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| From: | Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director |
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| To: | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |
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| Subject: | COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council at the first reading on the adoption of a Regulation of the European Parliament and of the Council on **medical devices**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |

Delegations will find attached document COM(2017) 129 final.

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COM(2017) 129 final

2012/0266 (COD)

# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

**pursuant to Article 294(6) of the Treaty on the Functioning of the European Union**

**concerning the**

**position of the Council on the adoption of a Regulation of the European Parliament and of the Council on medical devices**

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## 1. BACKGROUND

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| Date of transmission of the proposal to the European Parliament and to the Council | |
| (document COM(2012) 542 final – 2012/0266 COD): | 26.09.2012 |
| Date of the opinion of the European Economic and Social Committee: | 14.02.2013 |
| Date of the opinion of the Committee of the Regions: | 08.02.2013 |
| Date of the position of the European Parliament, first reading: | 02.04.2014 |
| Date of adoption of the position of the Council: | 07.03.2017 |

## 2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The medical devices sector is estimated to comprise more than 500 000 products, covering a huge spectrum of products, from sticking plasters to contact lenses, X-ray machines, pacemakers or blood tests.

Medical devices other than *in-vitro* diagnostic medical devices are currently regulated by two main Directives: Directive 90/385/EEC[1] regarding active implantable medical devices (*e.g.* pacemakers) and Directive 93/42/EEC[2] regarding medical devices (*e.g.* contact lenses). These two Directives, adopted in the 1990s, are based on the 'New Approach' and aim to ensure the smooth functioning of the internal market and a high level of protection of public health and patient safety. Medical devices are not subject to a pre-market authorisation by a regulatory

[1] OJ L 189, 20.7.1990, p. 17
[2] OJ L 169, 12.7.1993, p. 1

authority but to a conformity assessment procedure which, for medium and high-risk devices, involves an independent third party, known as 'notified body'. Notified bodies are designated and monitored by the Member States and act under the control of the national authorities. Once certified, devices bear the CE marking which allows them to circulate freely in the EU/EFTA countries and Turkey

The existing regulatory framework has proved its merits, but certain significant weaknesses and divergences in the interpretation and application of the rules have been revealed suggesting its urgent revision. In addition, the highly innovative and competitive nature of this sector requires the EU to dispose of appropriate and up-to-date regulatory instruments and provide all relevant economic operators with the necessary legal certainty.

It is in that context that the Commission adopted on 26 September 2012 a proposal for a Regulation on medical devices.

The main objectives of the proposal were the following:

– Wider and clearer scope for EU legislation, which is extended to include some products (*e.g.* implants for aesthetic purposes)

– Updated risk classification rules, as well as safety and performance requirements, to keep pace with technological and scientific progress;

– Stricter rules for designation and stronger supervision of notified bodies by national competent authorities;

– More powers for notified bodies, to ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections;

– Scrutiny mechanism for high-risk devices allowing a case-by-case assessment on scientifically valid grounds of the notified body's preliminary conformity assessment by a committee of national experts;

– Clearer obligations for manufacturers, authorised representatives, importers and distributors, which also apply in case of diagnostic services and internet sales;

– Harmonised rules on reprocessing of single-use medical devices;

– Stricter requirements for clinical evidence to support assessments of devices;

– Reinforced rules on vigilance and market surveillance;

– Improved EU medical devices database (EUDAMED) to provide comprehensive information on devices available on the EU market;

– Better traceability of devices throughout the supply chain to enable a swift and effective response in case of safety problems (*e.g.* recalls); and

– Enhanced coordination between national authorities, with the Commission providing scientific, technical and logistic support.

## 3. COMMENTS ON THE POSITION OF THE COUNCIL

The Council's position overall endorses the objectives pursued by the Commission proposal, namely to ensure an increased level of patient safety and public health protection, facilitate the smooth functioning of the internal market and support innovation in this important sector. However, the Council makes certain changes as regards the manner in which these aims are achieved. The major changes proposed by the Council and the Commission's position on these changes can be summarised as follows.

*a) Inclusion of certain products without a medical purpose in the scope of the medical devices Regulation*

Under the Council's position, the application of the Regulation to certain listed groups of products without a medical purpose (e.g. contact lenses; equipment for liposuction, lipolysis or lipoplasty; equipment intended for brain stimulation) is dependent on the adoption of common technical specifications ('CS') covering the risk management and, where necessary, the clinical evaluation regarding safety aspects. The CS would apply as of six months after their entry into force or date of application of the Regulation, whichever is the latest.

-> Although the inclusion of the listed groups of products in the scope of the medical devices legislation is not automatic, as the Commission proposed, but is dependent on the adoption of the CS, the position of the Council can be supported as the specifications may be useful to elaborate some specific aspects concerning the application of the medical device legislation to these products.

*b) Exemption of devices manufactured and used in the same health institution from some requirements of the legislation*

Under the Council's position, devices manufactured and used in the same health institution are exempted from the Regulation, with the exception of the relevant general safety and performance requirements, if a number of conditions are fulfilled. These conditions include a prohibition to transfer the device to another legal entity, the requirement for manufacture and use of the device under an appropriate quality management system, the obligation for the health institution to draw up and maintain a documentation for the device, as well as justify in this documentation that the patient's needs cannot be met adequately by a marketed device. The exemption does not apply to devices manufactured on an industrial scale.

-> Although this exemption is introduced for the first time for medical devices, the position of the Council can be supported as it offers acceptable guarantees for control of these 'in-house' devices.

*c) Financial coverage by manufacturers in case of damage caused by defective medical devices*

The Council's position accepts the spirit of the EP 1st reading position introducing a compulsory liability insurance for manufacturers, as it recalls the right of natural or legal persons to claim compensation for damage caused by defective devices in accordance with applicable Union and national law. To this end, however, the Council's position does not retain the compulsory liability insurance envisaged by the EP, while opting instead for the manufacturers' obligation to have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC concerning liability for defective products. Such financial coverage shall be proportionate to the risk class, type of

device and the size of the enterprise. This obligation introduced by the Council is without prejudice to more protective measures under national law.

-> This new feature of the legislation can be supported as it offers an important guarantee for patients and users of medical devices, while providing sufficient flexibility for manufacturers as regards the specific means to ensure such financial coverage.

*d) Liability of authorised representatives*

The Council's position reinforces the role and responsibilities for authorised representatives well beyond the terms of the Commission's proposal. In particular, the authorised representative would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices.

-> The Commission's proposal had provided limited legal responsibilities of the authorised representatives, taking into account that the authorised representatives have a limited role with regard to the placing on the market of a medical device and are generally not in a position to possess all relevant knowledge on the device design and the manufacturing process. However, in the course of the legislative negotiation it became clear that there are many specific enforcement problems linked to devices produced by non-EU manufacturers that the current horizontal liability regime does not properly address. These enforcement problems could be highly detrimental to the protection of damaged patients. Therefore, the Council's position can be supported in the interest of public health protection and patient safety.

*e) Reprocessing of single-use medical devices*

Under the Council's position, the reprocessing of single-use medical devices may only take place when authorised under national law and in accordance with the provisions of the medical devices Regulation. When reprocessing is allowed, the reprocessor must assume the obligations of a manufacturer. However, a different regime is applied in the case of reprocessing by health institutions and by third parties on the request of health institutions. Under this regime Member States may decide not to apply certain rules relating to manufacturers' obligations if certain conditions are fulfilled, namely compliance with common specifications. The Commission is required to adopt these common specifications by the date of application of the legislation and if it fails to do so, harmonised standards and national provisions would apply. Compliance with the relevant common specifications or national provisions and harmonised standards would have to be certified by a notified body. Member States should encourage and may require health institutions to provide information to patients on the use of the reprocessed device within the health institution; they may adopt stricter provisions or ban reprocessing on their territory (so-called 'opt-out').

-> This approach is significantly different from the Commission's proposal which foresaw that all reprocessors would be considered as manufacturers and that single-use devices for critical use could not be reprocessed. Nevertheless, given the diversity of national approaches and the sensitivity of the issue from a public health and patient safety point of view, the Council's position appears to be an acceptable way forward to establish EU-wide minimum rules applicable to the reprocessing of single-use medical devices and can therefore be supported.

*f) Use of hazardous substances in invasive medical devices*

The Council's position accepts the spirit of the EP 1st reading position, as it sets a stricter regime for the use of certain hazardous substances in medical devices. According to the Council's position, manufacturers must provide a justification to the notified body regarding the presence of CMR substances and/ or endocrine disruptors above a certain concentration in invasive medical devices and devices that transport and store medicinal products, or other substances to be (re)administered into or removed from the body. For this purpose, the Commission is required, as soon as possible and at the latest one year after the date of entry into force of this regulation, to provide the relevant Scientific Committee with a mandate to prepare guidelines on the presence of phthalates. The Commission shall also mandate the relevant Scientific Committee to prepare guidelines in relation to other CMR or endocrine disrupting substances, where necessary. Moreover, the list of such substances contained in such devices must appear on the label of the device and/or on the packaging for each unit or, where appropriate, on the sales packaging.

-> This approach can be supported, as it aims at an increased level of patient and user protection.

*g) Identification and traceability related obligations and establishment of a Unique Device Identification (UDI) System*

As in the Commission's proposal, economic operators would be required to identify any economic operator from whom they have received a device and to whom they supplied a device (including health institutions and healthcare professionals). However, contrary to the Commission's proposal which only sets out the legal basis and the main principles of the future UDI system, leaving the details to the implementation stage, the Council's position sets out detailed rules for the implementation of the UDI system. The main features of the position are the requirement for manufacturers to have the UDI code assigned to their devices by the date of application and the requirement for the UDI carrier to be placed on the device and all higher levels of packaging gradually depending on the risk class of the device. Storage of the UDI code by health institutions and economic operators is mandatory for class III implantable devices. Further storage obligations can be defined by implementing acts for economic operators and imposed by Member States for health institutions.

-> While this diverges from the Commission's position, it is overall acceptable in terms of device identification and traceability potential that the new system is going to ensure.

*h) European Databank on Medical Devices ('EUDAMED')*

The Council's position contains more extensive requirements for information upload in EUDAMED and greater transparency of the information it contains, in particular, as regards clinical data for devices on the market. In addition, it foresees that the operation of EUDAMED and the application of provisions related to it should be subject to an independent audit of the functionality of the database.

-> While it should be acknowledged that the Council's position creates significant obligations for the Commission in establishing a very extensive database and in setting a rather onerous procedure for the verification of the database functionality, this is acceptable as it would ensure greater transparency of information regarding devices on the market.

*i) Strengthened criteria for designation of notified bodies*

According to the Council's position, the criteria for designation of notified bodies are described in greater detail, especially as regards process requirements. In addition, the procedures for their oversight have been detailed based on experience of joint assessments already under the current legislation.

-> The Commission supports the enhancement of the requirements for the designation and oversight of notified bodies.

*j) Clinical evaluation consultation for certain high-risk devices*

The Council's position, building on the rationale of the Commission proposal's scrutiny procedure and taking into account certain elements of the scope of this procedure as defined in the EP 1st reading position, sets out a consultation with an expert panel applicable to certain high-risk devices. According to this procedure, an expert panel could select a file based on specified criteria and provide a scientific opinion to the notified body on its assessment of the manufacturer's clinical file. While the notified body would not be bound by the opinion, it would have to provide a justification for not following it. All relevant documents regarding the opinion and the final decision of the notified body would be publicly available in EUDAMED. The concerned manufacturers may be subject to pay fees, the structure and level of which would be set out in implementing acts.

-> The Commission can support the position which is very much in line with the Commission's objectives.

*k) Reinforced requirements for clinical investigations and clinical data*

Building on the Commission's proposal and the EP 1st reading position, the procedures for authorisation of clinical investigations have been further aligned with the rules on clinical trials on medicinal products, particularly as regards provisions on informed consent and protection of vulnerable subjects. The obligations for manufacturers to carry out clinical investigations for high-risk devices have been strengthened with exemptions for well-established technologies. A longer transitional period has been foreseen for the coordinated procedure for assessment of applications for clinical investigations in more than one Member State so as to allow Member States to gain the necessary experience on a voluntary basis.

-> These reinforced requirements are supported by the Commission and the Commission considers appropriate and well justified both the exemptions for well-established technologies and a longer transitional period for the coordinated assessment procedure.

*l) Post-market surveillance by manufacturers and extended scope of trend reporting*

The Council's position details the obligations of manufacturers to follow-up on the real-life use of their devices after their placing on the market. This includes the requirements for a post-market surveillance system of the manufacturer and a post-market surveillance plan. The conclusions drawn on the basis of the analysis of all relevant post-market data are to be set out in a post-market surveillance report for low-risk devices and in a periodic safety update report for devices of a higher risk class. For class III and implantable devices, manufacturers would be required to submit the report to their notified body via EUDAMED. In addition, trend reporting obligations are no longer limited to the highest risk devices as was the case in the original Commission's proposal.

-> All of these elements can be supported as they constitute a clear improvement of the Commission's proposal.

*m) Transitional periods*

While the Council's position maintains the general transitional periods of 3 years, some specific provisions have been added. In particular, Member States have to designate the national competent authority in charge of medical devices within 12 months after the entry into application. Certificates issued under the old legislation become void at the latest 4 years after the date of application. Devices lawfully placed on the market under the old directives prior to the date of application may continue to be made available on the market or put into service until 5 years after that date.

-> The Commission supports the above outcomes.

## 4. CONCLUSION

The Council acted unanimously.

In conclusion, the Commission supports the position adopted by the Council.