Comments of the German Statutory Health Insurance Funds

AOK-Bundesverband, Bonn

The Federal Association of Local Health Insurance Funds

BKK Bundesverband, Essen

The Federal Association of Company Health Insurance Funds

IKK-Bundesverband, Bergisch Gladbach

The Federal Association of Guild Health Insurance Funds

Bundesverband der landwirtschaftlichen Krankenkassen, Kassel

The Federal Association of Agricultural Health Insurance Funds

Knappschaft, Bochum

The Insurance Fund for Miners

Verband der Angestellten-Krankenkassen e. V., Siegburg

Federation of Salaried Employees' Health Insurance Funds

Arbeiter-Ersatzkassen-Verband e. V., Siegburg

The Federation of Workers Alternative Health Insurance Funds

to the public consultation of the European Commission in preparation of a legal proposal to combat counterfeit medicines for human use

6 May 2008

The German Statutory Health Insurance Funds welcome the Commission's public consultation in preparation of a legal proposal to combat counterfeit medicines for human use.

There are different types of counterfeited drugs:

- original product with counterfeit leaflet
- blister pack, package and leaflet are misplaced
- total counterfeit medicines.

Counterfeiting of medicinal products is a condemnable offence because health and life of people are compromised. Confidence and faith in pharmacotherapy are undermined.

Counterfeiting of medicinal products is a criminal offence that predominantly has to be combated by national and European authorities of criminal prosecution. It is essential to enforce their possibilities via a more intensive cooperation between the responsible authorities within the EU and within a member state and also via establishing an international convention of effective prosecution. Especially an intensive supervision and prosecution of illegal internet trade is necessary.

Furthermore it is the duty of the manufacturers, traders, wholesalers and pharmacies to guarantee safe and effective medicines. We welcome and support their efforts.

A safer distribution chain will help to combat counterfeits. The German Statutory Health Insurance Funds fully agree to the Commission's proposals

- to subject all participants of the distribution chain (wholesaler, brokers, agents, traders) to the obligations for wholesaler that especially includes the acceptance of GMP and GDP and also regular audits by qualified authorities
- to strengthen provisions of inspections and supervisions, including more inspections in third countries, by making them compulsory

Furthermore, they call on the Commission to contribute and support the WHO International Medical Products Anticounterfeiting Task Force (IMPACT).

The Commission proposes "improving product integrity through a unique seal from the manufacturer to retailer or wholesaler, using a risk-based approach, supported by a ban on repacking". A "ban of repacking" would deactivate the parallel trade with pharmaceuticals. Parallel trade is legal according to the European Treaty so a general ban of repacking would not be helpful. Furthermore the "parallel trade system" is a safe way of distribution. A general ban of repacking would criminalize a whole group of stakeholders, i.e. re- or parallel importers. If a seal-system is used parallel traders will have to use their own seals. This also would correspond to the fact that parallel traded pharmaceuticals have to be authorised and approved in the member state of their use. They are treated as separate medicinal products. From the German Statutory Health Insurance Funds' point of view an alternative option could also be to fix a seal on the blister pack together with a corresponding advice in the leaflet.

The traceability of a medicinal product can be improved via using a "track & trace"-system of mass serialisation. Indeed such a system has to be established within the EU, national solutions won't be effective. Different systems are discussed by industry (e.g. RFID-technology or 2D-barcode) including a pedigree (central register). However a short-term realisation is not realistic.

The German Statutory Health Insurance Funds call on the Commission to amend the current legislation by stipulating that each product should be identified through its INN. This would also contribute to strengthen the security of the product user.

The German Statutory Health Insurance Funds support the Commission's following proposals:

- to submit the manufacturing and import of active ingredients to a mandatory notification procedure
- to control substances
- to make GMP and GDP binding
- to make audits of substance suppliers (manufacturer, importers of medicinal products and substances) mandatory
- to amplify the audits of participants of the distributing chain.

Furthermore the German Statutory Health Insurance Funds call on the Commission to consider following additional measures:

- to enlarge the initiative on nutriments
- to sensitize patients, physicians and pharmacists to the problem of counterfeiting.