European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

European Industrial Pharmacists Group statement on the implementation of the Delegated Regulation laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

The European Industrial Pharmacists Group (EIPG) has followed with interest the implementation of a European medicines verification system in line with the provisions of the Falsified Medicines Directive and the Delegated Regulation laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. EIPG is aware that the implementation of this system by the deadline of February 2019 represents a considerable challenge for all stakeholders, and that all players will need to be involved in the process to ensure its success. With this principle in mind, EIPG dedicated a Working Group at its recent 50th General Assembly in Paris, and approved the following observations and recommendations.

a. A new version of Annex 16 (Certification by a Qualified Person and Batch Release) to the Good Manufacturing Practices (GMP) Guidelines came into operation on the 15th April 2016. Although the Annex came into operation after the publication of the Delegated Regulation, it contains little specific guidance in respect of the Delegated Regulation, the Unique Identifier or the Repositories System. ***EIPG therefore recommends that work should start immediately on a new review of Annex 16 to determine Qualified Persons' responsibilities and appropriate Qualified Person guidance in respect of the Delegated Regulation.***

b. The verification and authentication of medicinal products will involve Responsible Persons at wholesale dealer levels. The European Commission's Good Distribution Practices (GDP) Guidelines include recommendations for qualification and approval of suppliers, as well as provisions for documentation that need to take into account the way the repositories system will maintain records. ***EIPG recommends that, within the time period required to set up the repositories system, practices falling within the scope of the European Commission GDP Guidelines need to be regularised and harmonised across Member States, and that work should start immediately on a review of the GDP Guidelines to determine Responsible Persons' responsibilities and appropriate guidance in respect of the Delegated Regulation.***

c. The Delegated Regulation states that "*It should be left to the choice of the wholesaler whether to scan individual unique identifiers or aggregated codes, where available, or the timing of the verification, provided that the wholesaler ensures the verification of all unique identifiers of those products at higher risk of falsification in his physical possession.*" The recent Question and Answer document issued by the Commission furthermore indicates that "*it is possible to verify the authenticity of or decommission multiple unique identifiers by scanning an aggregated code rather than scanning each individual pack, provided that the requirements of Regulation (EU)*

No 2016/161 are complied with." ***EIPG recommends that more specific guidance be issued with regards to the use of aggregation in the contexts of verification and decommissioning.***

d. The Delegated Regulation provides for a number of scenarios where requirements are to be established by the Member States, such as the inclusion of a national reimbursement number or other national number identifying the medicinal product in the unique identifier. A timely decision by Member States is required to allow manufacturers and marketing authorisation holders to prepare for the implementation of the Regulation, since such decisions can impact the activities of many marketing authorisation holders. Such timeliness and coordination is even more necessary where packs are shared between Member States. ***EIPG therefore recommends that Member State decisions required by the Delegated Regulation are taken as soon as possible, and coordinated between Member States in order to allow marketing authorisation holders to make the necessary preparations for the implementation of the Regulation within the established timeframes.***

e. EIPG has determined that, in the light of the various activities described within the Delegated Regulation, in particular Article 23, which provides that "*Member States may require, where necessary to accommodate the particular characteristics of the supply chain on their territory, that a wholesaler verifies the safety features and decommissions the unique identifier of a medicinal product before he supplies that medicinal product to any of the following persons or institutions*", Responsible Persons, or individuals to whom Responsible Persons may have delegated their duties, can, insofar as the activities of verification and decommissioning are concerned, be considered to be assuming responsibilities identical to those of persons entitled to supply medicinal products to the public. EIPG is therefore of the opinion that such individuals, or their representatives, are, as provided in Article 31 of the Delegated Regulation, entitled to be consulted and to participate in the legal entity or entities responsible for setting up and managing the repositories system, on a voluntary basis, at no cost. EIPG therefore recommends that, as a matter of principle:

(i) ***Associations of stakeholders at a national or a pan-European level representing users or potential users of the European or National Medicines Verification System (EMVS or NMVS) for verification and/or authentication purposes should be eligible for affiliate membership in the European or National Medicines Verification Organisation (EMVO or NMVO), respectively***

(ii) ***Affiliate members should enjoy the right to be consulted on all activities of the EMVO or NMVO that will affect their members, and not only those activities that may be decided by the voting members of the EMVO or NMVO***

(iii) ***Affiliate members should enjoy the right to be consulted at no cost, and therefore, without obligation to pay any form of membership or participation fee.***

18th July, 2016