Press Release

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Progress towards a European Medicines Verification System: the European Stakeholder Model and securPharm link-up

(Brussels – 4 March 2014) – ESM and securPharm e.V. - a pan European and a German organisation, respectively, of stakeholders involved in the manufacturing and distribution of pharmaceuticals - will join forces: In July 2014, they will link securPharm's German system to ESMs European Hub. In this way they want to demonstrate for the first time how European and national components of the European Medicines Verification System (EMVS) can be linked. This will pave the way for other country verification systems to be linked. A fully integrated supply chain protection – rather than multiple incompatible national systems – will be the result. This is good news for patients who will be protected from falsified medicines andf for drug manufacturers that deliver goods to Europe's complex supranational supply web. ESM and securPharm presented their joint project during during a workshop held in Brussels on 26 February 2014 for marketing authorization holders.

In Europe, the Falsified Medicines Directive, FMD (2011/62/EU) is an important step in betterprotecting patients from counterfeit medicines. Towards this end, EFPIA has joined together with PGEU (Pharmaceutical Group of the European Union), GIRP (Groupement International de la Repartition Pharmaceutique) and EAEPC (the European Association of the Euro- Pharmaceutical Companies) to develop the ESM (European Stakeholder Model). These partners came together with the aim of developing a system that will provide a high level of security for patients while being cost-effective, pan-European and interoperable – and capable of being effectively integrated into existing national structures and practices in the distribution chain. The result is the European Medicines Verification System (EMVS), a system designed to ensure the medicines are making it safely from the point of manufacture to the point of sale – to the patient.

Richard Bergström, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA) comments on behalf of the ESM: "We look forward to the start up project as another opportunity to demonstrate the effectiveness of ESMs European Hub. The collaboration with securPharm is invaluable in demonstrating the Hub's potential, furthering our efforts to fight falsified medicines in Europe as a whole. I encourage manufacturing authorization holders to join us in moving this initiative ahead."

Reinhard Hoferichter, spokesman of securPharm, states: "The securPharm system is already running under real-life conditions of the German pharmaceutical market. We welcome this opportunity to join forces with the ESM in the fight against falsified medicines. We are looking forward to

demonstrate that a powerful European solution can be created by building upon national systems that have been tailored to the specific requirements of each country."

Both the Hub and the securPharm system are run by stakeholders of the drug supply chain – drug manufacturers, wholesalers and pharmacies, and their respective business associations. Both are based on the concept of end-to-end verification: Drug companies generate a unique randomized serialization number for each package they supply. This number is not only printed on the package (as part of a Data Matrix Code) but also uploaded to a protected data base. In the pharmacies the code is being scanned and checked for authenticity before the packages are handed out to the patients.

Both ESM's Hub and securPharm's system are in accordance with the Falsified Medicines Directive, FMD (2011/62/EU). Also, they are in line with the outcomes of a recent related impact assessment on behalf of the European Commission that favours a stakeholder based end-to-end verification system under the supervision of competent authorities and using Data Matrix Codes over alternative approaches that had been considered in the past.

The German participants of the securPharm system – drug manufacturers, wholesalers and pharmacies – will not have to alter their procedures when the systems are linked.

For more information, please visit www.securPharm.de.