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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 ***in vitro*** **diagnostic medical devices** and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Delegations will find attached document COM(2017) 127 final.

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EUROPEAN
COMMISSION

Brussels, 9.3.2017
COM(2017) 127 final

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**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 in vitro diagnostic medical devices

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1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document COM(2012) 541 final – 2012/0267 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

In-vitro diagnostic medical devices (IVDs) (*e.g*. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics) are currently regulated by Directive 98/79/EC[1]. This Directive, adopted in 1998, is based on the 'New Approach' and aims to ensure the smooth functioning of the internal market and a high level of protection of public health and patient safety. IVDs are not subject to a pre-market authorisation by a regulatory authority but to a conformity assessment procedure which, for medium and high-risk devices listed in Annex II of Directive 98/79/EC and a few other 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

[1] OJ L 331, 7.12.1998, p. 1

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. Moreover, there was a need to align the European rules on IVDs with certain consolidated international principles.

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

The main objectives of the proposal were the following:

– Wider and clearer scope for EU legislation, which is clarified particularly as regards genetic testing and companion diagnostics;

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

– 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;

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

– Reinforced rules on vigilance and market surveillance;

– Improved EU medical devices database (EUDAMED) to provide comprehensive information on IVDs 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's 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) Information and counselling for genetic testing

The Council's position, building on certain elements of the EP 1st reading position, includes some minimum provisions requiring Member States to ensure that where a genetic test is used on individuals in the context of healthcare, the subject to the testing must be provided with relevant information on the nature, significance and implications of the test, as appropriate. In particular, there should be appropriate access to counselling where genetic testing provides information on diseases that are considered to be untreatable. The Commission will make a statement about its future report concerning these provisions (see point 5 below).

-> These provisions aim to ensure a reinforced level of public health protection and patient safety as well as enhanced information provision and can therefore be supported.

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 extended to all classes of IVDs, 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 IVDs, 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) 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. Specific 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.

f) 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 burdensome procedure for the verification of the database functionality, this is acceptable as it would ensure greater transparency of information regarding devices on the market.

g) 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.

h) Clinical evaluation consultation for certain high-risk devices

The Council's position, building on elements of the Commission proposal's scrutiny procedure, sets out the verification by a designated reference laboratory of the performance claimed by manufacturers of class D IVDs and a consultation with an expert panel applicable to Class D IVDs devices, in the case of their first certification and when common technical specifications are not available. According to this procedure, an expert panel would 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.

i) Reinforced requirements for clinical performance studies and clinical evidence

Building on the Commission's proposal, the procedures for authorisation of some performance studies 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. 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.

-> The Commission can support the reinforced requirements and considers appropriate and well justified a longer transitional period for the coordinated assessment procedure.

j) 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. 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.

k) Transitional periods

While the Council's position maintains the general transitional periods of 5 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; reference laboratories need to be designated by 18 months before the date of application. Certificates issued under the old legislation become void at the latest 2 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 3 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.

5. STATEMENTS

The Commission will make the following two statements:

(1) Commission statement regarding the provisions for information and counselling in the field of genetic testing in Article 4 of the Regulation on in vitro diagnostic medical devices

No later than five years after the date of application of the Regulation and in the framework of the review of the functioning of Article 4 foreseen in Article 111 of the Regulation, the Commission will report on the Member States' experience with the implementation of the obligations in Article 4 for information and counselling in the context of use of genetic tests. In particular, the Commission will report on the different practices in place in light of the double objective pursued by the Regulation, namely to ensure a high level of patient safety and guarantee the smooth functioning of the internal market.

(2) Commission statement regarding genetic testing used for lifestyle and wellbeing purposes

With respect to genetic tests intended for wellbeing or lifestyle purposes, the Commission stresses that devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered by Article 2 (Definitions) of the Regulation on in vitro diagnostic medical devices. Nonetheless, the Commission intends to monitor, on the basis of the market surveillance activities carried out by Member States, specific safety issues which might be linked to the use of these devices.