Competent Authority Conference on Medical Devices

Maria Donawa

A wide range of topics from national initiatives to European-level policies and actions were addressed at a conference hosted by the Italian Ministry of Health on 7–8 June 2007 in Rome, Italy. This article reviews the important issues that were discussed and the benefits of these types of conferences.

This article was first published in *Medical Device Technology*, vol. 18, no. 5, September 2007.

Unique opportunity

The conference that the Italian Ministry of Health organised was unique for a number of reasons. Competent Authorities (CAs) periodically organise meetings or conferences to discuss national issues, but the Italian conference also covered activities and evolving policy at the European level. Speakers reflected this broader intent and experts came not only from Italy, but also from other CAs such as The Netherlands, the United Kingdom, Ireland and Portugal, and the head of the medical devices unit of the European Commission also attended. Simultaneous translation services were provided.

In her opening remarks, Senator Livia Turco, the Italian Minister of Health, noted that it was the first time that the Italian government had organised a conference on medical devices. No other CA has organised a conference dedicated to discussing such a wide range of issues related to medical devices.

Scope

The two-day programme was divided into eight sessions: update on national and European level medical device regulation, technological innovation, spending and cost-control initiatives in Italy, clinical risk considerations, national and European issues related to in vitro diagnostic (IVD) products, national surveillance activities, national and European activities related to medical device vigilance, and concluding remarks and future issues.

The presentations in these sessions covered important European level issues including the revision of the medical device Directives, problems with borderline and combination products, the role of Notified Bodies and their oversight by CAs, the European experience with IVD products, procedures for improving cooperation among CAs, and issues related to vigilance activities in Member States. New requirements in Italy for classifying and registering medical devices were also discussed by Ministry officials and others.

The conference programme and presentations can be accessed on the Italian Ministry of Health's website: www.ministerosalute.it/dispositivi/dispomed.jsp. The programme and most of the presentations are in the Italian language; however, the presentations from other CAs are in English.

The revision of the device Directives

Ms Sabine Lecrenier, Head of Unit, Cosmetics and Medical Devices, European Commission, provided an insight into the current status of the revision of the Medical Device (MD) and Active Implantable Medical Device (AIMD) Directives. All parties have agreed on the final text of the Directives, which must be translated into the European Union (EU) languages and published in the *European Official Journal*. She pointed out the difficulty of estimating a date of completion of the translation process; however, it is expected that the text will be published in September or October 2007. This will be followed by a 15-month transition period and a 15-month implementation period.

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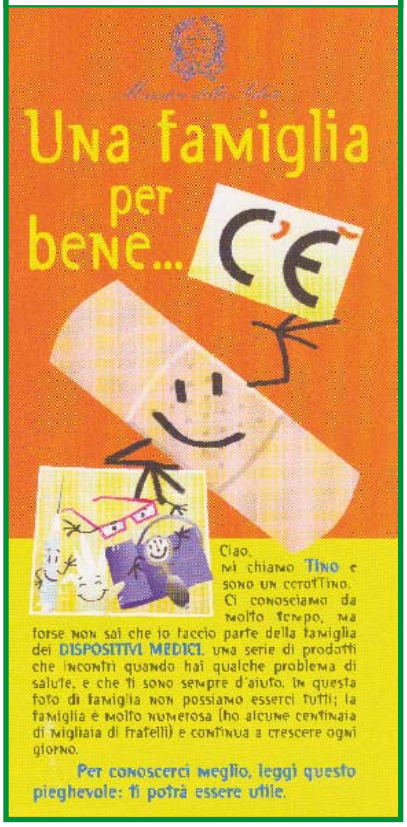
physician, pathologist and pharmacist with 25 years' regulatory experience, worked with the US FDA before becoming President of Donawa Consulting, an international consultancy firm, which provides clinical research, quality management system, regulatory affairs, and European Authorised Representative services to medical technology companies.

Therefore, if the text is published in September 2007, the new requirements will become mandatory in March 2010.

She also reviewed some of the more important changes that are being made in the Directives. For example, there is a more precise delineation between medical devices and personal protective equipment, medicines and biocides. The requirements for clinical evaluation and postmarket surveillance have been strengthened and clarified. There is now a definition of clinical data and clearer requirements for clinical evaluation. It is now explicitly clear that Notified Bodies must check technical documentation as part of the assessment process. A new essential labelling requirement on the use of phthalates, which are classified as carcinogenic, has been introduced. There was intense pressure to include the control of reprocessing in the revised MD Directive. However, the European Commission believes that this is a complex issue related to widely varying practices; therefore, the only change made is the inclusion of a new definition for single-use devices. The Commission
will have three years to study the issue and report on the reprocessing of medical devices in Europe. In fact, a short time after the conference, the Commission published a questionnaire on its website requesting a response by 15 August 2007, and will consider the responses received in the development of its report.

Figure 1: General public guide to medical devices in Italy, which serves as a means of gathering information on the use and safety of medical devices.



Lecrenier also discussed the problems that can occur during the process of transposing the Directives into national law, including incorrect transpositions and overly restrictive transpositions. Steps are being taken to prevent this from occurring, including use of the European Medical Device Experts Group (MDEG) to assist in the transposition process. For example, Member States will transmit the drafts of transpositions to the Commission so that problems can be identified before they are published in final form.

Borderline, combination and innovative products

Sabina Hoekstra-van den Bosch, Pharm.D., of The Netherlands Ministry of Health, Welfare and Sport, outlined current developments related to borderline, combination and innovative products. These products are becoming more complex and some of these complex technologies are being used outside the hospital. There is a blurring of the traditional boundaries between product categories and a shift from combination products to products in which technology is converging. The increasing convergence of medical devices, tissue products and medicines will create more borderline and combination products in future.

The Medicinal Products Directive (2001/83/EC) and the medical devices Directives are not aligned in the way that they define drugs and medical devices. This is leading to continuing discussions on borderline products and it is not clear how this difference will be resolved. In future, it may be necessary to consult with medical device authorities on drug–device combination products that are regulated under pharmaceutical regulation.

New technology group

Sabina Hoekstra-van den Bosch also discussed the European Union Working Group (WG) on New and Emerging Technologies in Medical Devices. This WG is responsible for examining new and innovative developments, considering the safety of patients and users and actions that will not hamper innovation, and actively considering the legal framework for new and emerging technologies.

The initial work being done by this WG concerns medical devices manufactured using nanotechnology. An assessment of existing regulations concluded that, in general, the medical device Directives are adequate to address these types of products; however, several recommendations were made. For example, with regard to the MD and AIMD Directives, the WG recommended that free nanoparticles are classified as Class III products, that regulatory guidance should be developed, and that new mandates for standardisation should be issued by the European Commission. A report was endorsed by the MDEG on 31 May 2007. The European Commission will

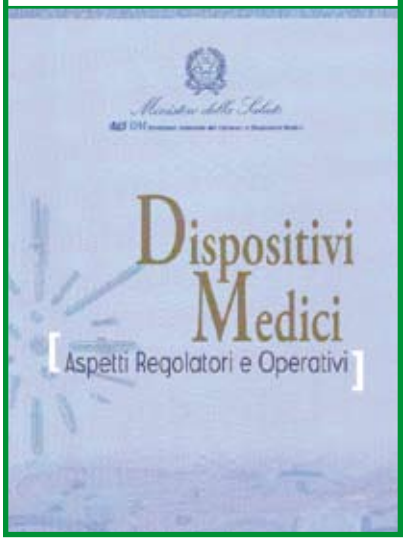


Figure 2: A 135-page booklet for professionals provides an overview of the regulation of medical devices in Italy.

consider the recommendations and its report is to appear on the European Commission website at: http://ec.europa.eu./enterprise/medical_devices. The report was not on this site at the time of writing.

New Italian activities and initiatives

In addition to the presentations, the conference also served as a forum for announcing a number of national initiatives. For example, the Italian Ministry of Health has published a guide for the general public on medical devices (Figure 1), which is being distributed with Italian news publications. This four-page brochure in the Italian language is written in a nontechnical manner that is aimed at adults and young readers. It provides information on what types of products constitute medical devices and how numerous and varied they are, and details the type of information that should be found on a medical device package, including the CE mark. It states that all information provided on or with a medical device must be in the Italian language. It also provides basic information on the way that medical devices are regulated and actions that the Italian Ministry of Health and other European countries take to safeguard the public. These include the authorisation of Notified Bodies, checking manufacturers and the products that they produce, and even preventing the sale of medical devices or requiring their withdrawal from the market. The brochure also provides contact telephone numbers and e-mail addresses in case someone has doubts about the safety or efficacy of a medical device or if more information is sought. Thus, it serves as a means of gathering information on the use and safety of medical devices.

The Italian Ministry has also published a 135-page booklet (Figure 2) that provides an overview of the regulation of medical devices in Italy. It is in the Italian language and is intended for the professional reader who must understand and/or comply with European medical device requirements. The booklet is divided into two parts. Part I covers active implantable medical devices and medical devices and includes chapters on the requirements of the Directives, classification and procedures for demonstrating conformity with the requirements, clinical investigations, databases and new requirements in Italy on registering and classifying medical devices, surveillance and vigilance, publicity requirements, and sanctions. The new Italian registration requirements have been discussed elsewhere.[1,2] Part II covers IVD products and includes chapters that are analogous to those in Part I. It is a useful publication for understanding the Italian government's point of view regarding medical device regulation.

A CD ROM made available by the Italian Ministry of Health provides guidance on classifying medical devices into Classes I, IIa, IIb and III.

A CD ROM is also available that provides a guided approach to the classification of medical devices in accordance with the risk categories established in the MD Directive (Figure 3).

Future conferences

The Italian medical device conference had nearly 500 participants. If there had been no space limitations, another 100 or more would have been able to attend. Thus, the enormous interest in this type of conference is evident. The Italian Ministry of Health provided a means of discussing and exchanging views on issues and initiatives of vital interest to the medical device sector in Italy and beyond. Other CAs should consider doing the same.

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This article was first published in *Medical Device Technology*, vol. 18, no. 5, September 2007.