Introductory Speech of

Director General Heinz Zourek

1st European Parliamentary Symposium
"Putting an end to Drug Counterfeiting"

Round Table No. 1: "EU and International Initiatives against Counterfeiting"

"What does the European Union do to fight against drug counterfeiting?"

Brussels
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Dear Mme Grossetête,

Dear Members of Parliament,

Ladies and Gentlemen,

Dear Panel Members,

"Putting and end to drug counterfeiting" – This vigorous call from the European Parliament reflects the serious concerns of European citizens to become victims of counterfeit medicines. I also understand this call, as well as the numerous questions from the European Parliament to the European Commission over the past year, as a reminder to the international community and the EU to take action on this topic. I fully agree with the organisers who set the scene for this round table to address a global problem. Let me take the opportunity of this symposium to present our views and activities in a global context and at an EU level.

Let me start by highlighting the actions that have been taken at an international level:

Already in the 80ies, WHO started initiatives to combat counterfeit medicines, which include an acknowledged definition. When developing global technical guidelines for marketing, manufacturing and distribution of medicines, WHO did this with the particular view to minimise the risk of counterfeit medicines. WHO' s recommendations have been taken into account in the EU.

The Parliament has urged the Commission to support a WHO convention on counterfeit medicines, which would be a lengthy project but said to lead to the highest commitment of all parties. However, in a situation that requires urgent action, I think it is important to achieve short term results. For this reason, I highly support the concept of the International Medical Products Task Force IMPACT to establish recommendations in a "counterfeit-net-world".

At the end, all IMPACT partners must be convinced about the results agreed. This is the major challenge WHO has to face. In this spirit Directorate General Enterprise and Industry experts have played a constructive and decisive role at the conferences in 2006 in Rome and Bonn.

What has the European Community done to prevent counterfeit medicines? This is of course the question with which the Commission is confronted most frequently by the European Parliament.

As Director General of DG Enterprise and Industry with responsibility for managing initiatives concerning pharmaceutical legislation in the EC I have assigned utmost priority to aspects related to patient safety.

The pharmaceutical legislation was first adopted 40 years ago and the principles for marketing, manufacturing, importation, exportation and distribution – as they stand today – were adopted in 1975. The EC regulatory system covers defined responsibilities of the persons and companies involved into the various activities concerning the marketing, manufacturing and distribution of medicines.

Those who manufacture and import medicinal products must be authorised to do so. They are under close supervision by the competent authorities of the Member State to comply with Good Manufacturing Practice.

In addition, a "closed" distribution system is foreseen: Distributors, including wholesalers, must furnish proof that they buy medicines from reliable sources which are authorised to sell medicines. Member States supervise that these provisions are complied with.

As you are aware, the counterfeit problem in the legal supply chain has been described by WHO to be relatively low in regions such as the EU. I dare to say that this can also be attributed to the effective system of legislation and enforcement by supervisory authorities, police and customs.

Nevertheless, a changing environment requires careful monitoring and analysis: Member States have successfully established cooperation networks to exchange experiences on specific cases of counterfeit medicines.

Parallel to this, DG Enterprise and Industry has recently launched a specific project on combating counterfeit medicines to specifically analyse the current

situation and assess policy options for the pharmaceutical area. If the outcome of the project reveals the need for changes in legislation, we will take appropriate steps. Cooperation with European and international partners in this project is of key importance and consequently ensured.

Counterfeiting is a clear violation of intellectual property rights and this has been on the Commission's agenda for many years. When adopting legislation on the protection of such rights it was well understood that medical products belong to the most risky targets of counterfeiters but are not the only ones. New legislation on the enforcement of intellectual property rights, including relevant customs action reflects the level of agreement of the EU Member States and the European Parliament on these topics.

The results of this new legislation are impressive: Customs statistics indicate that the amount of fake medicines which were stopped at the EU external border are alarming and challenging for our systems. But at the same time they confirm the EU' s regulatory and enforcement strategy. I am sure that the representative from the Commission Directorate General Taxations and Customs Union will provide you with more details on this in today' s discussion.

A few weeks ago, a proposal for a Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights has been approved by the European Parliament in its 1st reading. EU-wide penalties are foreseen. This is a major step to combat counterfeit medicines.

In the field of technologies, the European Commission has just recently launched an initiative on RFID – Radio Frequency Identification Systems.

Substantial positive feedback was received in a public consultation on the future of this technology. In this consultation, the pharmaceutical sector was identified as an area which could benefit from RFID applications.

On the other hand I heard the concerns from various stakeholders that the technology needs further development before it will be affordable for health care systems. Therefore, as a first step I think it is important to define which objectives should be achieved. Different products and regions may need different technical solutions. However, joint activities of various services on RFID and other track and trace solutions are meant to already prepare today for the options of the future.

In view of this overall situation and our measures I strongly contradict the reproach that the EU has been the "Sleeping Beauty". On the contrary: We are striving forward our EU agenda to combat counterfeit medicines in the EU and as part of a global problem.

Today's conference provides an excellent opportunity for an exchange between different concepts. I am grateful for the opportunity to give the EU perspective and I welcome further discussions with our international partners.

This said I invite my round table partners to present their views.

Thank you very much for your attention.

Note: Only actual speech given is valid.