GIRP Response to the DG Enterprise and Industry of the European Commission stakeholders consultation on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance

GIRP – "Groupement International de la Répartition Pharmaceutique" – is the umbrella organization of pharmaceutical full-line wholesalers in Europe. It represents the national associations of over 600 pharmaceutical full-line wholesalers serving 32 European countries, including major pan-European pharmaceutical wholesaling companies. Employing 140,000 people across a complex web of facilities they distribute 100 billion Euro worth of medicines every year. In the performance of their public service role they absolutely guarantee the highest levels of quality, integrity and excellence. GIRP members are the trusted supply chain partners of manufacturers, pharmacists, healthcare professionals and, above all, patients for medicines' safety.

GIRP welcomes the opportunity to comment in this consultation process on legislative proposals to strengthen and rationalise the EU system of pharmacovigilance. We regard it as a very valuable exercise in finding the most effective and safe ways to further improve the community system.

We have no specific comments to make on the individual provisions highlighted in the consultation document. However, we would again like to stress that pharmaceutical full-line wholesalers are the vital link in the continuous and safe distribution of medicines from manufactures to retail pharmacies, as well as in some countries to hospitals. Pharmaceutical wholesalers can play an important role in the future in helping to communicate drug safety issues from health authorities and manufacturers to pharmacies using the same forwards and backwards logistics for data information, as currently in place for medicines.

Pharmaceutical full line wholesalers are involved in questions of pharmacovigilance specifically with respect to the ***delivery of medicines, as well as, if necessary, their recall involving reverse logistics***. Recall procedures are in place in order to protect the safety of the patients.

Pharmaceutical full-line wholesalers carry out highly efficient recall procedures in case there is doubt concerning a product within a very short time period.

National recall and emergency procedures are in place to ensure that products are recalled from the market if problems are encountered with a medicine or the marketing authorisation is withdrawn. In most European countries when wholesalers receive notification of a recall (from manufacturers and (or) the authorities) pharmaceutical full-line wholesalers then swiftly inform all pharmacies about the product recall and take the recalled product back from them. However, as mentioned in our response to

the 2006 consultation, such a procedure does not exist on a European level. It could be envisaged to establish, under the control of the EMEA, an interlinked alert system for defective products and for events such as the withdrawal of a marketing authorisation in order to insert a second layer for products with a European marketing authorisation

We would suggest in assessing the result of this consultation that the European Commission services would consider how best to reflect or incorporate a proposal in the legislation to address this matter.

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