PGEU would like to welcome EDQM's involvement in the fight against counterfeit medicines entering the European supply chain.

However, EAEP, EPFIA, GIRP and PGEU are convinced that it is essential to develop a practical and cost-effective solution to implement the requirements of the Falsified Medicines Directive in Europe. "Our *European Stakeholder Model (ESM)* is easily adaptable to any existing national systems. It offers a product verification solution which can be implemented without unnecessary cost or disruption", says PGEU Secretary General **John Chave**.

EAEP, EPFIA, GIRP and PGEU are jointly working on the ESM to prevent falsified medicines from entering the European supply chain and improve patient safety. "This joint approach clearly offers distinct advantages in terms of efficiency and expertise to run the system", underlines **Monika Derecque-Pois**, Director General of GIRP. **Heinz Kobelt**, EAEP European Affairs Director adds: "We believe serialisation is an effective tool to undermine the business model of counterfeiters. This joint stakeholders' system represents a big step forward in ensuring the safety of the medicinal supply chain for European patients and operators alike".

Richard Bergström, EPFIA Director General, concludes: "Our vision is to develop a harmonized system that provides a high level of security for patients while being cost effective and integrating into existing structures in the distribution chain".

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Note of the editor

More information on the EAEP-EPFIA-GIRP-PGEU European Stakeholder Model is included in the joint position paper in appendix.

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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.

~About EAEPCC~

EAEPCC 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 EAEPCC members have national or EU regulatory approval and are exclusively sourced from and sold to EEA countries using authorised trade channels.

~About GIRP~

GIRP is the European umbrella organization 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 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 in 31 European countries, including EU Member States, EEA members and EU applicant countries.

Appendix

Joint Position Paper EAEP-EPFIA-GIRP-PGEU on EDQM's "eTact" Project

The European Directorate for the Quality of Medicines and Healthcare (EDQM), an inter-governmental organisation that is part of the Council of Europe based in Strasbourg, has announced that it is developing a traceability system for medicines called "eTact". The system is being developed in the context of the Council of Europe Convention on counterfeiting of medical products and the EU Directive on Falsified Medicines, published on 1 July 2011.

EAEP, EPFIA, GIRP and PGEU (respectively the European licensed parallel distribution industry, the research-based pharmaceutical industry, the wholesalers and pharmacists at EU level) welcome EDQM's involvement in the fight against counterfeit medicines entering the EU legitimate supply chain. However, EAEP, EPFIA, GIRP and PGEU see significantly greater efficiencies in the European Stakeholder Model ("ESM") which is under development by the four organisations and supported by key stakeholders in the pharmaceutical supply chain. In comparison to the eTact system, the ESM represents a practical and cost-effective means of implementing the requirements of the EU Falsified Medicines Directive in Europe:

- 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. The ESM, governed by a not-for-profit stakeholder organisation, provides for such a system.
- The decentralised structure of the ESM will permit **highly flexible implementation at national level** within a structure that guarantees high levels of security and robust legal principles for data protection.
- The **efficiency and cost-effectiveness** of the ESM have already been successfully demonstrated via a pilot run in Sweden in 2009-2010, and a further pilot will be launched in Germany in 2013. Thorough cost estimates have been developed by EAEP, EPFIA, GIRP and PGEU demonstrating the ESM to be a robust and cost-effective way of implementing the Falsified Medicines Directive. The eTact system is currently untested and uncoded beyond a meeting room-level prototype.

EAEP, EPFIA, GIRP and PGEU have already taken key steps in the proactive development of a pan-European Point-of Dispense Verification System, in partnership with all supply chain partners, in order to improve supply chain security. A stakeholder-driven approach as put forth by the proposed ESM clearly offers distinct advantages in terms of efficiency and expertise to run the system. It also provides additional benefits such as verification by legitimate online pharmacies, batch recall, counterfeit reporting information and the ability to expand geographically and evolve with technical advancements including the future possibility of patient verification.

The four organisations have therefore developed a joint Memorandum of Understanding, and are involved in advanced technical discussions, laying the foundation for the full development of the stakeholder-governed Point-of-Dispense Verification System.