Press release

Distributors fear strict interpretation of obligations in upcoming EU medical device legislation will result in supply chain disruptions

Vienna, Austria, 2nd June 2014 – The 55th Annual General Meeting of the European Association of Pharmaceutical Full-line Wholesalers (GIRP) is currently getting underway in Vienna, Austria. GIRP is the representative organization for wholesale distributors of pharmaceuticals, medical devices and in-vitro medical devices.

As their annual gathering opens in Vienna, the members of GIRP have a considerable number of issues to discuss, among them recent developments in the revision of the European Unions' medical device legislation.

The members of GIRP purchase, store and supply a significant number of medical devices and in vitro medical diagnostic devices ranging 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 sterile implants, pregnancy tests or diagnostic test kits.

Distributors' offer their customers (healthcare professionals) 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 not permitted to open the primary or even the secondary packaging of medical devices or modify in any way the product itself.

Proposals to revise the EUs medical devices and in-vitro medical devices legislation were first presented by the European Commission in September 2012. Since then the European Parliament was active amending the proposals. In April 2014 it formally adopt 260 amendments.

The European Council (which is composed of Member State representatives through the Working Party on Pharmaceuticals and Medical Devices) is currently assessing the proposals with a view to formulating a position at that level in order to open negotiations with the Parliament to finalizing the legislation.

Despite the progress made at the level of the Parliament a number of problematic areas (for distributors) remain in the text and which is of major importance for GIRP members.

Article 12 of the proposals for the regulations presents that largest challenge for distributors. Despite the fact that distributors (not to be confused with importers) are generally speaking not allowed to open the outer or inner packaging of products, the European Commission and Parliament sets out an obligation for distributors to open each pack of medical device and in-vitro medical device to verify the information the manufacturer has included with the actual product.

Furthermore, an amendment proposal by the EU Greek Presidency sets out in a position paper addressed to the Council Working Party on Pharmaceuticals and Medical Devices for Chapters I and III a worrying development for distributors. Clearly an extension of the obligations on distributors to check that all products are accompanied by the required EU declaration of conformity is an impossible requirement for distributors to fulfill.

GIRP deeply fears Member States will take a strict interpretation of the requirement(s) in Article 12.

GIRP is calling for a pragmatic re-wording of the requirement to specify that *"The distributor should not check each product individually, unless he believes that the manufacturer or importer have not fulfilled their requirements."* Such a clarification would make much more sense when considering the nature of the supply chain.

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".

For further information please contact the GIRP office. girp@girp.org

*****

For further information please contact:

Martin FitzGerald, Deputy Director General

Rue de la Loi 26, 10th floor, box 14 — B - 1040 Brussels — Belgium

P: + 32 496 114330 E: m.fitzgerald@girp.org

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.

Through their network of operational facilities, GIRP members employ about 140,000 people and serve over 170,000 pharmacies and other healthcare professionals dispensing medicines to the public. In the performance of their public service role, pharmaceutical full-line wholesalers absolutely guarantee the highest level of quality, integrity and excellence. GIRP members are the trusted supply chain partners of manufacturers, pharmacists, healthcare professionals and, above all, patients, guaranteeing medicines' safety.