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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

Accompanying the document

Proposals for Regulations 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

and

on in vitro diagnostic medical devices

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1. INTRODUCTION

The regulatory framework for medical devices consists of three main directives[1] which cover a huge spectrum of products, from sticking plasters or wheelchairs to X-ray machines, scanners, pacemakers, drug-eluting stents or blood tests. All three directives, adopted in the 1990s, are based on the "New Approach" and aim to ensure the functioning of the internal market and a high level of protection of human health and safety. Medical devices[2] are not subject to a pre-market authorisation by a regulatory authority but to a conformity assessment which, for medium and high risk devices, involves an independent third party, a so-called "Notified Body". Once certified, devices bear the CE marking which allows them to circulate freely in the EU/EFTA countries and Turkey.

The impact assessment is divided in a main part (Part I) that focuses on the systemic issues which are relevant for the entire regulatory framework, and two separate annexes (Part II) dealing with specific issues relevant either only for medical devices other than *in vitro* diagnostic medical devices or only for *in vitro* diagnostic medical devices (IVDs), respectively. Supporting documents are compiled as appendices (Part III).

2. PROBLEM DESCRIPTION

The existing regulatory framework has demonstrated its merits but it has been in place for 20 years and like any regulatory regime dealing with innovative products, needs revision. Moreover, it has recently come under harsh criticism in the media and the political arena, in particular after findings of the French health authorities that a French manufacturer (*Poly Implant Prothèse*, PIP) over several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval provided by the notified body, causing potential harm to thousands of women around the world. Several weaknesses which undermine the main objectives of the three medical devices directives, i.e. the safety of medical devices and their free circulation within the internal market, were identified in a public consultation held by the Commission in 2008, followed by another public consultation targeted at IVD-related aspect held in 2010. In the light of the envisaged revision of the EU regulatory framework for medical devices, the Commission's services also analysed the PIP breast implant case and found further shortcomings of the existing regulations in addition to the already identified weaknesses. The findings, however, do not suggest that the EU system for regulating medical devices is fundamentally unsound. The present revision aims at overcoming the flaws and gaps while maintaining the overall objectives of the legal framework.

2.1. Systemic issues

The main weaknesses of the current system exist in the following areas:

Oversight of Notified Bodies

Notified Bodies take responsibilities in areas of public interest and remain answerable to the competent authorities of the Member States. Currently 78 Notified Bodies are designated under the three medical devices directives. Authorities, manufacturers and Notified Bodies themselves report significant differences as regards, on the one hand, the designation and monitoring of the Notified Bodies and, on the other hand, the quality and depth of the

[1] Council Directive 90/385/EEC on active implantable medical devices (AIMDD), Council Directive 93/42/EEC on medical devices (MDD), and Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices (IVDD).

[2] In this text, medical devices shall be understood as referring also to *in vitro* diagnostic medical devices.

conformity assessment performed by them, in particular in relation to the assessment of the manufacturers' clinical evaluation or the use of their existing powers, such as unannounced factory inspections or product checks. This leads to an uneven level of protection of patients' and users' safety as well as to a distortion of the competition between manufacturers of similar products.

Post-market safety

A central pillar of the regulatory system is the right of Member States to restrict or ban the marketing of a device when it may compromise the health and safety of a patient, user or third person or when the CE marking has been illegally affixed to a product. But experience with the application of the vigilance system and other legal instruments available to the Member States (e.g. safeguard clauses) has shown that national competent authorities do not have all the necessary information available and react in different ways to the same problems which puts into question a harmonised level of protection of patients and users in the EU and also creates obstacles to the internal market.

Transparency and traceability

No exact data exist as regards the medical devices placed on the European market. Several Member States have set up their own electronic registration tools. Multiple registration requirements in individual Member States place a considerable administrative burden on manufacturers and authorised representatives when they want to market a product in different Member States. Some European countries have also started imposing traceability requirements on economic operators (manufacturers, importers, distributors, hospitals) since the traceability of medical devices is currently not regulated at EU level. The national systems, however, are not compatible with each other and do not allow traceability across borders which would be necessary for an EU-wide high level of patient safety.

Access to external expertise

External experts (e.g. healthcare professionals, academics) are currently not involved in the regulatory process in a structured way. Regulators, healthcare professionals and manufacturers have expressed the need to make the advice of scientific and clinical experts available in the decision-making process to keep pace with the innovation of products.

Management of the regulatory system

The management of the regulatory system at EU level has shown weaknesses which have been reported by various interested parties, i.e. healthcare professionals, patients, insurers, manufacturers and the media. It is considered as not sufficiently efficient and effective. Indeed, there is no legal basis in the medical devices directives to ensure an overview of the situation at EU level and appropriate coordination between the Member States. There is a lack of technical, scientific and logistic support to the cooperation between Member States, of solid IT tools to manage the system, and of consolidated scientific and clinical expertise. This leads to a lack of uniform application of the rules and of common reactions in the European market and compromises patient and user safety as well as the good functioning of the internal market.

Moreover, the demarcation between the medical device directives and other regulatory frameworks applicable to e.g. medicinal products, biocides, food or cosmetics is not always clear which leads to the application of different legal regimes in the various Member States to the same products (so-called "borderline" cases**)**. Finally, the obligations of economic operators are currently not clearly spelt out or not covered at all by the directives. Both issues may put patient safety at risk and lead to a fragmentation of the internal market.

2.2. Specific issues

Regulatory gaps or uncertainties exist with regard to certain products. For example, products manufactured utilising non-viable human tissues or cells, implantable or other invasive products without a medical purpose, and the reprocessing of single-use devices are currently not regulated by the EU legislation on medical devices. In the field of IVDs, "in house" tests are currently exempted from the IVD Directive but the application of the exemption diverges amongst the Member States. Moreover, regarding genetic tests, the application of the IVD directive is not sufficiently clear and might lead to diverging interpretation in the EU. This leads to different levels of protection of patients and public health and hinders the creation of an internal market for those products.

An important issue is the **classification of IVDs** for which the current approach in the IVD Directive, i.e. a list of high risk IVDs in an annex to the directive, is different from the classification approach taken for the other medical devices and recent developments at international level. In 2008, the Global Harmonization Task Force for medical devices (GHTF) adopted a classification system for IVDs based on the risk linked to their use which is more robust to technological evolution than the current EU approach.

Furthermore, the requirements of the IVD Directive, which has not been amended since its adoption in 1998, need to be **adapted to technological, scientific or regulatory developments**, for example with regard to the clinical evidence to be provided by manufacturers, the requirements for point-of-care or near-patient testing or to align to relevant modifications introduced over time for the other medical devices. Also in the field of medical devices, some legal provisions, such as the essential requirements and the criteria for the risk classification of devices, do not sufficiently reflect the technological and scientific developments as for example in the case of ingested devices or devices incorporating nanomaterials. Uncertainties also exist with regard to the requirements concerning the clinical evaluation of devices.

Finally, EU legislation currently does not make provision for any coordination between Member States regarding the assessment of applications for **clinical investigations on medical devices to be conducted in more than one Member State**. Manufacturers/sponsors must submit their documentation to each Member State and are then subject to multiple queries for additional information which increases the administrative burden and costs. In addition, the assessments of the Member States concerned may lead to different outcomes as regards technical and safety aspects related to the same investigational device. This also means that patients participating in the same multi-national investigation are subject to different safety levels. Moreover, this revision provides the opportunity to align the provisions regarding clinical investigations on medical devices, where appropriate, with the recently adopted Proposal for a Regulation on clinical trials on medicinal products for human use[3].

3. NEED FOR EU ACTION AND SUBSIDIARITY

The current medical devices directives are based on the Treaty provisions regarding the establishment and functioning of the internal market (now Article 114 TFEU). The Lisbon Treaty has added a legal basis in the area of public health for the adoption of measures setting high standards of quality and safety of medical products (Article 168(4)(c) TFEU). Both policies are a shared competence between the Union and the Member States.

[3] COM(2012)369.

According to the current medical devices directives, devices that bear the CE marking, in principle, can freely circulate in the EU. The proposed revision of the existing directives, which will integrate the modification of the Lisbon Treaty regarding public health, can only be achieved at Union level. This is necessary to improve the level of protection of public health for all European patients and users, as well as to prevent Member States from adopting varying product regulations which would result in a further fragmentation of the internal market. Harmonised rules and procedures allow manufacturers, especially SMEs that represent more than 80% of the sector (90% for IVDs), to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety for all European patients and users.

4. OBJECTIVES OF THE EU INITIATIVE

This revision pursues three **overall objectives**:

- Overall objective A: To ensure a high level of protection of human health and safety
- Overall objective B: To ensure the smooth functioning of the internal market
- Overall objective C: To provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry

In addition, several **specific objectives** related to the individual problems identified contribute to the achievement of the overall objectives:

- Objective 1: Uniform control of Notified Bodies
- Objective 2: Enhanced legal clarity and coordination in the field of post-market safety
- Objective 3: Cross-sectoral solution of "borderline" cases
- Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability
- Objective 5: Enhanced involvement of external scientific and clinical expertise
- Objective 6: Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales
- Objective 7: Governance - efficient and effective management of the regulatory system

In respect to the specific issues relevant either for medical devices other than IVDs or only for IVDs, some **additional specific objectives** are pursued to address the problems in the respective sectors, such as

- Covering of legal gaps and loopholes, specific to the fields of medical devices or IVDs
- Appropriate legal requirements taking into account technological, scientific and regulatory developments, specific to the fields of medical devices or IVDs
- Appropriate and robust classification and conformity assessment of IVDs
- Enhanced legal certainty and coordination in the field of clinical evaluation and investigations, in particular those conducted in more than one Member State, in the field of medical devices.

5. POLICY OPTIONS

Three main options are discussed in the impact assessment:

- No EU action (baseline scenario);
- Fundamental change: marketing authorisation of medical devices;
- Evolution: reinforcement of the current regime keeping the same legal approach.

The third option is situated between the two extreme scenarios and builds on the strengths of the "New Approach", on which the current regime is based, while remedying the weaknesses identified. In the framework of this option, i.e. the further evolution of the current regulatory regime, several policy options have been developed to respond to each of the specific objectives and to address the individual problems identified.

6. COMPARISON OF POLICY OPTIONS AND ASSESSMENT OF THEIR IMPACTS

The **"no EU action"** had to be **discarded** from the outset because the Commission is committed to aligning, where appropriate, existing legislation to the New Legislative Framework for the Marketing of Products[4]. More importantly, no action would mean that the problems described above would continue to exist, or even increase, putting public health and the protection of device users and patients at risk. In addition, no action at EU level would likely prompt Member States to take action at national level which would further undermine the internal market. The PIP breast implants scandal made it evident that "no EU action" is not a defendable policy choice.

The option of a **fundamental change** with the introduction of a marketing authorisation of medical devices was also **discarded**. The transfer of the responsibility for the assessment of the safety and performance of medical devices from Notified Bodies to regulatory authorities and the replacement of the CE marking by a marketing authorisation was widely rejected during the public consultations and the subsequent dialogue with competent authorities, manufacturers and most other stakeholders.

A *decentralised* marketing authorisation (done by Member States) would have a significant negative impact on the internal market for medical devices because the application of the mutual recognition of national authorisations would not provide automatic access to the market of the other Member States which could refuse the admission of products on grounds of health protection. It would therefore run counter to one of the main objectives of the current directives. A *central* marketing authorisation (at EU level) would require building a new EU public body with a sufficiently skilled staff to assess devices, similar to the US FDA. It would have significant impact on the EU budget, on manufacturers in terms of costs and administrative burden and on innovation in terms of time to market.

Despite calls in the aftermath of the PIP breast implant scandal to shift to a system of pre-market authorisation, the case has not provided any evidence that a marketing authorisation granted by a governmental authority would have prevented deliberate fraudulent practices of a manufacturer occurring once a product is approved for being placed on the market. In fact, the PIP case rather evidences the need for a reinforced system for post-market safety which is dealt with in the policy options relating to objective 2. In the absence of evidence which

[4] Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements on accreditation and market surveillance for the marketing of products, and Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products.

would support a centralised evaluation by a regulatory authority in order to achieve the objectives of this revision, such a radical shift in the regulatory system would be inappropriate.

Hence, the option of an **evolution of the current regime keeping the same legal approach** has been **chosen**. This will allow to evolve the existing system which has served as a model for international convergence of the legislation on medical devices and to make it fitter for purpose. It is supported by competent authorities, manufacturers and many other stakeholders and is best suited to achieve the overall objectives of the legislative initiative. This policy choice is further detailed by individual policy options, some of them are alternatives whilst others may be cumulative, to achieve also the specific objectives pursued by the revision and to remedy the problems identified. The table below indicates the preferred policy options for each specific objective pursued.

However, the impact assessment leaves the choice of the preferred option open for a decision to be taken at political level with regard to the following two issues:

- Objective 1 (uniform control of Notified Bodies):
  - transfer of the competence for the designation and monitoring of Notified Bodies to an EU body, or
  - designation and monitoring of Notified Bodies by the Member States after involvement of "joint assessment teams" composed of assessors of other Member States and of an EU body.
- Objective 7 (governance - efficient and effective management of the regulatory system):
  - extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency, or
  - management of the medical device regulatory system by the European Commission (with involvement of its Joint Research Centre) and creation of a Medical Device Expert Group supported by this institution.

Specific Objectives	**Preferred Policy Options**
Problem 1: Oversight of Notified Bodies	
Objective 1: Uniform control of Notified Bodies	New minimum requirements for Notified Bodies, *and* *either* Designation and monitoring of Notified Bodies by an EU body *or* Designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams" *and* Notification requirement regarding new applications for conformity assessment and possibility for ex ante control
Problem 2: Post-market safety (vigilance and market surveillance)	
Objective 2: Enhanced legal clarity and coordination	Clarification of key terms and of the obligations of the

in the field of post-market safety	parties involved in the field of vigilance *and* Central reporting of incidents and coordinated analysis of certain high risk incidents *and* Promotion of cooperation of market surveillance authorities
Problem 3: Regulatory status of products	
Objective 3: Cross-sectoral solution of "borderline" cases	Creation of a cross-sectoral expertise on borderline issues and possibility to determine the regulatory status of products at EU level in certain sectors
Problem 4: Lack of transparency and harmonised traceability	
Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability	Central registration of economic operators and listing of medical devices placed on the EU market *and* Requirement for the traceability of medical devices
Problem 5: Access to external expertise	
Objective 5: Enhanced involvement of external scientific and clinical expertise	Designation of an expert panel and EU reference laboratories
Problem 6: Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales	
Objective 6: Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales	Alignment with Decision 768/2008, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services *and* Addressing internet sales by soft-law action
Problem 7: Management of the regulatory system	
Objective 7: Governance - efficient and effective management of the regulatory system	*either* Extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency *or* Management of the medical device regulatory system by the European Commission and creation of a Medical Device Expert Group supported by this institution

The following two tables indicate the preferred policy options in the field of medical devices other than IVDs and in the field of IVDs, respectively, in relation to the additional specific objectives pursued in the respective sectors:

Issues relevant for medical devices <u>other</u> than *in vitro* diagnostic medical devices	
Specific Objectives	**Preferred Policy Options**
Problem MD-1: Scope - regulatory gaps or uncertainties	
Objective MD-1: Covering of legal gaps and loopholes	Regulate products manufactured utilising non-viable human cells and tissues as medical devices *and* Regulation of certain implantable or other invasive devices without a medical purpose within the MDD *and* Harmonized regulation of the reprocessing of single-use medical devices
Problem MD-2: Adaptation of legal requirements to technological, scientific and regulatory developments	
Objective MD-2: Appropriate legal requirements taking into account technological, scientific and regulatory developments	Review of the classification rules and essential requirements regarding specific devices or technologies
Problem MD-3: Clinical evaluation and clinical investigations, in particular those carried out in more than one Member State	
Objective MD-3: Enhanced legal certainty and coordination in the field of clinical evaluation and investigations, in particular those conducted in more than one Member State	Introduction of the term "sponsor" for clinical investigations and further clarification of key provisions in the field of clinical evaluation and investigations *and* Coordinated assessment of multi-national investigations by the Member States where the investigation is performed

Issues relevant for *in vitro* diagnostic medical devices (IVD)	
Specific Objectives	**Preferred Policy Options**
Problem IVD-1: Scope – regulatory gaps or uncertainties	
Objective IVD-1: Covering of legal gaps and loopholes	Clarify the scope of the exemption for "in house" tests, require a mandatory accreditation for "in house" test manufacturers and subject high risk (class D) "in house" tests to the requirements of the IVDD *and* Amendment of the legal definition of an IVD to include tests providing information "about the predisposition to a medical condition or a disease" *and* Regulation of companion diagnostics under the IVD regulations and interaction with the medicinal products sector

Problem IVD-2: Classification of IVD and their appropriate conformity assessment, including batch release verification	
Objective IVD-2: Appropriate and robust classification and conformity assessment of IVD	Adoption of the GHTF classification rules and adaptation of the conformity assessment procedures to the relevant GHTF guidance *and* Batch release verification for high risk IVD by the manufacturer under the control of a Notified Body and EU reference laboratory
Problem IVD-3: Unclear legal requirements and need for their adaptation to technological progress	
Objective IVD-3: Clear and updated legal requirements for enhanced safety and performance of IVD	Legislative clarification of the requirements for the clinical evidence for IVD *and* Clarification of the legal requirements in respect to point-of-care or near-patient IVD medical devices *and* Alignment to the MDD where appropriate

The preferred policy options have been selected as they are the most suitable to enhance the protection of public health and patient safety throughout the EU, to improve the functioning of the internal market and to provide a regulatory framework that is supportive of innovation and the competitiveness of the European medical device industry, especially SMEs.

In the selection of the options, the different benefits and costs have also been taken into account[5]. Some preferred options, such as a central registration of economic operators and medical devices or requirements for the traceability of medical devices, will lead to administrative costs for economic operators. But these costs are justified by the objectives of this revision and will by far be compensated by savings due to the reduction of administrative costs of the same nature which currently or in the future incur at national level. For example, costs for the central registration of around €21.6mio would be compensated by savings of around €81.6mio to €157.1mio caused by multiple registration requirements in the various Member States. Economic operators will therefore obtain a net benefit from a combination of the preferred options whilst at the same time the levels of transparency and of protection of public health will significantly be enhanced.

There will also be some savings of costs for the national administrations: in the future some tasks will be transferred at EU level, such as the registration of economic operators and medical devices; duplication of tasks between some Member States will be avoided due to for example the coordinated analysis of certain serious incidents; some skills, knowledge and equipment will be shared, such as in the field of market surveillance.

At EU level, the estimated budgetary needs for the implementation of the preferred policy options range from €8.9mio/year to €12.5mio/year depending on the choice between the options left for a political decision. The biggest part of the financing will be needed for human resources (between 35-50 Full Time Equivalents, depending on the choice of policy options) dedicated to the technical, scientific and corresponding operational tasks necessary to ensure a

[5] An overview of the costs and benefits of the preferred polify options is given in Appendix 9 of Part III of the impact assessment.

sustainable and efficient management of the system at EU level. The second biggest share will be needed for the development and maintenance of an IT infrastructure necessary to achieve the objectives of the revision (in average ca. €2mio/year in 2014-2017 and €1.8 in 2018 et sqq.).

7. CONCLUSIONS, MONITORING AND EVALUATION

The preferred options will contribute to a robust regulatory framework that

- is adapted to present and future technical and scientific progress,
- contains clearer rules, more easily to be followed by economic operators and to be implemented by national authorities, and
- provides the necessary instruments for a sustainable, efficient and credible management at EU level.

The positive aspects of the current system (supportive to innovation, giving rapid access to market, cost efficient) will be maintained, while the negative aspects (unequal protection of public health, inconsistent implementation of legal requirements, lack of trust and transparency) will be remedied. This will enhance the safety for all European patients and users and reinforce Europe's position in the forefront of innovation in the field of medical technology. It will boost the confidence in the CE marking for medical devices both in Europe and in the world and will thus lead to a smoother functioning of the internal market and international trade. The revision of the regulatory framework for medical devices therefore contributes to the Single Market Act and to the Innovation Union, both part of the EUROPE 2020 strategy.

The legislative initiative will also contribute to the Commission's simplification programme by transforming the existing three main directives, their three amending directives and two Commission implementing directives into two regulations of the European Parliament and of the Council, by maintaining the co-regulation approach supported by standardisation and by a single registration instead of multiple national requirements.

The successful implementation of the future regulatory framework for medical devices will depend on several factors. Some of the monitoring or evaluation tools set out in the impact assessment are the following:

- Assistance to Member States regarding alignment of the national legislation to the future EU regulatory framework and monitoring of this process.
- Roadmap set up by Commission and Member States for the assessment and designation of all existing Notified Bodies according to the new requirements and designation process, at the latest three years after entry into force of the new legislation.
- Annual statistics regarding the number of incidents reported to the central vigilance database and the number of coordinated analysis regarding corrective actions.
- Timely deployment of the IT infrastructure in close co-operation between the operational services and the IT specialists.
- Full implementation of a European Unique Device Identification (UDI) system ca. 10 years after entry into force of the new legislation in close co-operation with international partners, in particular with the US FDA, to ensure global compatibility and allow traceability between the respective jurisdictions.

- Report of the Commission to the European Parliament and to the Council about the achievements of the 'medical device package', ten years after its adoption, addressing the impact of the new rules with respect to public health/patient safety, internal market, innovativeness and competitiveness of the medical device industry (with special attention to SMEs).