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.

Dear Madam/Sir:

Attached please find the results of a survey conducted by the European Qualified Person Association regarding European Commission's 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.

In order to support the request of the EU Commission, the Board of the QP Association has set up a questionnaire with the intention to obtain feedback from our members, which we consider to be one of the affected stakeholders of the processes outlined in the key ideas.

The questions posed are as follows:

1. Do you think that the problem of counterfeit medicines is well addressed in the EU Commission proposal?

2. Are the responsibilities as well as the task to be fulfilled by the Qualified Persons correctly addressed?

3. Do you support EMEA's idea to regulate products imported for the purpose for exportation as stringent as products imported to be placed on the Community market?

4. Do you think that a system for mandatory GMP inspections at API manufacturers by EU Authorities (in the EU and outside of the EU) should be established?

5. Do you think that the various initiatives (European Commission, EDQM, WHO, OECD, FDA) are coordinated in a sufficient way?

Besides a mere yes/no answer there was the possibility to submit individual comments, an option that was exercised extensively by the respondents.

Please find attached the charts showing the overall agreement or disagreement expressed by the respondents and all comments as submitted in an attachment.

The comments to the individual questions may be summarised as follows.

1.) Although 75 % of the respondents consider the problem of counterfeit medicines well addressed in the EU Commission proposal there is concern about the following points:

- National legislation allowing or encouraging parallel imports and internet trade
- Counterfeit medicines being considered a GMP issue rather than a criminal activity and therefore shifting responsibility from authorities to the already overloaded quality systems of manufacturers
- Missing definitions of the role and responsibilities of the regulators, law enforcement organisations and the manufacturers and brokers, traders and agents

2.) Only 50 % of the respondents consider the responsibility of the Qualified Person correctly addressed in the proposal. This might in part be influenced by a growing tendency in Member States to address tasks to QPs that are not directly covered by the European regulations.

- As the QP declaration on APIs is widely misinterpreted as a responsibility of the QP to personally perform audits at API manufacturers, there is considerable concern that in future the QP when certifying a batch may also have the responsibility to assure Good Distribution Practice throughout the product's supply chain
- Therefore a clear definition of responsibilities of the QP of manufacturer or licence holder would be highly appreciated.

3.) A majority of 90 % of the respondents agree with the idea to regulate products imported for the purpose for exportation as stringent as products imported to be placed on the Community market?

- There are only a few comments not in favour for this idea.

4.) Also a majority of 85 % of the respondents would welcome a system for mandatory GMP inspections at API manufacturers by EU Authorities (in the EU and outside of the EU).

- The actual situation is considered an intolerable burden on both API producers and on drug product manufacturers that leads to inconsistent approach by several respondents.
- On the other hand a number of comments pointed out, that authority inspections would be less efficient, costly, slow, and reduce flexibility.
- Focus is seen on API manufacturers outside EU and US.
- Several respondents strongly advocate a system to solve this problem globally by accepting GMP inspections of non EU Authorities also and to accept third party audit reports.

5.) Only a minority of 35 % of the respondents believe that the various initiatives (European Commission, EDQM, WHO, OECD, FDA) are coordinated in a sufficient way

- We consider this an alarming result; although some of the comments indicate there is little knowledge about all the ongoing initiatives.
- As counterfeit drugs are a global problem and the criminal organisations behind this activities are well organised globally acting, our members consider an isolated European approach including numerous possible interpretations in the individual Member States as not sufficient promising.

Best regards,
Dr Bernd Renger
Chairman, European QP Association