

## **Prague Resolution on counterfeit medical devices**

The competent authorities for medical devices met in Prague, under the Presidency of the Czech Republic for their 23<sup>rd</sup> Meeting of Competent Authorities for Medical Devices on 24 - 25 February 2009. They discussed the situation regarding certain initiatives currently being under consideration in other forum on the authorisation of the manufacturing and the supply chain of medical products as well as their ingredients / components.

The competent authorities for medical devices note that there are currently two initiatives on the table and one pending which could influence the working of the medical devices sector.

The two initiatives currently under discussion are:

- a) A Draft Convention of the Council of Europe on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health;
- b) A WHO IMPACT draft document on Draft Principles and Elements for National Legislation against Counterfeit Medical Products;

The pending document is a document on counterfeit medical devices and parallel imports being produced as a result of a recent questionnaire of the European Commission requesting stakeholders input on the scale of the medical devices supply chain problem.

The competent authorities for medical devices expressed concern at their meeting that a quick analysis of the Draft Convention of the Council of Europe and the WHO IMPACT document indicates that medical devices are included within their scope. The competent authorities for medical devices furthermore expressed concern that some of the requirements in the two documents are not appropriate for medical devices and are directed more at the pharmaceutical system. There was also concern that these documents were being produced with no sufficient consultation/discussion with the medical devices sector across Europe.

The competent authorities for medical devices noted that a European debate as to whether there was an issue with counterfeit medical devices in terms of public health concerns has yet to take place. Any such debate should take place within the medical devices sector where on the basis of experience of the sector informed decisions could be taken as to whether there was a problem. If the conclusion was that a problem existed, then the sector can consider how best this could be addressed. This could be within the current boundaries of the existing medical devices directives or by amendments to those directives. On an international level this subject could be addressed within the Global Harmonisation Task Force (GHTF).

The competent authorities for medical devices therefore respectfully request those drafting the draft Convention of the Council of Europe and the WHO IMPACT document consider removing the references to medical devices from their documents. The competent authorities also ask that the European Commission publish their Options Document as a matter of urgency so that an informed debate can take place within the medical devices sector.