Press release

European Stakeholder Model (ESM) partners hold workshop in a drive for national implementation of medicines verification systems

Vienna, Austria, 3rd June 2014 - GIRP (the European Association of Pharmaceutical Full-line Wholesalers) in collaboration with European Stakeholder Model (ESM) partners EAEPC (The European Association of Euro-Pharmaceutical Companies), EFPIA (European Federation of Pharmaceutical Industries and Associations, and PGEU (Pharmaceutical Group of the European Union) hosted a national workshop on the pan- European Medicines Verification System (EMVS). The workshop is taking place at the occasion of GIRP's 55th Annual General Meeting business conference.

The aim of the workshop is to present to national stakeholders progress in terms of the ESM project's development, appeal to national stakeholders for faster progress in the development of national systems and set out what stakeholders can expect from 2017 onwards.

Opening the workshop Mr. Stefano Soro, Head of Unit, Directorate General for Health and Consumers, European Commission, provided a progress update on the status of the drafting of the delegated acts. He explained to workshop attendees that the Commission is right in the middle of drafting the text and consulting with Member States. While not going into specific details about the wording he did however outline further on the announced policy options for inclusion into the delegated acts:

- Harmonisation of the composition of the verification number and the data carrier
- Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors
- Establishment and management by stakeholders with supervision by the relevant competent national authorities

Representative from all stakeholder organisations spoke about the system - GIRP Director General, Ms. Monika Derecque-Pois, Dr. Heinz Kobelt, European Affairs Director for EAEPC; EFPIAs market access Director Mr. François Bouvy, and Mr. John Chave, Secretary General of PGEU – during a joint presentation which outlined the legal framework for the system, design and architecture, governance approach and the cost effectiveness of the approach.

The ESM partners have joined forces to develop a safe, cost-effective and partnership based pan-European medicines verification system to combat falsified medicines and ensure patient safety. The founding principle of the ESM approach is that each pack of medicine is checked individually before it is dispensed to the patient, ensuring that the patient receives a genuine product.

Since 2010, the ESM partners have developed and tested an interoperable and scalable pan-European medicines verification system. It uses an internationally recognised 2D barcode (data matrix) to verify medicines at the point- of-dispensing. The Data Matrix carrier contains a code with five key main elements: product number, batch number, expiry date and random serial number, and a national number (eg. for reimbursement) where it exists. The data matrix also has the capacity to contain other information such as national codes and meet the needs of national authorities.

The codes are generated and applied by manufacturers and parallel distributors using the 2D data matrix barcode and are uploaded to a European Hub, established as an interface to regional or national databases. Pharmacies and wholesalers connect to these databases in order to authenticate medicines: pharmacies at goods entry but at the latest at the point of dispensing, while wholesale distributors will also perform risked based authentication. By simply and systematically scanning the barcode, any unregistered code will immediately alert the user to the possibility of a falsified product.

This system is a direct response to the European Falsified Medicines Directive (FMD) and is being developed in parallel to the writing of the additional legislation which set out the more specific principle for medicines verification systems in the EU.

As the project stands, the ESM is envisaged to be overseen by a not-for-profit stakeholder organisation, called the European Medicines Verification Organisation (EMVO). The European Medicines Verification System (EMVS) will be run by the EMVO which will oversee the European Hub that links national systems (National Medicines Verification Systems (NMVSs)) throughout Europe. It will also serve as the central point from which product recall actions can be initiated. The ESM system will not generate, process or store any personal or patient data.

National stakeholders will have the flexibility to either develop their own national verification systems (an example of such was outlined by Mr. Lothar Jenne on behalf of the German national medicines verification system - securPharm) or use a foreseen cost-effective template as an 'off-the shelf solution') that will developed by the ESM stakeholders when a cost effective number of countries indicate ambitions to use it.

The workshop concluded with an appeal to national stakeholders to get together on this project and act swiftly in order not to miss an opportunity to be ready for 2018 when the verification system is expected to be mandatory.

Mr. Adrian van den Hoven, Director General, of the European Generic medicines Association (EGA) outlined the views of his industry on the ESM approach. He indicated that the successful outcome of discussions with EFPIA and EAEPC on the cost-allocation model for the running of the repository systems would be a critical milestone to allow the EGA to join the ESM. The EGA is engaging constructively with EFPIA and EAEPC to find a practical, fair and straightforward cost allocation model which, if successful, will enable the generic medicines industry to engage with the ESM partners in rolling out the medicines verification system across the EU."

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The European Association of Euro-Pharmaceutical Companies (EAEPC)

The European Association of Euro-Pharmaceutical Companies (EAEPC) is the representative organisation of the European licensed parallel distribution industry. Through national associations and individual company membership, it encompasses 88 firms from 23 countries in the European Economic Area (EEA).

The European Federation of Pharmaceutical Industries and Associations (EFPIA)

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research based pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies.

The European Association of Pharmaceutical Full-line Wholesalers (GIRP)

European Association of Pharmaceutical Full-line Wholesalers (GIRP) is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. It represents the national associations of over 750 pharmaceutical full-line wholesalers serving 32 European countries, including major Pan-European pharmaceutical full-line wholesaling companies.

The Pharmaceutical Group of the European Union (PGEU)

The Pharmaceutical Group of the European Union (PGEU) is the European association representing community pharmacists. PGEU's members are the national associations and professional bodies of community pharmacists in 33 European countries including EU Member States, EU candidate countries and EEA/EFTA countries.

European Stakeholder Model (ESM)

The European Stakeholder Model (ESM), a partnership of key supply chain stakeholders, including the pharmaceutical industry, parallel traders, wholesalers and pharmacists are demonstrating how efficiently and cost effectively they can conceptualise, develop, deploy and govern medicines verification systems.