GIRP RESPONSE TO: European Commission Public Consultation: Assessment of the Community System of Pharmacovigilance

Name:

European Association of Pharmaceutical Full-line Wholesalers (GIRP)

Type of stakeholder:

European Association of Pharmaceutical Full-line Wholesalers

Organisation (e.g. European patient group or National industry association - if relevant):

n/a

Your comments:

GIRP, the European Association of Pharmaceutical Full-line Wholesalers, embraces the launch of the European Commission consultation process in this respect and regards such a consultation as a useful means of assessing the current system of pharmacovigilance and for assessing ways to further improve the community system.

- **on the specific areas highlighted in the Commission sponsored study which can be summarised as follows:**

  1. **Data sources and safety issue detection**
  2. **The legal framework and new legal tools**
  3. **Decision making in pharmacovigilance**
  4. **Impact of communications and actions**
  5. **Facilitation and monitoring of compliance with pharmacovigilance requirements**
  6. **The need for quality management and continuous quality improvement.**

- **on your experiences of the Community system overall**

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 full-line wholesalers are therefore involved in questions of pharmacovigilance specifically with respect to the dispensing of medicines, as well as, if necessary, involved in their recall. Recall procedures are in place in order to protect the safety of the patients.

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Pharmaceutical full-line wholesalers offer very efficient recall procedures in case there is doubt concerning a product within a very short time period. In the event of a product recall due to doubt concerning the product, the pharmacist has to confirm:

a. that the medicines have not been dispensed, and
b. that the medicine has been delivered from the wholesalers carrying out the backward logistics.

Therefore, national recalls and emergency procedures are in place to ensure that products are recalled from the market if they have problems. National health authorities inform the national association of pharmaceutical full-line wholesalers and their members in case of a necessary recall.

- **on any part of the Community system (section 1 of this consultation paper describes the system and those involved directly)**

Please refer to the above mentioned.

- **on how you could better contribute to the Community pharmacovigilance system**

It could be envisaged that pharmaceutical wholesalers play a role in the future in communicating 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.

- **on suggestions to strengthen the Community pharmacovigilance system**

To date there is no information system in place neither for product recalls or pharmacovigilance concerns which would strengthen the system. It would be advantageous to communicate product recalls and pharmacovigilance concerns to the European Association of Pharmaceutical Full-line Wholesalers. If there is no communication system in place to inform about a pharmacovigilance concern or case, there is no possibility to act against, or to correct the movement, or to recall the product. The European Association of Pharmaceutical Full-line Wholesalers can inform all national associations, as well as the pan European wholesaling companies in addition to national systems already in place.

- **any other comments**