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GROUPEMENT INTERNATIONAL DE LA REPARTITION PHARMACEUTIQUE
EUROPEAN ASSOCIATION OF PHARMACEUTICAL FULL-LINE WHOLESALERS

AVOIDING THE RISK OF COUNTERFEIT MEDICINES ENTERING THE MARKET

GIRP Position Paper

Introduction

GIRP, "Groupelement International de la Répartition Pharmaceutique Européenne", is the umbrella organisation of pharmaceutical full-line wholesalers in Europe. GIRP represents the national associations of over 600 pharmaceutical full-line wholesalers serving 31 European countries, as well as major pan-European pharmaceutical wholesaling companies.

GIRP members employ about 140,000 people and distribute medicines with an annual value of over 100 billion Euro. GIRP is the communication platform between its members and all players in the healthcare sector, providing information and co-ordinating informed opinions on all matters relevant to the distribution of medicines.

Background:

Pharmaceutical full-line wholesalers are anxious about the risk of counterfeit medicines in the market, as counterfeit medicines endanger the health of patients and citizens.

Some of the principal types of counterfeit products include:

- High value lifestyle medicines
- High value lines
- High volume, mid-priced, medicines

The highest risks of counterfeits entering the market are certainly the internet and mail order sales of medicines. Medicines ordered through the internet and delivered by mail are impossible to control. Consumers and patients alike need to be fully informed of the dangers inherent in obtaining medicines from unqualified, uncertified Web-Sites or mail order stores without the actual involvement of a pharmacist.

GIRP members are committed to a zero tolerance approach to the risk of counterfeit medicines in the trusted legitimate supply chain!

However, to maximise impact, an anti-counterfeiting strategy requires a co-ordinated long-term stakeholder effort where:

- all share accountability
- all bear responsibility
- all invest resources

Main risk factors for counterfeit medicines entering the legitimate supply chain

- **'Spot market' for medicines:** Manufacturers often sell to other traders large quantities of products at prices far below the wholesalers purchase price. Transparent ex-manufacturers' prices which would avoid 'spot markets' are not existing.
- **Insufficient license controls and GDP compliance for non pharmaceutical full-line wholesalers:** In countries where only full-line wholesalers can legally exist (public service obligations) on the market, often other distributors are active.
- **Selling to and buying from unlicensed sources:** Not all actors sell and buy only to and (or) from registered and controlled actors, who respect the Guidelines on Good Distribution Practice.
- **Supply quota systems:** Supply quota systems imposed by manufacturers on pharmaceutical full-line wholesalers create unnecessary shortages on the market.
- **No communication to the supply chain about existing counterfeit medicines:** Manufacturers are usually more informed of counterfeit medicines detected on the market.

GIRP Members' actions to avoid the risk of counterfeits medicines entering the supply chain

GIRP's members implement a package of practical measures to ensure that the risk of counterfeit medicines entering the supply chain is minimised. GIRP members carefully select suppliers, undertake sample checks, specifically train staff, and run counterfeit risk awareness campaigns as part of their activities:

1. **Careful selection of suppliers:** Purchase systems ensure that medicines are only bought from manufacturers or other wholesalers which are officially authorised.
2. **Sampling system from new suppliers:** Pharmaceutical full-line wholesalers operate a sampling system upon delivery by carrying out random, yet systematic, sampling checks of the delivery, especially in the case of a delivery from a new supplier.
3. **Special training:** Staff at the product receiving and return areas are fully trained in the good distribution practices, including the identification and handling of counterfeit medicines. Information tools such as brochures and posters have been produced in this respect.
4. **Tracking and Tracing:** Pharmaceutical full-line wholesalers advocate the development of a harmonised tracking and tracing system. GIRP members are continuously following the developments with respect to enhanced tracking and tracing systems and constantly keep themselves up to date on the state of the art technology. However, a uniformed track and trace system for Europe still lacks the affordable, well proofed and effective technology which would allow for the implementation of a seamless track and trace procedure throughout the supply chain without resulting either in sky rocketing costs or, unacceptable delays for pharmacies and patients. The national identification number, expiry date and batch number in machine readable format are prerequisites for any kind of coding system.
5. **Identification of potential counterfeit medicines:** If ever there is doubt concerning a product, the regulatory authority will be immediately alerted, as well as the original manufacturer, and can in case of doubt implement effective measures to ensure products are not dispensed to patients.
6. **Recall procedures:** 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 that it may be a counterfeited medicine, 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

7. **Auditing:** In order to obtain and keep a license as a full-line wholesaler, full compliance with Good Distribution Practice (GDP) is necessary and is controlled by the authorities of the Member States. Governments and health authorities should regularly control the licenses and GDP compliance of non pharmaceutical full-line wholesalers. Additionally, pharmaceutical full-line wholesalers thoroughly and systematically 'screen' new suppliers. GIRP members are very willing to collaborate with health authorities and all stakeholders in the further development of auditing systems for the supply chain, as well as for suppliers.
8. **Transparency:** GIRP members are committed to cooperate with all manufacturers in the fight against counterfeit medicines which can only be successful if done together. These challenges should be faced in the spirit of togetherness involving manufacturers, authorities and all supply chain partners.

There are still remaining challenges to cope with to avoid counterfeits entering the legitimate supply chain. These challenges should be faced in collaboration with health authorities, manufacturers and all partners of the supply chain.

Conclusion

GIRP firmly supports further actions on ways forward to avoid the risk of counterfeit medicines entering the legitimate supply chain. Pharmaceutical full-line wholesalers are ready for further and stronger collaboration with all stakeholders. An improved and closer collaboration between the public health administrations, European and national authorities, manufacturers, wholesalers and pharmacies to develop an efficient and fast information system, which will contribute to decreasing the risk of counterfeit medicines entering the legitimate supply chain, is necessary.

GIRP, as the European Association of Pharmaceutical Full-line Wholesalers has on many occasions called for close collaboration between health authorities, manufacturers and the supply chain in order to develop an efficient early warning system.

The only way to avoid the risk of counterfeits in the supply chain is to develop and maintain **a close, interlinked, collaborative information system involving health authorities, manufacturers and all partners of the supply chain**. Moreover, government policies and programs have to support the full integration of the supply chain in all plans in order to fight against the risk of counterfeit medicines in the legitimate supply chain.

Further measures to avoid the risk of counterfeit medicines in the market should include:

- the regulation of Internet and mail order pharmacies and information to consumers that they risk their health by buying unsafe medicines over the internet.

Specific measures for the legitimate supply chain should include:

- control of the legal provisions that all actors in the supply chain only buy and sell from/to certified sources;
- control of licenses and GDP compliance as well for non full-line distributors, in order to ensure that no counterfeit medicines can appear on national markets;
- provision against "spot markets" for medicines; and
- legal actions to avoid supply quota systems, which are creating severe product shortages on national markets.

However, GIRP would like to emphasise that sufficient and effective measures against counterfeit medicines entering the legal supply chain can only be taken when ALL partners closely work together!



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ANNEX I

Legal Aspects

The following Directive as well as the following Guidelines legally offer guidance to pharmaceutical full-line wholesalers in combating the risk of counterfeit products:

- Directive 2001/83/EC, as amended by Directive 2004/27/EC
- Guidelines on Good Distribution Practice 94/C 63/03

Directive 2001/83/EC, as amended by Directive 2004/27/EC

The Community Code relating to pharmaceutical products for human use, Directive 2001/83/EC, was amended in 2004 after a two-year review process by Directive 2004/27/EC.

Articles 46 to Article 51 of Directive 2001/83/EC of European Parliament and Council, as amended by Directive's 2004/27/EC provisions relate to the use of only active substances as starting materials for a medicinal product, which have been manufactured in compliance with Good Manufacturing Practice. Article 80 and Article 111 provide the legal provisions for inspections at manufacturers of the active substances used as starting materials. Thus these provisions provide the appropriate legal basis for common activities.

Guidelines on Good Distribution Practice 94/C 63/03

Also, the Guidelines on Good Distribution Practice of Medicinal Products for Human Use ('GDP Guidelines', 94/C 63/03) guarantee the quality of the medicines delivered.

Article 31 of the GDP Guidelines provides that counterfeit medicinal products found in the distribution network should be kept apart from other medicinal products to avoid any confusion. They should be clearly labeled as not for sale and competent authorities and the holder of marketing authorisation of the original product should be informed immediately.