Press Release

EU patient safety rules welcomed by GIRP, but room for improvement

Brussels, Belgium 16th February 2011 – GIRP, the European Association of Pharmaceutical Full-line Wholesalers welcomes the adoption of the falsified medicines directive by the European Parliament. Reacting to the outcome of today's vote, GIRP Director General Ms. Monika Derecque-Pois took the view that the adopted proposal is a significant step forward to ensuring patient safety.

GIRP welcomes the definition of 'falsified medicines' that now excludes unintentional quality errors arising from manufacturing or distribution processes. According to the Director General "it is important to make a clear distinction between actual falsified medicines and those medicines which are genuine, but could be regarded as falsified due to unintentional inaccuracies in the recording of data".

With regard to wholesaler-specific provisions, GIRP considers the requirement that wholesalers must verify that the products purchased are not falsified by checking the safety features on every single pack of medicines to be onerous. Products received directly from trusted manufactures are genuine. The checking of every single box of medicines from these sources is a redundant, costly and time-consuming exercise. A pragmatic approach is needed in this respect. Ms. Derecque-Pois stressed "the need for flexibility by the European Commission in the delegated act, taking into account that wholesale distributors need to be able to deliver medicines to any patient via their pharmacist within the average European delivery time of 2 to 4 hours".

The delegated act will set out the characteristics and technical specifications of the unique identifier, considering its cost effectiveness. When considering the modalities of verification of the safety features, the particular characteristics of the supply chain should be taken into account in addition to ensuring that the impact of verification measures for the supply chain actors is proportionate. The focus has to be on a result-orientated process such as the proposed end-to-end verification approach, which ensures patient safety.

GIRP furthermore welcomes the clear definition of brokering and the new requirements applicable to brokers, which place these currently discrete operators under the spot light. Brokers need to register minimum information with the national authority 60 days after starting their brokering activities. They are to be held in a national registry accessible to the public. The new GDP guidelines should include provisions for brokering activities. Brokering activities are to be inspected by the national authority of the Member State in which the activity is registered. If brokers fail to comply with the requirements of the directive, they will be removed from the national registry. However, the adopted legislation does not go far enough as it does not foresee a European centralised database for keeping information on their licensing or inspection status. This means that full transparency of all actors associated with the supply chain has not been achieved.

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