

Prague Resolution on recast of medical devices directives

The competent authorities for medical devices met in Prague, under the Presidency of the Czech Republic for their 23rd Meeting of Competent Authorities for Medical Devices on 24 - 25 February 2009.

During the meeting, member states noted the intention of the European Commission to revise the medical devices directives to both simplify the regulatory regime but also to strengthen and improve its functioning.

To assist this programme, member states conducted an analysis of those areas that currently did not work as well as they should and suggested various proposals of improvements that should be made.

Such areas and measures included:

1) Notified bodies – the meeting agreed that the designation and control of individual notified body should remain the responsibility of individual member states. However, Member States identified a need for more specific and mandatory designation criteria. Consideration should also be given to updating the Designating Authorities Handbook and giving it a legal status. Additionally, a mandatory programme of Peer Review covering both notified bodies and those organisations responsible for their designation and control should be introduced.

2) EUDAMED – member states reinforced their belief that the European Regulatory Data Base should be an essential post market surveillance tool. However, the meeting agreed that both the information collected and the systems operation and issues of accessibility to data collected needed to be revised to maximise its effectiveness.

3) In-vitro Diagnostic medical devices directive – The meeting agreed that this important directive was urgently in need of fundamental review and updating.

Member states also felt that this should remain as a separate directive and not merged with other medical device directives.

4) Quasi medical devices -The meeting concluded that amending the legal definition of medical device contained in the medical device directive to include “quasi medical devices” would be wrong and, in fact, could cause confusion and uncertainty overall.

5) Decision Making – member states concluded that the consistent interpretation and implementation of the medical device directives was hindered by the absence of an effective process which allowed for decisions to be made that would be binding on all member states.

The meeting agreed that the above issues needed to be addressed in any future revision exercise. It agreed that a small ad hoc group of member states be formed to develop the themes above. The Group’s work would then be discussed in detail at the 24th Meeting of Competent Authorities for Medical Devices in Sweden in July 2009.

The meeting also discussed the growing issue of counterfeit medical devices. It was concerned to note that initiatives appeared to have been taken to deal with this matter by organisations and people with no devices expertise and understanding.

The meeting, therefore, agreed to draft a “Resolution on counterfeit medical devices” to the relevant organisations respectively asking that they refrain from such actions and call upon the European Commission to publish its own Options Paper as a matter of urgency so that an informed debate within the medical devices sector can then take place.