Press Release

European Parliament Health Committee vote on medical devices to hinder the smooth distribution and access to medical devices

Brussels, 27 September 2013 – the European Association of Pharmaceutical Full-line Wholesalers (GIRP), the representative organization for distributors of pharmaceuticals, medical devices and in-vitro medical devices, expresses strong concern at the result of a vote in the European Parliament's Committee for Environment, Public Health and Food Safety (ENVI).

Distributor purchase, store and supply a significant number of medical devices and in vitro medical diagnostic devices. The products range from medical devices with a low risk profile such as first aid bandages, syringes, thermometers, rubber condoms, tongue depressors, and examination gloves, to higher risk categories including products such as pregnancy tests and diagnostic test kits.

Distributors' offer their customers (mainly pharmacies) a one stop shop and high speed supply services for all their needs as part of their mission as primary healthcare providers upon which patients rely daily.

Unlike manufacturers or importers, distributors are by law not permitted to interfere with the actual medical devices or their secondary packaging.

GIRP's major concern relates to the fact that Parliament Health Committee has voted in favor of legislation that will force distributors to open each pack in order to check whether or not manufactures have complied with their product safety requirements. For instance, distributors will become responsible for checking if manufacturers have included the correct information with the product.

This will mean that each device pack will have to be opened during the distribution process before the products reach the hands of pharmacists and healthcare professionals who dispense them to patients.

Reacting to the vote Ms. Monika Derecque-Pois, GIRPs Director General explained "unless Member States at the level of the Council intervene and remove the unworkable and even risky requirements, distributors will no longer be able to supply these products as done today which will ultimately result in significant access problems". She went on to outline how "distributors have a duty to provide for a high level of quality in the supply chain so that the safety and quality of the product is maintained and not compromised as the products pass through the distribution channel. Distributors are not qualified to carry out policing duties related to actual product safety which lies best in the hands national inspectorates".

GIRP calls on Member States to re-assert their authority and ability to police quality and safety requirement of actual medical device products and supervise distributors to ensure a high level of quality in the supply chain so that product safety is not compromised.

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About GIRP

GIRP is the umbrella organization of pharmaceutical full-line wholesalers in Europe. GIRP represents the national associations of over 750 wholesale distributors serving 31 European countries. Through their distribution network, GIRP members employ about 140,000 people and serve over 170,000 retail pharmacies and other healthcare professionals dispensing medical devices and in-vitro medical devices. In the performance of their public service role, they absolutely guarantee the highest level of quality, integrity and excellence.

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