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European Commission
Enterprise and Industry Directorate-General

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_03/consult_counterfeit_20080307.pdf

EC CONSULTATION:
KEY IDEAS FOR BETTER PROTECTION OF PATIENTS AGAINST THE RISK OF COUNTERFEIT MEDICINES

The counterfeiting of pharmaceuticals violates health and safety legislation and regulation. The counterfeiting and piracy of pharmaceutical products is subject to numerous legislations and regulations in the field of pharmaceutical products, intellectual property rights, criminal and penal field, customs and border, etc.

Brand-name, generic and over-the-counter pharmaceuticals have been the subject of counterfeiting activities. In addition, the basic components of pharmaceutical products – active pharmaceutical ingredients (APIs) and excipients - have also been the subject of counterfeiting activities.

Distribution of pharmaceutical products throughout the world is complex and varies significantly from jurisdiction to jurisdiction. Regulation, investigation and enforcement of activities in the pharmaceutical sector are governed by a multitude of legislation and regulation covering diverse fields, including regulatory approval and safety, criminal and penal activities, intellectual property, customs and border activities as well as consumer protection.

The National Agency for Medicines (NAM, Finland) welcomes this initiative of the European Commission.

Detailed comments

The European Commission has identified three areas of regulation of medicinal products where improvements to the regulatory framework can make a contribution to protecting against counterfeit medicinal products:

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1. Medicinal products placed on the market;

2. Medicinal products brought into the Community without being placed on the market; and

3. Active ingredients supplied to the manufacturer of medicinal products placed on the market.

These initiatives of European Commission concentrate mainly for enforcement improvements around regulatory and inspection issues for medicinal products.

Medicinal products placed on the market

For area 1 (Medicinal products placed on the market) the NAM endorses the initiative (4.1.1.) that the responsibility of all players (brokers, distributors) around EU in logistic chain should be same as to those of wholesalers. However, this should be realized by auditing instrument without significant increase of the work load of authorities.

The NAM proposes that the outer packaging of medicinal products to be sealed (key idea 4.1.3.), should be applied to only categories of products chosen on a risk-based approach. We cannot see the ban of repacking as solution for a potential misuse of original packs. It should be taken into account that the re-packing is still one possibility for solution of availability problems in EU's small markets. In Finland, dividing packages in pharmacies is also common for example in cases of dosage dispensing. Possibilities for pharmacies to open packages in such cases should be at least clarified.

The NAM endorses the key idea (4.1.5.) to require the possibility of tracing ownership and transactions of a specific batch. However, mass serialisation (4.1.6) feature on the outer packaging should be applied only on a risk based approach.

The NAM endorses the idea of increase transparency concerning authorised wholesalers through a Community database.

Medicinal products brought into the Community without being placed on the market

It is important that transit shipments through an EU Member State will be covered by the legislation. For example, a lot of counterfeit medicines may be shipped in large containers from Far East countries and delivered e.g. through Finland to Russia. Since these are transit shipments the customs authority has only limited possibilities to inspect and confiscate counterfeit products. The National Agency for Medicines endorses that the Directive

2001/83/EC is amended to state that the Directive does apply to these kind of transhipment of medicinal products.

Active ingredients supplied to the manufacturer of medicinal products placed on the market.

In Europe, regulation of API manufacture and distribution is conducted at a much less intense level than for medicinal products. The types of control are variable and inconsistent between European states. Thus it becomes possible for uncontrolled APIs (and also excipients) to enter the legal manufacturing process. Current global Heparin case may be an example of progress in this field.

The NAM endorses the key ideas of 4.3.1 requirement of a mandatory notification procedure for manufacturers/importers of active substances and 4.3.2 enforceability of GMP. It is the opinion of the NAM that the acceptance of third-party audits is not connected to the counterfeit issue of drugs. The NAM cannot see the addition of inspection responsibilities of authorities as practical and feasible solution to the counterfeit problem connected to the API's. Additionally to key ideas presented strengthening the rules for appropriate sampling and testing procedures of received APIs and raw materials should be carefully considered.

Conclusion

It is the opinion of the National Agency for Medicines that the important phenomenon behind the drug counterfeiting issue is the lack of definitions for counterfeits and pharmaceutical crime in the EU legislation. Based on this the National Agency for Medicines proposes that the definitions of counterfeit medicinal product and pharmaceutical crime should be taken into account when discussing the key ideas.

There is real need for legislative definitions for these issues. This can be made by adding definitions to the Directive 2001/83/EC as European-level binding instrument for the issue. It should be pointed out that there is also a need for real European-level coordinating body with clear definition of role and responsibility in the area of anti-counterfeiting of drugs.

In Finland internet is the main source of counterfeit medicines that are reaching patients. We would like to propose internet pharmacies and internet commerce of drugs to be included EU commission's initiatives in the area of anti-counterfeiting. Internet is currently a widely used route for supplying counterfeit medicines and problems related to it should be properly taken into consideration.

Training (health authorities, customs, law enforcement personnel, etc.) and public education should be also taken in the list of key ideas.

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