



Recast of the European Medical Devices Directives: an opportunity to reinforce patient safety

- *Response to the public consultation on the recast of the Medical Devices Directives (1); deadline 2 July 2008*

The *Medicines in Europe Forum* (MiEF), *Health Action International Europe* (HAI Europe), the *International Society of Drug Bulletins* (ISDB) and the *European Association of Hospital Pharmacists* (EAHP), like the European Commission, consider that the current situation of medical devices in Europe is worrying, and that the entire legal framework needs to be reinforced (for active implantable medical devices, medical devices, and in vitro diagnostic devices) (1).

For example, the recent failure of some implantable defibrillators underlines the lack of proper premarketing assessment and postmarketing surveillance, as well as unacceptable alert periods and the inadequate nature of documents informing health professionals and patients on how to react to an alert. Alerts concerning medical devices (usually due to manufacturing quality issues) are frequently issued by healthcare product regulatory Agencies.

Some of the Commission's proposals go in the right direction, but they are not sufficient to ensure the safety of European citizens.

Strengthen before harmonizing

Medical devices, the number and diversity of which have multiplied in a relatively uncontrolled manner in recent years, generate considerable healthcare expenditures and raise a wide range of public health issues.

An ambiguous notion. The very notion of "medical devices" is ambiguous. The classification of medical devices should take into account their intended purpose. For example, medical devices with preventive or curative properties should be considered as "healthcare products", and such "healthcare-product medical devices" should be subject to largely the same rules as medicinal products.

Yes to an harmonization towards the "highest level". The existence of different national classifications of medical devices and different regulatory demands undermines European patients' interests and safety. European patients need a common classification of medical devices, as well as more demanding pre- and post-marketing assessment procedures.

Harmonization towards the "highest level" would mean implementing thorough evaluation of clinical devices that are in fact healthcare products, that are intended for therapeutic or diagnostic purposes and/or carry a risk of adverse effects; and evaluating the added value of new medical devices relative to existing diagnostic or therapeutic means.

To this end it will be necessary:

- to create a central specialized Committee within the European agency (EMA), endowed with the expertise required to assess medical devices, and especially new health technology products;
- to reinforce pre-marketing assessment (especially clinical studies), and also the post-marketing vigilance and surveillance system for "healthcare-product medical devices";
- to improve the transparency of both the decision-making process and pre- and post-marketing evaluation;
- to eliminate existing conflicts of interest with respect to assessment and norms, by placing Notified Bodies under public control.

Reinforce the entire legal framework. The priority is to strengthen the rules, and to produce a "Medical Devices Directive" that will have the same founding impact as the 1965 Human Medicines Directive, which has been gradually modified over the years (becoming, in codified form, Directive 2001/83/EC in 2001, and modified *inter alia* by Directive 2004/27/EC in 2004). Such a Medical Devices Directive, largely resembling the Medicines Directive, would, by its very nature, meet the twin objectives of harmonization and legal simplification.

In brief, what is needed is a regulatory framework close to what already exists for medicinal products. Marketing authorization should be granted for products that are shown to offer real therapeutic or diagnostic

progress, safety, and pharmaceutical quality (good manufacturing practices, systematic quality controls, appropriate packaging, etc.).

Welcomed Commission proposals

MiEF, HAI Europe, ISDB and EAHP take the opportunity provided by this Public Consultation to lend its support to those of the Commission's proposals that are in line with the concept of a true Medical Devices Directives (1).

1. Field of application

Item 1 – legal simplification: it is effectively desirable, for reasons of convenience, to merge the different Directives on medical devices. But this consolidation is not enough to create a solid regulatory framework: what is needed is a founding Medical Devices Directive.

Item 2 – risk-based classification: the classification of medical devices must take into account their intended purpose. Some devices with preventive or curative properties must be considered as "healthcare products" or medicinal products, as this will offer patients more solid guarantees of quality and safety. Similarly, medical devices composed exclusively of non viable human cells and tissues and/or their derivatives must be considered as medicinal products (Regulation on Innovative Therapies n° 1394/2007) if they are intended for medical uses. A risk-based classification must not overlook the fact that medical devices should offer added diagnostic or therapeutic value compared with existing means. Only added efficacy can warrant exposing patients to the possible adverse effects of new devices, and can justify their costs for society.

Item 4 – the status of implantable or invasive medical devices with no medical purpose: implantable and invasive devices already on the market, with no medical purpose ("quasi medical devices"), often intended for cosmetic uses, must at least be considered as medical devices (option 1 proposed by the Commission). This status is more demanding and therefore offers more safety guarantees than "cosmetic product" status. If there is the slightest doubt between two classifications, then patients' interests must be held uppermost: this means in effect that the device in question must be given the most demanding regulatory status.

3. Assessment procedures

Item 6 – necessary changes in essential requirements: as a general rule, the technical documentation of "healthcare-product medical devices" – and especially all medical implantable devices and class III medical devices – should contain more clinical data, including the results of pre-marketing clinical studies. For these devices, a true centralised marketing authorisation procedure would have the merit of eliminating national disparities regarding the use of the EC label and the application of harmonized norms.

Item 8 – Proposals on the functioning and activities of notified bodies: marketing applications for "healthcare-product medical devices" must follow a centralised procedure in order to optimally harmonize the competence, performance and activities of bodies responsible for assessing medical devices, and to guarantee the same level of safety of medical devices for all European citizens. Notified bodies could be integrated within national health product safety agencies and act as rapporteurs, producing assessment reports for EMEA in a transparent manner.

This centralised procedure would avoid the abuses inherent in the mutual recognition procedure for medicinal products, where companies apply first to the least demanding national authority ("forum shopping" denounced by the Commission in proposal 5).

In this context, *MiEF, HAI Europe, ISDB and EAHP* lend most weight to the following Commission proposals:

-proposal 1: to increase transparency into the activities of notified bodies, associated with option 2: creation of "a centralised system of final designation and of control of monitoring by the Commission [we would add: based on the opinion of the specific EMEA committee] with the assistance of [we would add: independent, without conflict of interest] experts";

-proposal 4: to impose the application by the Member States of sanctions and penalties on Notified Bodies if they fail to act properly, associated with option 1 ("the reinforcement of controls on the nomination (including setting out and defining the role of accreditation) and monitoring of the Notified Bodies by Member States");

-proposal 5: to put an end to "forum shopping" [choice of the Notified Body most likely to provide a favourable opinion] by manufacturers.

Items 9 and 10 – Marketing authorisation for all "healthcare-product medical devices": Companies marketing medical devices in the highest-risk category, and also all "healthcare-product medical devices", must be obliged to obtain marketing authorisation before releasing their products. This marketing authorisation must be centralised and be granted by EMEA within a period no shorter than that provided for medicines' evaluation (210 days, including at least 80 days for data analysis by the rapporteurs); a longer period may be required in order to take into account the specificities of these medical devices, and the difficulties of finding the necessary independent expertise. EMEA should create an internal multidisciplinary expert group on medical devices.

Item 11 – EMEA intervention in the assessment of medical devices: with respect to EMEA opinions on highest-risk medical devices and on all "healthcare-product medical devices", manufacturers should submit their applications directly to EMEA. EMEA would then give an opinion to the European Commission on the granting of marketing authorisation for the device in question, based either on the decision of the specific EMEA committee (option 1) or after calling on at least two national agencies to act as rapporteur and co-rapporteur (option 2). The option 2 would allow member states with less expertise in the field of medical devices to benefit from the know-how of other, more "expert", member states. National agencies must also use specific committees, composed for example of former members of Notified Bodies.

Options 3 and 4, that would maintain the overall responsibility of the Notified Body delivering the certificate, do not offer European citizens the best guarantees of safety and run against several other proposals to improve assessment harmonization within the European Union by aiming for the "highest level" (notably proposal 5 of point 8).

Item 12 – Access by the specific EMEA Committee to assessment reports of Notified Bodies [or specific committees of national agencies]: extension of EMEA medical device Committee controls to all assessment reports written by Notified Bodies corresponds to good practice: it is crucial for the transparency and credibility of the system, and is needed to improve assessment quality and to be able to demand corrective measures if need be. These assessment reports should be used for producing public assessment reports by Agencies, which have to be accessible to citizens (Regulation 1049/2001).

4. Vigilance

Item 13 – Proposals to improve medical device surveillance: To correct the obvious under-notification of accidents within the European Union, and to ensure that all member states react in the same way to alert and surveillance data, all five of the Commission's proposals are important.

Proposal 1 proposes to "*to establish an obligation for the medical establishments and healthcare professionals to report incidents and to invite patients to do the same, to introduce timelines for reporting and corrective actions, to give certain publicity to the corrective actions of the manufacturer*"; we propose to add that:

-these reports must be submitted to Member State healthcare authorities, in the language of the reporter (for reasons of convenience), and in a simple manner (for example, online, through the healthcare authority's website);

-manufacturers must also be obliged to notify incidents of which they become aware through their own surveillance system.

National authorities must then send their reports to EMEA, so that EMEA can "*coordinate vigilance reports and detect signals*" (proposal 3).

To "*allow the Commission to impose restrictive measures, on the basis of the opinion of the Medical Device Committee in EMEA*" (proposal 4) seems indeed to be the best way of ensuring that Member States rapidly take all the measures necessary to protect patients.

Exchanges of information among national healthcare authorities, and also with the public, on incidents and corrective measures must be improved, and must go beyond the GHTF framework (proposal 5).

5. Market surveillance

Market surveillance includes ensuring product conformity and taking appropriate sanctions. Yet, in 2008, too often, random checks (EC labels based on conformity as claimed by manufacturers or their representatives) are considered sufficient, and regulatory monitoring of medical device conformity (inspections for example) is lacking. Dissuasive Europe-wide sanctions must be applied to manufacturers whose products fail to conform to EU standards.

Item 14 – Reinforcing market surveillance: The measures proposed by the Commission to strengthen market surveillance while tackling for poor cooperation due to a lack of resources in some countries are necessary, especially the creation of a "*central European registration system for devices*" and "*in cases where the Commission has to take a decision, to have the possibility to ask for a scientific opinion of the Medical Device Committee in EMEA*".

6. Borderline cases

Item 15 - Appropriate product qualification. The possibility of asking healthcare authorities for preliminary opinions before starting product development would create an extra workload that would be costly and could divert experts from their examination of marketing applications, that require definitive opinions. Furthermore, it would effectively mean that the authorities would be acting as consultants for the private sector.

In the case of products that are borderline between medical devices and medicinal products, the status offering patients the best guarantees of safety should be adopted.

7. GHTF

Item 16 – Adopting GHTF guidance documents within the European framework? It may be of interest to adopt a risk-based classification for in vitro diagnostic devices, as proposed by the Global Harmonization Task Force (GHTF), provided that the independence of this task force can be guaranteed. The adoption of this classification must be fully transparent, and must involve consultation of members of civil society.

In 2008, the GHTF is composed of volunteers representing the regulatory authorities and companies working in the field of medical devices. This model is similar to that of the International Conference on Harmonization (ICH) for medicinal products, whose guidelines tend to disregard public safety issues.

EMA may draw on GHTF documents when composing its guidelines but must submit them for consultation to members of civil society.

8. Imports, exports and counterfeiting

Item 17 – Different treatment of imported medical devices and devices manufactured in the EU: To guarantee European citizens the same level of protection from all medical devices, products imported into Europe must be submitted to the same health authority verifications and controls as products manufactured within the European Union.

In conclusion: a more ambitious, global approach is called for

MiEF, HAI Europe, ISDB and *EAHP* encourage the Commission to adopt the most demanding proposals contained in its Consultation Paper.

They wish that the Commission expresses more clearly the need to endow Europe with a far-reaching Medical Devices Directive. Such a legal framework must take into account the fact that some medical devices are in fact healthcare products, which therefore should be subject to the same regulatory requirements as medicines in terms of quality, safety, efficacy, and convenience, in order to protect European citizens.

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*except the Association Internationale de la Mutualité (AIM) who provides an individual reply to the consultation.

Reference:

1- Recast of the Medical Devices Directives – Public Consultation (deadline for responses 2 July 2008): http://ec.europa.eu/enterprise/medical_devices/recast_docs_2008/Public_consultation_en.pdf: 16 pages.