Statement on the Proposed Medical Devices Regulation

Executive Summary

The proposal for new European medical device legislation comes at a time when healthcare systems are simultaneously facing greater demand and austerity. It is therefore imperative that new legislation not only protects patients from undue harm, but ensures that continuous innovation in healthcare can be achieved to meet growing demands for care in already overburdened systems.

Health First Europe believes that the current proposal is rightfully focused on patient protection and transparency. However, HFE remains concerned that the approach to approval of medical devices taken in this proposal limits the current access patients have to new technologies which may, in the long term, present additional challenges to patients, healthcare professionals and health systems.

Background

Against the backdrop of increasing demand being placed on health systems due to changing demographics, shortages of healthcare professionals and shrinking healthcare budgets, medical technologies will play an ever increasingly important role in the delivery of high quality, sustainable care for patients throughout the European Union. In this context, it is imperative that the *Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009*, fosters high quality, efficient healthcare to meet the growing demands of patients, as well as ensure the safety of medical devices for patients and healthcare professionals.

From technologies that support independent and active living for sufferers of chronic conditions, to devices that provide timely and accurate diagnoses for healthcare professionals, medical devices are an essential part of today's health systems. Medical devices are a part of every aspect of healthcare – from every provider of care (acute, primary, community) to every aspect of the delivery of care along the patient pathway (diagnosis, monitoring, treatment and follow-up). It is therefore essential that the upcoming discussions on the revision of the current medical devices legislation focus on the needs of the patients who utilise these technologies to support their everyday quality of life.

As a multi-stakeholder organisation representing patients, healthcare professionals, hospitals, academics and industry, Health First Europe believes that we can offer a unique perspective as these discussions get underway.

Health First Europe
Rue de Trône 60, 1050 Brussels
Tel: +32 (0)2 62 61 999, Fax:+32 (0)2 62 69 501
info@healthfirsteurope.org
www.healthfirsteurope.org

Medical device regulation

Since the 1990s, medical devices have been regulated by three EU directives focusing on active implantable medical devices, medical devices (generally) and in vitro diagnostics.[i] Together, the directives created a de-centralised system for medical technologies where authorities in each [or "any"] Member State (referred to as notified bodies) oversee approval of new devices. Once approved, all medical technologies receive a CE marking and can be placed on the market in the EU. Focused on both safety and efficiency, the current EU regulatory structure has facilitated rapid access for patients and healthcare professionals to new technologies as well as stimulating an environment for innovation in healthcare.

However, the European Commission has determined that certain aspects of the current directives have become outdated. According to the Commission, with new technologies developing, there is no longer legal clarity for how new, innovative devices in mobile and tele-health should be regulated and this legal uncertainty has raised questions about approval oversight and safety. The European Commission has decided that in order to ensure greater harmonisation, clarity and safety, the previous directives require revision.[ii]

The new regulatory proposal was published on 26 September 2012 and aims to:

1. Give patients, consumers and healthcare professionals' confidence in the devices they might use every day;[iii]
2. Allow industry to bring safe, effective and innovative products to market quickly and efficiently;[iv]
3. Increase the ability of innovative companies to attract investors, estimate costs and anticipate procedures.[v]

HFE's position

Health First Europe welcomes the European Commission's proposal for a new medical devices regulation and supports the Commission's focus on safety and transparency for patients. We must all strive for the highest level of safety for patients and users of medical devices as well as transparency of relevant information about medical technologies for patients and professionals. Allowing users to make informed decisions about their care is an important contributor to safety.

HFE believes there are three main areas contained in the proposal that will have the greatest impact on patients, namely: safety, transparency and access.

1. Safety

HFE believes that the new proposals for safety are appropriately focused on the patient and protection from harm, while also fostering greater confidence for patients in the devices. HFE believes that reliability and consistency of the regulatory system is of utmost importance and agrees that strengthening the independence

Health First Europe
Rue de Trône 60, 1050 Brussels
Tel: +32 (0)2 62 61 999, Fax:+32 (0)2 62 69 501
info@healthfirsteurope.org
www.healthfirsteurope.org

and quality of the bodies overseeing the approval of medical devices helps to support greater patient safety. In particular, requirements for regular checks and unannounced visits on manufacturers will enhance confidence in the regulatory system.

Additionally, HFE welcomes the establishment of improved reporting systems for patients and healthcare professionals about the safety and performance of medical devices. Providing a simple mechanism to allow direct reporting on technologies facilitates accuracy and efficiency of data collection directly from users regarding safety issues.

Lastly, new requirements for traceability of medical products are also appreciated by HFE, whose members consider it a positive step and a further contributor to patient safety. The introduction of a unique device identifier (UDI) should facilitate improved device tracking and assist rapid coordinated action where needed. Though, we believe a harmonised system must be in place to make the UDI effective.

2. Transparency

Increased transparency requirements for medical technologies are also welcomed by Health First Europe as they support greater health literacy and help to empower patients. Patients will now have access to the database of medical technologies (Eudamed) as well as access to appropriate public information about the performance and safety of high risk devices to help inform choices about care. Making this information available will help to inform patients about the correct use of products, as well as facilitate greater discussions with medical professionals about the best and most appropriate products for treatment. However, it is important to ensure the level of information provided is suitable for patients (and not overly complex) so that it enables informed decision-making.

Moreover, making current clinical evaluations of medical technologies available in a publicly accessible system is also a step forward for medical professionals so that they can be fully informed when determining the use and scope of various medical devices. HFE also gladly accepts the proposal for European Commission oversight of this system as the Commission is the appropriate actor to compile, monitor and publish the safety and performance evaluations of medical devices in an electronic system.

3. Access

While HFE is encouraged by the proposals on safety and transparency, we are concerned how certain aspects of the directive will impact the *access* of patients to medical technologies. The proposal foresees moving from a de-centralised approval system to a more centralised approval system which advocates additional compliance burdens as part of a longer approval processes. While HFE is fully supportive of requirements that encourage safety, we are concerned that this change is not fostering greater safety for patients, but rather is delaying the access of patients to life-saving technologies for treatment.

Health First Europe
Rue de Trône 60, 1050 Brussels
Tel: +32 (0)2 62 61 999, Fax:+32 (0)2 62 69 501
info@healthfirsteurope.org
www.healthfirsteurope.org

HFE considers that the requirements contained in the proposal are sufficient to protect patients and worries that by moving towards a centralised system, access will be compromised without any additional benefits for patient safety. In fact, without access to these medical devices, the ability of medical professionals to save lives is put at risk, as well as the capacity for patients to remain independent and productive members of society.

Conclusions

The patient-centric approach taken in the proposal for a new regulation for medical devices is the correct path for achieving safe, effective and innovative medical devices in Europe to meet the challenges faced by health systems. HFE is generally delighted by this philosophy and general approach. Ongoing improvements to the regulatory environment that encourage confidence in medical technologies for professionals and patients, benefits all health systems.

However, as with most things, balance is important. We believe that it is vital that the legislative framework does not underestimate the importance of access for patients and professionals to those same technologies. We also have some concerns regarding the impact of certain aspects of the proposal on Europe's future attractiveness for research investment, which has been very important to our healthcare systems.

We call on our fellow stakeholders and European policymakers to address the issue of ensuring a balanced approach to regulation that will ensure continued timely access to life-saving and life-changing technologies.

---

[i] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:en:HTML

[ii] Proposal for a regulation of the European Parliament and the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) 178/2002, and Regulation (EC) 1223/2009. http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

[iii] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee and the Committee of

[iv] Ibid.

[v] Ibid.

Health First Europe
Rue de Trône 60, 1050 Brussels
Tel: +32 (0)2 62 61 999, Fax:+32 (0)2 62 69 501
info@healthfirsteurope.org
www.healthfirsteurope.org