EPHA Position on Proposals for Regulations on Medical Devices & IVD

epha
european public health alliance

EPHA Position Paper

Proposals for Regulations on Medical Devices & IVD

*The European Public Health Alliance (EPHA) is the European Platform **bringing together public health** organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. Our membership includes representatives at international, European, national, regional and local level.*

*EPHA's mission is **to protect and promote public health in Europe**. EPHA brings together organisations across the public health community, to share learning and information and to bring a public health perspective to European decision-making. We help build capacity in civil society participation across Europe in the health field, and work to empower the public health community in ensuring that the health of European citizens is protected and promoted by decision-makers. **Our aim is to ensure health is at the heart of European policy and legislation.***

*Visit **www.epha.org** for more information.*

Please direct inquiries to:

European Public Health Alliance (EPHA)

Publications

Rue de Trèves, 49-51, 1040 Brussels, Belgium
Tel. +32 (0)2 233 3876

Fax: +32 (0)2 233 3880

epha@epha.org

This publication can be downloaded at no cost at **www.epha.org/a/5721**

Summary

The objective of the European Commission (EC) with this proposal is to strengthen the EU regulatory system for medical devices and *in vitro* diagnostic medical devices through stricter pre- and post-marketing authorisation controls while facilitating timely access to safe devices as a fundamental right.

Overall, EPHA supports the objectives of the EC and agrees that **patient safety must be at the heart of the revision** in order to address the weaknesses of the current legislation and protect individuals and public health at large. Nonetheless EPHA feels that certain issues require clarification and/or refinement in order to ensure an adequate level of patient protection and transparency: this includes, *inter alia*, clarification over the inclusion/exclusion and classification of certain medical devices; further reflection on the role and tasks of the Medical Devices Coordination Group of experts; making independent ethics reviews for clinical investigations / performance studies mandatory; setting up a comprehensive, interoperable and user-friendly European database that will allow for increased collaboration between authorities and make information available in the public domain; enforcing stricter rules pertaining to the activities of Notified Bodies and manufacturers; and ensuring a more streamlined marketing authorisation system with clear responsibilities for all stakeholders. There should also be more comprehensive definitions and better protection measures for self-testing and certain diagnostic devices..

Given the ubiquity and impact of medical devices, EPHA believes that, if properly implemented, the proposed revision will bring an additional layer of health protection and play an important role for public health.

Recommendations

- Introduction of a **more stringent and aligned marketing authorisation procedure that can deliver increased patient safety** without compromising timely access to life-saving medical devices
- Guarantee **transparency throughout the authorisation process**, including adequate access to and disclosure of key information about medical devices for the public and health professionals via a comprehensive and interoperable European databank
- Stricter controls, mandatory reporting and operational requirements for **manufacturers and Notified Bodies**
- **Mandatory involvement of independent ethics committees** in authorising clinical investigations / performance studies
- **Strengthen the mandate of the Medical Devices Coordination Group** and expand its activities
- Make sure that the **concerns of patients and health professionals are taken into account** and include them in the governance structure for medical devices
- **Information to patients and instructions** must be clear, consistent and understandable for lay persons, especially concerning **self-testing IVD devices**

EPHA Position on Proposals for Regulations on Medical Devices & IVD

Introduction

The medical devices industry constitutes a key sector for healthcare. It is also one of the most dynamic, improving and saving lives every day by providing innovative solutions for diagnosis, prevention and treatment[1]. According to the EC, there are currently around 500,000 different medical devices on the EU market. Given that European health systems operate in a constantly evolving context, which entails similar challenges for all Member States, such as the ageing of the population and concomitant increases in chronic diseases, medical devices and *in vitro* diagnostic medical devices will be of increasing importance to public health and medical care.[2]

The Commission aims to ensure a high level of human health and safety, the efficient functioning of the Internal Market, as well as innovation in medical technology for the benefit of patients and healthcare professionals. Following the proposal on a new EU regulatory framework for medical devices[3] and *in vitro* diagnostic medical devices[4] released in September 2012, EPHA developed the following Position, which has been revised in July 2013 to reflect the progress of the discussions at European Parliament and Council level.

Scope of the Regulations

Concerning the scope of the medical devices proposal, the extension of the legislation to other products, such as implants for aesthetic purposes is to be welcomed. However, EPHA feels that more clarity is required on what products would be excluded from the scope, and regarding the requirements to be met for medical devices received by patients treated in another Member State.

Since it is likely that more Europeans will be seeking (or be sent for) treatment in another Member State, and engage in 'medical tourism' to meet increased demands for personalised healthcare[5], the legislation will need to **warrant continuity of care in the context of cross-border healthcare**.[6] This means information must be available in all relevant languages, and patients must be well instructed by health professionals so that they are able to utilize devices correctly and understand interactions with other devices and technologies.

Borderline cases between medicinal products and medical devices are particularly challenging and even the EC admits they are difficult to draw[7]. For example, certain medical devices are composed of devices combined with medicinal products, such as drug-eluting coronary stents[8] which have caused doubts over their classification and the applicable legislation; it is not uncommon for the same device to be classified differently in another Member State. There are also inconsistencies regarding products that could be classified as food products or cosmetics. To put an end to such unnecessary discrepancies, the proposed Medical Devices Coordination Group should pool its expertise of national legislations and provide solid advice on the most suitable classification decision.

---

[1] European Commission (2010).Exploratory process on the future of the medical devices sector.
[2] See COM (2012) 540.
[3] See http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf
[4] See http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf
[5] See EPHA Briefing on the Medical Devices Directive.
[6] See Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
[7] COM(2012) 542 final, Proposal for a Regulation on Medical Devices
[8] European Commission (2009) Medical Devices: Guidance document.

Moreover, while the proposed Regulations explicitly include devices that incorporate software and stand-alone software, there is no mention of the rapidly developing eHealth sector, including mobile health 'apps' for use by individuals on their smartphones, some of which arguably fulfil the function of medical devices. In this regard EPHA recommends providing clarity about their definition and utilisation, and regarding overlaps with other evolving EU legislation (e.g., general data protection[9]). This also applies to a number of traditional health tools that increasingly rely on digitisation, e.g. in order to monitor chronic conditions remotely.

Transparency

Identification and registration

EPHA welcomes the proposed measures for **improved identification and traceability of medical devices** so that products can be associated with their manufacturer and traced along the supply chain (which might also involve authorised representatives, distributors and importers). The EC proposal contemplates a system that would include a Unique Device Identification (UDI) system based on international guidance. In this context it is particularly important that this system will be compatible with the existing traceability system for human medicines to avoid two parallel processes and cost escalation.

In addition, the UDI system also plays an important role in improving procurement and stock management functions by e.g. pharmacists or hospitals, which means it needs to be linked in with existing authentication systems to avoid unnecessary complication.

Registration of manufacturers, importers and their devices should occur in a European databank to allow users and authorities to view all the principal information about a device, including how a product has been assessed, and the clinical evidence gathered in support of its safety and efficacy.

Combined, these measures shall ensure a high level of safety and a more transparent system in order to restore patients', consumers' and healthcare professionals' confidence, which has been low following the *Poly Implant Prothèse* (PIP) breast implant debacle and other high profile cases involving faulty medical devices.

European Databank

The information contained in the European databank (Eudamed) – which will comprise a number of electronic systems enabling increased cooperation, reporting and information sharing on various aspects of medical devices, including also clinical performance, vigilance and market surveillance - should be **robust, transparent and user-friendly.** EPHA strongly believes that accessibility is crucial for ensuring efficient use of the databank as patients have the right to be informed about medical devices' functions, risks and benefits. Hence the results of clinical investigations, including information about safety and performance aspects, should be publicly available. Crucially, **Eudamed must be interoperable with already existing databases** to avoid duplication and prevent that information is scattered and important records get lost.

EPHA recommends **consulting patients and healthcare professionals** during the development of the European databank to make sure that end user needs are being met in an adequate way.

[9] COM(2012) final, European Commission Proposal for a Regulation on General Data Protection

Reporting

EPHA would like to see measures to encourage vigilance reporting by users and healthcare professionals. This includes **protecting the anonymity of healthcare professionals and patients reporting suspected serious adverse events** to avoid negative consequences for individuals who may otherwise be reluctant to report incidents in order to protect their own or their institution's reputation. Linking incidents to individuals can also represent a barrier for patients who might mistakenly associate reported events with professional malpractice. Similarly, patients must feel entirely confident that their reports are appreciated and taken seriously, but without putting them in an uncomfortable situation.

Moreover, reporting should also be encouraged for events caused by **replacement parts or components** as opposed to only the entire device

It must also be ensured that information regarding adverse events is reported back to manufacturers.

Product evaluation

Ethics Committees

By definition 'clinical investigation' means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device[10]. Since the human body is the laboratory for the testing of medical devices, EPHA calls for the **mandatory involvement of independent ethics committees** to ensure compliance with obligations concerning patient safety and to address issues of a scientific, medical and ethical nature. In particular, clinical investigations and performance studies should only take place following a positive evaluation by an ethics committee, and hence it is vital that the members of ethics committees possess the relevant qualifications and experience. It should also be compulsory to establish ethics committees in Member States where they do not currently exist.

Additionally EPHA supports the proposed requirement regarding the **registration of all clinical investigations and performance studies** in a publicly accessible electronic system set up by the Commission.

Disclosure of data

As specified in the EC proposal, clinical evaluation is required to demonstrate conformity with general safety and performance requirements in order to support the intended purpose of a device and the intended benefits to the user; this represents an obligation for manufacturers. Clinical evaluation follows a medical device over its lifecycle and comprises pre-market conformity assessment and post-market clinical follow-up in the light of new safety and performance information.

In this context EPHA welcomes the provision which establishes that the **results of clinical evaluations should be fully accessible to the public and to healthcare professionals,** including for studies that were terminated early.

For high risk devices, manufacturers should also be obliged to provide a summary of the main safety and performance aspects, including any possible adverse effects along with the results of the clinical evaluation / performance study in a public document.

[10] COM(2012) 542 final, Proposal for a Regulation on Medical Devices

Increased safety

Marketing authorisation for high risk devices

While the Commission proposal foresees a scrutiny mechanism for high risk devices, the reports produced by the ENVI Committee Rapporteurs have steered discussions around the issue of centralised versus decentralised pre-market authorisation procedures (PMA). Centralised PMA at EU level, as proposed by the Rapporteur of the Medical Devices report[11], MEP Dagmar Roth-Behrendt (S&D, Germany), would only concern a small percentage of medical devices classified as high risk, e.g. innovative implantable devices and devices manufactured utilising tissues or cells of human or animal origin or their derivatives, which are non-viable or rendered non-viable. In order for PMA to work, an enhanced role is foreseen for the European Medicines Agency (EMA) to oversee the process.

While on one hand, centralised PMA - if able to operate as swiftly as foreseen, i.e. within about nine months – could provide for an added layer of protection similar to the FDA process in place in the United States, on the other hand there is a risk that the proposed timelines cannot be met, with the consequence that European patients would need to wait considerably longer for potentially life-saving devices to enter the market than is currently the case. It is also debatable whether the potential costs involved in setting up an effective centralised procedure, and the time it would take to find, recruit and relocate the necessary experts, would hinder the speedy implementation of the proposed legislation. Moreover, there is no guarantee that centralised PMA would be any more successful in avoiding the problems encountered in the past, especially where fraudulent practices are concerned.

In light of this EPHA welcomes the Commission's plan to tighten up the existing legislative framework and apply stricter controls, in particular regarding the conformity assessments undertaken by Notified Bodies. That said, the revision needs to be firm and unambiguous to avoid different interpretations in the Member States that can put patients' lives in peril. In particular, **strong safeguards are required for ensuring a stringent and more streamlined authorisation process** including a number of compulsory requirements to **exert sufficient pressure on all relevant actors to align their activities** and operate in a fully transparent fashion**.**

Post-market surveillance

Regardless of the way in which marketing authorisations for high risk devices will be obtained, the problems encountered with unsafe products in the past have stressed the importance of ensuring that adequate post-market surveillance is part and parcel of the process. In this regard EPHA supports the idea that regular mandatory summaries containing vigilance and market surveillance information about devices are being made publicly available, as an added layer of security.

Liability insurance

In addition to the requirement of providing more comprehensive information to end users, EPHA would also like to see **mandatory liability insurance by manufacturers** in order to compensate patients for health damage caused by unsafe medical devices (including the costs incurred to restore patients' physical and mental health) and protect patients in the case of insolvency.

[11] 2012/0266(COD), ENVI Committee draft report on medical devices

Notified Bodies

Supervision

Crucially, it will be necessary to initiate **stricter monitoring of Notified Bodies' activities** by relevant competent authorities at national and EU level, including an increased mandate for the MDCG (see below). Scrutinising more rigorously Notified Bodies' preliminary assessments for devices requiring conformity assessments– especially in cases where novel devices are concerned, where the risk of incidents could be high, or for which no technical specifications exist - , as well as their own control activities, should ensure more patient safety. In order for this to work, it is essential that national authorities possess the appropriate expertise and resources to fulfil their job.

Notified Bodies should conduct conformity assessments in an impartial manner and must hold the necessary know-how to evaluate subcontractors where these are involved. They should be obliged to inform national authorities in a timely manner in case of changes regarding their staff, facilities, subcontractors, etc.

EPHA also supports the EC's provision that the Notified Bodies must be able to **exert more control over manufacturers**, including unannounced factory visits.

Competence

Having sufficient ''in house'' capability could be an effective approach to ensure more safety. Competent expertise to assess clinical evidence from manufacturers should avoid incidents caused by undetected faulty devices. Hence EPHA supports the **recruitment of experts within Notified Bodies,** including medical doctors, pharmacists, engineers, and other specialised professions.

Moreover, Notified Bodies must be reorganised in such a way that profit motives become secondary to their prime function as guardians of public health working in tandem with public authorities. In this respect EPHA recommends that **Notified Bodies should specialise in certain categories of devices** to develop their expertise and favour quality assessments over quantity.

Harmonised fees

The European Commission proposal establishes a fee system for Notified Bodies (and/or other conformity assessment bodies), however there is no mention of how it would work across Member States. A transparent fee system must involve **standard fees applying in the Member States that should be made publicly available to allow for international comparison.** This is important in order to avoid competition and prejudicial 'forum shopping' for conformity assessments, which can be harmful for patients.

Medical Devices Coordination Group

The Medical Devices Coordination Group (MDCG) is an important component of the Commission proposal. Composed of one member and an alternate chosen by each Member State based on relevant expertise, its role is to give advice to the Commission on medical devices and *in vitro* diagnostic devices, and to assist the Commission and the Member States in ensuring that the implementation of the Regulations will occur in a harmonised fashion. The idea is for the group to be chaired by the

Commission, with organisations representing the interests of the medical devices industry, healthcare professionals, laboratories, patients and consumers at Union level as observers.

EPHA calls for a strong contribution of the MDCG, especially when it comes to recommendations concerning the classification of medical devices, the Notified Bodies (e.g., suspension and re-instalment) and their coordination group, which should be overseen by the MDCG. In addition, the MDCG can add value by providing expertise for decisions pertaining to post-market surveillance and other sensitive information for public release. That said, its members must have no conflicts of interest that could impede their independence, and there must be a mechanism in place to guarantee that the MDCG does not act against the views of patients and healthcare professionals.

Safety features

EPHA supports the **implementation of provisions concerning the cleanliness** of medical devices. This should come under greater scrutiny as problems have been reported with e.g. hip implants that contained a manufacturing residue[12].

Several types of devices are being placed on the market every day, some designed for single use only and others for multiple uses. As a consequence, some devices are subject to reprocessing rules. Whatever the purpose of a medical device, EPHA recommends **unequivocal information to patients regarding reprocessing**. Medical devices should always be labelled for their intended purpose and it should be clearly indicated whether or not they can be reprocessed. Furthermore, the appropriate healthcare professional should be obliged to inform the patient concerning the purpose of the device, and whether the product has been reprocessed. Patients have the right to know what type of equipment is used as part of their treatment or medical intervention.

Moreover, EPHA would like to see **tougher health and safety requirements to avoid patient harm and professional accidents,** e.g. sharp-needle injuries and infections, but also harm caused by devices containing hazardous chemicals and nanoparticles.

In Vitro diagnostic medical devices

Concerning specifically the EC's proposal for IVD medical devices, EPHA backs the introduction of additional and/or more precise definitions for fundamental tools falling under the Regulation, especially regarding companion diagnostics and devices for genetic testing.

Informed consent

The importance of informed consent was strengthened during the European Parliament discussions. The Rapporteur of the EP Report on *In Vitro* Diagnostic Medical Devices[13], MEP Peter Liese (S&D, Germany) stressed its significance for patients, particularly in the context of genetic testing (see below). EPHA fully agrees with this line of thought and endorses **strengthened provisions to ensure that consent is informed, freely given and revocable**, and that additional safeguards are in place for protecting incapacitated adults and minors.

[12] See EPHA Briefing on the Medical Devices Directive.
[13] 2012/0267(COD), ENVI Committee draft report on in vitro diagnostic medical devices

Self-testing

EPHA also endorses the provision related to **self-testing**, i.e. any device intended by the manufacturer to be used by lay persons – including devices purchased via information society services - should direct users to **obtain correct advice from a health professional**. Knowing where to find appropriate guidance is vital for individuals using self-testing kits since they can have a serious impact on individuals if they are used erroneously or results are being misinterpreted, pregnancy and HIV tests being two commonly cited examples.

To avoid harm and incorrect deployment, the **format and language(s) of the instructions and package must be user-friendly and comprehensible for lay persons**, i.e. by avoiding medical or technical jargon and using supplementary graphics and colour-coding where appropriate.

Genetic tests

Even more critically, there needs to be a **clear protocol for genetic testing and compliance with minimum standards**. EPHA believes they must only be permissible and take place under the supervision of an appropriate medical professional who must also ensure that the individual receives appropriate information on the nature and potential implications of the genetic test to be performed .

In addition, the individual concerned must receive mandatory genetic counselling by a qualified physician where testing goes beyond routine procedures, e.g. for tests used for DNA predictive prognosis.

Prescription-only devices

Some devices should be placed on the market as prescription-only products, especially certain high risk self-testing devices, devices used for genetic testing and companion diagnostics. It is thus important for the Regulation to contain clear definitions, which are comprehensive enough to cover the full range of such devices and their potential applications.

Moreover, EPHA strongly opposes direct-to-consumer advertising for these types of devices.

Exemptions from Regulation

EPHA supports the idea that **single health institutions should have the possibility to manufacture, modify and use** high risk (class D) in vitro diagnostic devices by themselves to meet unmet patient needs where no commercial products are available. This will be useful for supporting public health needs, such as the identification of emerging pathogens and diagnosing rare diseases.

Investments in infrastructure

The revision of the legislative framework involves increased involvement of authorities at European and at national level so that the necessary checks can be undertaken, information on various aspects of medical devices can be collated and disseminated, etc. This implies that, in order for these Regulations to be implemented successfully, **adequate funds must be made available** for upgrading and setting up the required technological (IT), operational and administrative infrastructure, which also involves hiring additional staff.

Moreover, funding will be required for **ensuring the good functioning of expert groups**, which should include the 'real life' views of patients, health professionals and civil society representatives and work in a transparent manner. Representatives of these groups may also require additional training in order to participate effectively in expert settings.

Relationship with other EU legislation

What is more, the **relationship with other existing and evolving pieces of EU legislation** such as data protection, clinical trials, eHealth, and Pharmacovigilance needs to be clear.

As medical devices are increasingly digital and compact, the need for security of both their intended function and the information stored therein cannot be stressed enough. In particular, the risks associated with counterfeit health technologies and parallel trade must be considered, and not overshadowed by measures to reduce counterfeit medicines, which rarely include provisions to include medical devices. The risk to patient safety, particularly from those devices that are used to monitor vital signs or that are implanted into the body, is considerable and must be addressed.

Conclusions

Numerous types of medical devices are being placed on the EU market every week. They have the power to improve quality of life and, more importantly, they can save lives. However, incorrect assessment or insufficient surveillance can be fatal. Therefore it is imperative to have the best mechanism in place to ensure patient safety.

EPHA is particularly in favour of those provisions that promise an added layer of patient safety and transparency over the entire process, in particular stricter controls of the Notified Bodies' conformity assessments by competent authorities and other measures that will lead to a more harmonised assessment process for all medical and in vitro diagnostic devices, and especially those falling into high risk categories. Quality information to patients, presented in a user-friendly way, should be considered as a core ingredient of successful treatment and/or medical intervention.

Whatever the appropriate type of marketing authorisation, EPHA calls for a transparent process that can guarantee patient safety without creating unnecessary delays.

This document arises from the European Public Health Alliance which has received funding from the European Union, in the framework of the Health Programme. Sole responsibility for this position lies with EPHA and the Executive Agency is not responsible for any use that may be made of the information contained therein.