EUROPEAN ASSOCIATION OF CHEMICAL DISTRIBUTORS

Brussels, May 2008

FECC CONTRIBUTION TO THE EC CONSULTATION ON
A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES

I. Introduction

The European Association of Chemical Distributors (FECC) represents around 1,200 European chemical distributors. FECC Members, many of them SMEs, create value in the supply chain meeting the demands of over one million downstream users.

FECC Members supply significant quantities of pharmaceutical starting materials to manufacturers of medicinal product throughout Europe. Therefore, FECC is an important stakeholder in the field of safety of medicines in Europe.

FECC is committed to actively promote the WHO – Good Trade and Distribution Practices (**GTDP**) for Pharmaceutical Starting Materials among its Members as a tool to reduce and manage the risks involved in supplying pharmaceutical starting materials to finished dosage form manufacturers, thereby contributing to ”healthy medicines”. FECC would like to request that the European Commission actively promotes the GTDP principles in order to maintain high quality standards in the supply chain, ensure full traceability and prevent contamination during the operations.

FECC welcomes the initiative of the European Commission to consult stakeholders on the amendment of the current regulatory framework. An appropriate cooperation among stakeholders and authorities is vital for a successful implementation and effect of future policy options.

FECC acknowledges the serious concern that counterfeit medicines create at European, but also international level. FECC underlines its willingness to contribute to the efforts to combat counterfeit medicines while preserving the competitiveness of the legitimate pharmaceuticals supply chain.

II. General comments

- FECC supports the call from the European Parliament for an enhanced cooperation at international level. International cooperation is crucial to prevent counterfeiting. FECC's commitment to the promotion of the WHO GTDP is the chemical distributors' contribution to increase the safety of medicines and to reduce the risk of counterfeiting.

- FECC would like to support a harmonised approach among Member States regarding the implementation and enforcement of current legislation and future measures.

- The rapid development of modern technologies and the broad access to the Internet have fostered the marketing of counterfeit medicines. The sales of these counterfeit products through the Internet should be tackled as a priority.

- An awareness campaign addressed to private consumers should be put in place to alert about the increasing number of counterfeit medicines in the market.

III. Specific comments to the consultation paper

In the context of the above mentioned consultation, and particularly the document 'Public Consultation in preparation of a Legal proposal to combat counterfeit medicines for human use. Key Ideas for better protection of patients against the risk of counterfeit medicines', FECC would like to highlight the following points:

- In the section 'A trend towards counterfeiting of life-saving drugs:' the 'total disrespect for patient health' is mentioned as one of the driving factors. Although such disrespect is favouring the trend it is certainly not one of the driving factors.

- In page 2, the concept of 'sub-standard' products is introduced. FECC believes that there should not be a differentiation between counterfeit and sub-standard. In this context, FECC suggests to define Counterfeit Medicinal Products as follows:

A counterfeit medicinal product is a product that is not the medicinal product that it pretends to be. This means that every medicinal product in the market that does not comply with its Marketing Authorization is a Counterfeit Medicinal Product - regardless if the non-compliance was caused by

- Fraud
- (Gross) negligence or

- Accident.

- FECC suggests taking into account the fact that during inspections by the competent authorities the focus is on GMP compliance. Very often the inspectors don't have detailed information regarding the Marketing Authorisations. Therefore they are not able to check the regulatory compliance (e.g.: Are the starting materials seen during the inspection the starting materials included in the Marketing Authorisation?).

- With regard to the tightening of the requirements for manufacture, placing on the market of active substances and inspections, FECC believes that 'active substances' should be replaced by 'pharmaceutical starting materials'. Some of the most serious incidents regarding counterfeit starting materials were caused by excipients. FECC believes that all excipients should be manufactured according to appropriate standards in order to maintain high quality standards in the supply chain.

- FECC supports an approach that promotes Supply Chain Integrity. In this context, batch traceability (particularly regarding: manufacturing batch number, original batch size, shipped and received quantity, packaging, labelling and sealing, transport and storage record, including deviations, damages, etc. during transport and /or storage) for all the stages of the supply chain should be possible from documents that accompany any shipment of an active substance. This documentation should be a kind of control

  a) to be established by the manufacturer when shipping the batch,

  b) to be completed at all the involved intermediate stages of the supply chain, i.e. by importers, traders, brokers, distributors, etc., and finally

  c) to be handed over with the shipped batch to the end user, i.e. the manufacturer of the medicinal product and/or MA holder, respectively.

- Regarding the minimum professional qualifications for auditors FECC is of the opinion that not only those requirements defined for the qualified person should be taken in consideration. It is more important and useful if the auditors are familiar with the processes (chemistry, physics, (micro)biology) which they have to audit. A suitable qualification might be the one required by API Compliance Institute (http://www.api-compliance.org/apicomp_auditors.html).

- FECC agrees with the proposal to make regular audits of active substance suppliers on GMP compliance by manufacturers ***or*** importers of medicinal products mandatory

- With regard to the requirement of control of active substances via sufficiently discriminating analytical techniques, it should be noted that Fingerprint technologies should be applied only if a

significant benefit can be achieved. There are only a few cases where NIR is a suitable tool for identification tests.

- FECC is concerned that the proposals under point 4.3 may lead to a kind of 'audit tourism'. An idea could be to centralize the audits within the competent authorities.

- Regarding the Regular audits of non-EU API-manufacturers, such audits should be conducted by qualified auditors. This qualified auditor could be (but not exclusively) the Qualified Person of the MA holder, or the Qualified Person of the holder of the import licence (importer). This should be complemented by announced or unannounced inspections by the competent authority, and wherever possible, by bilateral arrangements between countries applying GMP standards equivalent to those in the EU.

FECC is committed to give input to the European Commission and participate in the process for a potential amendment of legislation as well as technical guidance.

FECC will be pleased to provide further input on the points above. For further information:

Hendrik Abma
Director General
European Association of Chemical Distributors (FECC)
Rue du Luxembourg, 16B
1000 Brussels
Tel.: +32 2 679 02 60
Fax: +32 2 672 73 55
Website: www.fecc.org