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ANNEX X

CLINICAL EVALUATION

1. **General provisions**

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1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as 'clinical evaluation', where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on:

1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:

— there is demonstration of equivalence of the device to the device to which the data relates, and

— the data adequately demonstrate compliance with the relevant essential requirements.

1.1.2. Or a critical evaluation of the results of all clinical investigations made.

1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2.

1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is duly justified to rely on existing clinical data.

1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device.

1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented.

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.

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1.2. All the data must remain confidential, in accordance with the provisions of Article 20.

2. **Clinical investigations**

2.1. *Objectives*

The objectives of clinical investigation are:

— to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and

— to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

2.2. *Ethical considerations*

►M5 Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. ◄ It is mandatory that all measures relating to the protection

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of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

2.3. *Methods*

2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination.

2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device.

2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined.

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2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed.

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2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment.

The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device.

2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.

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ANNEX XI

CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES

1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body.

2. The notified body and its staff must carry out the assessment and verification operations with the highest degree of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications.

   Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.

3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II to VI and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. ►M1 This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I. ◄ It must also have access to the equipment necessary for the verifications required.

4. The notified body must have:

   — sound vocational training covering all the assessment and verification operations for which the body has been designated,

   — satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections,

   — the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except *vis-à-vis* the competent administrative authorities of the State in which their activities are carried out) pursuant to this Directive or any provision of national law putting it into effect.

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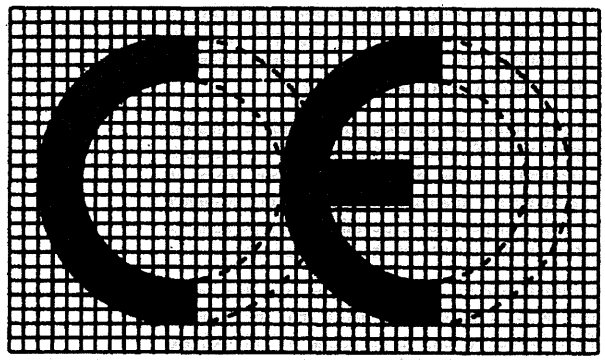
ANNEX XII

CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials 'CE' taking the following form:



— If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.

EUROPEAN COMMISSION

Brussels, 26.9.2012
COM(2012) 542 final

2012/0266 (COD)

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

(Text with EEA relevance)

{SWD(2012) 273 final}
{SWD(2012) 274 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The current EU regulatory framework for medical devices, other than *in vitro* diagnostic medical devices, consists of Council Directive 90/385/EEC on active implantable medical devices (AIMDD)[1] and Council Directive 93/42/EEC on medical devices (MDD)[2] which cover a huge spectrum of products. The MDD divides them into four classes of risk: class I (low risk, e.g. sticking plasters, corrective glasses), class IIa (medium-low risk, e.g. tracheal tubes, dental filling material), class IIb (medium-high risk, e.g. X-ray machines, bone plates and screws) and class III (high risk, e.g. heart valves, total hip replacements, breast implants). Active implantable medical devices (e.g. pacemakers, implantable defibrillators) covered by the AIMDD fall *de facto* into class III.

The 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 human health and safety. Medical devices are not subject to any pre-market authorisation by a regulatory authority but to a conformity assessment which, for medium and high risk devices, involves an independent third party, known as 'notified body'. Notified bodies, of which there are around 80 across Europe, 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 demonstrated its merits but has also come under harsh criticism, in particular after the French health authorities found that a French manufacturer (*Poly Implant Prothèse*, PIP) had for several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval issued by the notified body, causing harm to thousands of women around the world.

In an internal market with 32 participating countries[3] and subject to constant technological and scientific progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of medical devices and their free movement within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).

This revision aims to overcome these flaws and gaps and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework should be put in place that is 'fit for purpose'. This framework should be supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals.

This proposal is adopted alongside a proposal for a Regulation on *in vitro* diagnostic medical devices (IVDs), such as blood tests, which are covered by Directive 98/79/EC of the

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1 OJ L 189, 20.7.1990, p. 17.
2 OJ L 169, 12.7.1993, p. 1.
3 EU Member States, EFTA countries and Turkey.

European Parliament and of the Council (IVDD)[4]. The horizontal aspects that are common to both sectors are aligned whilst the specific features of each sector require separate legal acts.

2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENTS

In preparation for the impact assessment on this proposal and the proposal for a Regulation on IVDs, the Commission held two public consultations, the first from 8 May to 2 July 2008, and the second from 29 June to 15 September 2010. In both public consultations, the general principles and minimum standards for consultation of interested parties by the Commission were applied; responses received within a reasonable period after the deadlines were taken into account. After analysing all the responses, the Commission published a summary outcome and the individual responses on its website[5].

The majority of respondents to the 2008 public consultation (in particular Member States and industry) considered the proposed revision to be premature. They pointed to Directive 2007/47/EC of the European Parliament and of the Council[6], which amended the AIMDD and the MDD and was to be implemented by 21 March 2010, and also to the New Legislative Framework for the Marketing of Products which was due to enter into force with effect from 1 January 2010, and argued that it would be advisable to wait for these changes to be implemented, in order to assess the need for further adjustments better.

The 2010 public consultation focussed on aspects related to the revision of the IVDD and showed wide support for this initiative, linked to the revision of the regulatory framework for medical devices in general.

During 2009, 2010 and 2011, the issues to be tackled in the revision of the regulatory framework for medical devices were regularly discussed at meetings of the Medical Devices Expert Group (MDEG), the Competent Authorities for Medical Devices (CAMD) and specific working groups in the fields of notified bodies, borderline and classification, clinical investigation and evaluation, vigilance, market surveillance, *in vitro* diagnostics medical devices (IVD) and in an *ad hoc* working group on Unique Device Identification (UDI). A special meeting of the MDEG was held on 31 March and 1 April 2011 to discuss issues related to the impact assessment. Moreover, the Heads of Medicines Agencies (HMA) and the CAMD organised joint workshops on the development of the legal framework for medical devices on 27 April and 28 September 2011.

A further special meeting of the MDEG was held on 6 and 13 February 2012 to discuss issues related to the two legislative proposals, based on working documents containing initial drafting proposals. Written comments made on these working documents were taken in account for the further development of the proposals.

In addition, the Commission's representatives regularly participated in conferences to present ongoing work on the legislative initiative and hold discussions with stakeholders. Targeted meetings took place at senior level with representatives from associations representing industry, notified bodies, healthcare professionals and patients.

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4 OJ L 331, 7.12.1998, p. 1.
5 See http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm.
6 OJ L 247, 21.9.2007, p. 21.

Aspects linked to the appropriate regulatory framework were also discussed in the course of the 'Exploratory Process on the Future of the Medical Device Sector' organised by the Commission from November 2009 to January 2010. On 22 March 2011, the Commission and the Hungarian Presidency organised a high-level conference on innovation in medical technology, the role of the medical device sector in addressing the healthcare challenges facing Europe and the appropriate regulatory framework for this sector to meet the needs of tomorrow. This conference was followed by Conclusions of the Council of the European Union on innovation in the medical device sector adopted on 6 June 2011[7]. In its Conclusions, the Council requested the Commission to adapt the EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent and sustainable regulatory framework, which is central to fostering the development of safe, effective and innovative medical devices for the benefit of European patients and healthcare professionals.

Triggered by the PIP breast implants scandal, the European Parliament adopted on 14 June 2012 a Resolution on defective silicone gel breast implants made by the French company PIP[8] also calling on the Commission to develop an adequate legal framework to guarantee the safety of medical technology.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Scope and definitions (Chapter I)

The scope of the proposed Regulation corresponds to a large extent to the combined scopes of Council Directives 90/385/EEC and 93/42/EEC, i.e. it covers all medical devices other than *in vitro* diagnostic medical devices. On the one hand, however, the scope is extended to some products currently not covered by the AIMDD/MDD. And on the other hand, some products which, in some Member States, are placed on the market as medical devices are excluded from its scope.

The extension of the scope concerns:

- products manufactured utilising non-viable human tissues or cells, or their derivatives, that have undergone substantial manipulation (e.g. syringes prefilled with human collagen), unless they are covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products[9]. Human tissues and cells, or products derived from human tissues or cells, that are not substantially manipulated and that are regulated by Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[10] are not covered by the proposal;

- certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes);

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7 OJ C 202, 8.7.2011, p. 7.

8 Resolution of 14 June 2012 (2012/2621(RSP)); P7_TA-PROV(2012)0262, http://www.europarl.europa.eu/plenary/en/texts-adopted.html.

9 OJ L 324, 10.12.2007, p. 121.

10 OJ L 102, 7.4.2004, p. 48.

Additional provisions as regards products that are not covered by the Regulation have been included, more to clarify the scope with a view to ensuring harmonised implementation than to substantially change the scope of the EU legislation. They concern:

- products that contain or consist of viable biological substances (e.g. living micro-organisms);

- food covered by Regulation (EC) No 178/2002 on general principles and requirements of food law[11] (e.g. this may affect certain slimming products); in return, medical devices are excluded from the scope of Regulation 178/2002 (diagnostic probes or cameras, even when introduced orally, are therefore clearly excluded from the food legislation).

As regards products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body, the borderline between medicinal products and medical devices is difficult to draw. To ensure a high level of safety of those products regardless of their qualification, those products which fall under the definition of a medical device are classified in the highest risk class and should comply with the relevant requirements of Annex I of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[12].

To support Member States and the Commission in determining the regulatory status of products, the Commission may set up, in accordance with its internal rules[13], a group of experts from various sectors (such as medical devices, IVDs, medicinal products, human tissues and cells, cosmetics and biocides).

The definitions section has been significantly extended, aligning the definitions in the field of medical devices with well established European and international practice, such as the New Legislative Framework for the Marketing of Products[14] and guidance documents produced by the Global Harmonization Task Force (GHTF) for medical devices[15].

3.2. Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement (Chapter II)

This chapter contains provisions that are typical for product-related internal market legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives of non-EU manufacturers, importers and distributors). The regulatory instrument of 'common technical specification' (CTS), which has proven useful in the context of the IVDD, has been introduced in the broader field of medical devices to allow the Commission to further specify the general safety and performance requirements (laid down in

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11 OJ L 31, 1.2.2002, p. 1.

12 OJ L 311, 28.11.2001, p. 67.

13 Communication from the President to the Commission of 10.11.2010, Framework for Commission Expert Groups: Horizontal Rules and Public Registers, C(2010)7649 final.

14 Consisting of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30, and Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82.

15 http://www.ghtf.org/

Annex I) and the requirements on clinical evaluation and post-market clinical follow-up (laid down in Annex XIII). Such requirements however, leave manufacturers the possibility of adopting other solutions that ensure at least an equivalent level of safety and performance.

The legal obligations on manufacturers are proportionate to the risk class of the devices they produce. For example, this means that even though all manufacturers should have a quality management system (QMS) in place to ensure that their products consistently meet the regulatory requirements, the QMS-related responsibilities are stricter for manufacturers of high risk devices than for manufacturers of low risk devices. Manufacturers of medical devices for an individual patient, so called 'custom-made devices', must ensure that their devices are safe and perform as intended, but their regulatory burden remains low.

Key documents for the manufacturer to demonstrate compliance with the legal requirements are the technical documentation and the EU declaration of conformity to be drawn up in respect of devices placed on the market. Their minimum contents are laid down in Annexes II and III.

The following concepts are also new in the field of medical devices:

- A requirement has been introduced that within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance. Similar requirements exist in EU legislation on medicinal products and in the national laws transposing the AIMDD/MDD in some Member States.

- Since in the case of 'parallel trade' with medical devices application of the principle of free movement of goods varies considerably from one Member State to another and, in many cases, *de facto* prohibits this practice, clear conditions are set for enterprises involved in relabelling and/or repackaging medical devices.

- Patients who are implanted with a device should be given essential information on the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indication as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

- In accordance with Article 12a of the MDD, introduced by Directive 2007/47/EC, the Commission had to prepare a report on the reprocessing of medical devices and submit, where appropriate, a legislative proposal on this issue. On the basis of the Commission's findings set out in its report of 27 August 2010[16], which took into account the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of 15 April 2010, the proposal contains strict rules on the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. Reprocessing of single-use devices is considered as manufacture of new devices so that the reprocessors must satisfy the obligations incumbent on manufacturers. The reprocessing of single-use devices for critical use (e.g. devices for surgically invasive procedures) should, as a general rule, be prohibited. Since

[16] Report from the Commission to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC, COM(2010)443 final.

certain Member States may have particular concerns in terms of safety regarding the reprocessing of single-use devices, they retain their right to maintain or impose a general ban on this practice including the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing and on the access of reprocessed single-use devices to their market.

3.3. Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, Eudamed (Chapter III)

This chapter addresses one of the main shortcomings of the current system: its lack of transparency. It consists of:

- a requirement that economic operators must be able to identify who supplied them and to whom they have supplied medical devices;
- a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows traceability. The UDI system will be implemented gradually and proportionate to the risk class of the devices;
- a requirement that manufacturers/authorised representatives and importers must register themselves and the devices they place on the EU market in a central European database;
- an obligation for manufacturers of high-risk devices to make publicly available a summary of safety and performance with key elements of the supporting clinical data;
- and the further development of the European databank on medical devices (Eudamed), set up by Commission Decision 2010/227/EU[17], which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by notified bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the information in Eudamed will become publicly available in accordance with the provisions regarding each electronic system.

The establishment of a central registration database will not only provide a high level of transparency but also do away with diverging national registration requirements which have emerged over recent years and which have significantly increased compliance costs for economic operators. It will therefore also contribute to reducing the administrative burden on manufacturers.

3.4. Notified bodies (Chapter IV)

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system which has come under severe criticism in recent years due to significant differences as regards, on the one hand, the designation and monitoring of notified bodies and, on the other, the quality and depth of the conformity assessment performed by them, in particular in their assessment of the manufacturers' clinical evaluation.

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17 OJ L 102, 23.4.2010, p. 45.

In line with the New Legislative Framework for the Marketing of Products, the proposal sets out requirements for national authorities responsible for notified bodies. It leaves the ultimate responsibility for designating and monitoring notified bodies, based on stricter and detailed criteria laid down in Annex VI, with the individual Member State. The proposal thus builds on existing structures already available in most Member States instead of lifting the responsibility to the Union level which might have caused concerns in terms of subsidiarity. But any new designation and, in regular intervals, the monitoring of notified bodies are made subject to 'joint assessments' with experts from other Member States and the Commission, thus ensuring an effective control at Union level.

At the same time, the position of notified bodies vis-à-vis manufacturers will be significantly strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices. The proposal also requires rotation of the notified body's personnel involved in the assessment of medical devices at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments and the need to ensure continuous objectivity and neutrality in relation to the manufacturer subject to those assessments.

3.5. Classification and conformity assessment (Chapter V)

The proposal keeps to the well established approach (in Europe and internationally) of dividing medical devices into four classes, taking account of the potential risks associated with the technical design and manufacture. The classification rules (laid down in Annex VII) have been adapted to technical progress and experience gained from vigilance and market surveillance. For example, further to incidents that had occurred to blood plasma donors and a request submitted by France, aphaeresis machines have been moved from class IIb to class III. Active implantable medical devices and their accessories have been classified in the highest risk class (class III) to maintain the same level of safety as provided by Council Directive 90/385/EEC.

The classification of a medical device determines the applicable conformity assessment procedure for which the proposal follows the general lines of the AIMDD/MDD. The conformity assessment procedure for class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturer in view of the low level of vulnerability associated with these products. However, when class I devices have a measuring function or are sold sterile, a notified body must verify the aspects related to the measuring function or to the sterilisation process. For devices of classes IIa, IIb and III, an appropriate level of involvement of a notified body is compulsory proportionate to the risk class, with devices of class III requiring explicit prior approval of the design or of the type of the device and of the quality management system before they may be placed on the market. In the case of class IIa and IIb devices, the notified body checks the quality management system and, for representative samples, the technical documentation. After initial certification, notified bodies must regularly conduct surveillance assessments in the post-market phase.

The different conformity assessment procedures during which the notified body audits the manufacturer's quality management system, checks the technical documentation, examines the design dossier or approves the type of a device are laid down in Annexes VIII to X. They have been tightened and streamlined. The proposal reinforces the powers and responsibilities of notified bodies and specifies the rules according to which notified bodies perform their assessments, both in the pre-market and the post-market phase (e.g. documentation to be submitted, scope of the audit, unannounced factory inspections, sample checks) to ensure a

level playing field and avoid notified bodies being overly lenient. Manufacturers of custom-made devices continue to be subject to a specific procedure (laid down in Annex XI) which does not involve a notified body.

In addition, the proposal introduces the obligation for notified bodies to notify an expert committee (see below under 3.8.) of new applications for conformity assessment of high-risk devices. On scientifically valid health grounds, the expert committee will have the power to request the notified body to submit a preliminary assessment on which the committee can issue comments within a deadline of 60 days[18], before the notified body can issue a certificate. This scrutiny mechanism empowers the authorities to have a 'second look' at individual assessments and make their views heard before a device is placed on the market. A similar procedure is currently already applied for medical devices manufactured utilising animal tissues (Commission Directive 2003/32/EC[19]). Its use should be the exception rather than the rule and should follow clear and transparent criteria.

3.6. Clinical evaluation and clinical investigations (Chapter VI)

Building on the current Annex X of the MDD, this chapter lays down the key obligations of manufacturers as regards the performance of the clinical evaluation needed to demonstrate the safety and performance of their devices. More detailed requirements are set out in Annex XIII which addresses the pre-market clinical evaluation and post-market clinical follow-up that together constitute a continuous process during the life cycle of a medical device.

The process for conducting clinical investigations (the equivalent of clinical trials in the field of medicinal products), which is currently described in basic terms in Article 15 of the MDD, is further developed. First of all, the concept of 'sponsor' is introduced and aligned with the definition used in the recent Commission's Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use which aims at repealing Directive 2001/20/EC[20].

The sponsor can be the manufacturer, his authorised representative or another organisation, in practice often a 'contract research organisation' conducting clinical investigations for the manufacturers. The scope of the proposal, however, remains restricted to clinical investigations carried out for regulatory purposes, i.e. for obtaining or confirming regulatory approval for market access. Non-commercial clinical investigations that do not pursue a regulatory purpose are not covered by this Regulation.

In accordance with recognised international ethical principles, every clinical investigation must be registered in a publicly accessible electronic system which the Commission will set up. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations on medical devices should be interoperable with the future EU database to be set up in accordance with the future Regulation on clinical trials on medicinal products for human use.

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18 In accordance with Article 3(3) of Regulation (EEC, EURATOM) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, OJ L 124, 8.6.1971, p. 1) days referred to in this Regulation mean calendar days.

19 OJ L 105, 26.4.2003, p. 18. This directive will be replaced by Commission Regulation (EU) No 722/2012 (OJ L 212, 9.8.2012, p. 3) with effect from 29 August 2013.

20 COM(2012)369.

Before commencing a clinical investigation, the sponsor must submit an application to confirm that there are no health and safety or ethical aspects which would oppose it. A new possibility will be opened up for sponsors of clinical investigations to be conducted in more than one Member State: in future, they may submit a single application through the electronic system to be set up by the Commission. As a consequence, the health and safety aspects regarding the device intended for clinical investigation will be assessed by the Member States concerned under the direction of a coordinating Member State. The assessment of intrinsically national, local and ethical aspects (e.g. liability, suitability of the investigators and investigation sites, informed consent) will, however, need to be carried out at the level of each Member State concerned which will retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory. In line with the above-mentioned Commission's Proposal for a Regulation on clinical trials on medicinal products, also this proposal leaves it to the Member States to define the organisational set-up at national level for the approval of clinical investigations. In other words, it moves away from a legally required dualism of two distinct bodies, i.e. a national competent authority and an ethics committee.

3.7. Vigilance and market surveillance (Chapter VII)

A well functioning vigilance system is the 'backbone' of a robust regulatory framework in this sector because complications with medical devices that are designed to be implanted or to operate for many years or even decades might come to light only after a certain period of time. The main progress which the proposal will bring in this field is the introduction of an EU portal where manufacturers must report serious incidents and corrective actions they have taken to reduce the risk of recurrence. The information will be automatically forwarded to the national authorities concerned. Where the same or similar incidents have occurred, or where a corrective action has to be taken, in more than one Member State, a coordinating authority will take the direction in coordinating the analysis of the case. The emphasis is placed on work- and expertise-sharing to avoid inefficient duplication of procedures.

As regards market surveillance, the main objectives of the proposal are to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

3.8. Governance (Chapters VIII and IX)

The Member States will be responsible for implementation of the future Regulation. A central role in achieving harmonised interpretation and practice will be assigned to an expert committee (the Medical Device Coordination Group or MDCG) made up of members appointed by the Member States due to their role and experience in the field of medical devices and chaired by the Commission. The MDCG and its subgroups will allow to build a forum for discussions with stakeholders. The proposal creates the legal basis that for specific hazards or technologies EU reference laboratories, a concept that has proven successful in the food sector, may in the future be designated by the Commission.

As regards the management at EU level, the impact assessment identified as preferred policy options either the extension of the responsibility of the European Medicines Agency (EMA) to medical devices or the management of the medical devices regulatory system by the Commission. Taking into account the clear preference expressed by stakeholders, including many Member States, the proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG.

3.9. Final provisions (Chapter X)

The proposal empowers the Commission to adopt, where appropriate, either implementing acts to ensure uniform application of the Regulation or delegated acts to complement the regulatory framework for medical devices over time.

With this proposal, other Union legislation is amended where a link exists with medical devices. In the case of medicinal product/medical device combination products that are regulated under Directive 2001/83/EC, the AIMDD and MDD already require the device part to comply with the applicable essential requirements set out in the medical device legislation. However, compliance with this requirement is not currently verified as part of the authorisation process for the medicinal product. Annex I of Directive 2001/83/EC, which lays down the content of an application for marketing authorisation, is therefore amended to require the applicant to submit evidence (e.g. an EU declaration of conformity or a certificate issued by a notified body) that the device part is in conformity with the applicable general safety and performance requirements of the future Regulation on medical devices.

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[21] is amended to empower the Commission to determine whether or not a product falls within the definition of a cosmetic product. Such possibility already exists in the AIMDD and the MDD and is kept in this proposal. It also exists in the new Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[22]. This will facilitate the adoption of EU-wide decisions regarding 'borderline' cases where the regulatory status of a product needs to be clarified.

The Food Regulation 178/2002 is amended to exclude medical devices from its scope (see 3.1. above).

The new Regulation will become applicable three years after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. The Commission needs time to put in place the IT infrastructure and the organisational arrangements necessary for the functioning of the new regulatory system. The designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of the Regulation in order to ensure that by the date of its application, sufficient notified bodies are designated in accordance with the new rules to avoid any shortage of medical devices on the market. Special transitional provisions are foreseen for the registration of medical devices, relevant economic operators and certificates issued by notified bodies to allow for a smooth transition from registration requirements at national level to a central registration at EU level.

The future Regulation replaces and repeals Council Directives 90/385/EEC and 93/42/EEC.

3.10. Union competence, subsidiarity and legal form

The proposal has a 'double legal basis', i.e. Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU). With the entry into force of the Lisbon Treaty, the legal base for the establishment and functioning of the internal market, on which

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21 OJ L 342, 22.12.2009, p. 59.
22 OJ L 167, 27.6.2012, p.1.

the current Medical Devices Directives were adopted, has been complemented by a specific legal basis to set high standards for the quality and safety of devices for medical use. In regulating medical devices, the Union is exercising its shared powers under Article 4(2) of the TFEU.

Under the current Medical Devices Directives, devices that bear the CE marking can, in principle, move freely within the EU. The proposed revision of the existing directives, which will integrate the changes introduced by the Lisbon Treaty regarding public health, can be achieved only at Union level. This is necessary in order to improve the level of protection of public health for all European patients and users, and also to prevent Member States from adopting diverging product regulations which would result in further fragmentation of the internal market. Harmonised rules and procedures allow manufacturers, especially SMEs which make up more than 80% of the sector, to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety throughout the Union. In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary in order to achieve those objectives.

The proposal takes the form of a Regulation. This is the appropriate legal instrument as it imposes clear and detailed rules which will become applicable in a uniform manner and at the same time throughout the Union. Diverging transposition of the AIMDD and MDD by Member States has led to different levels of health and safety protection and created obstacles to the internal market which only a Regulation can avoid. Replacing the national transposition measures also has a strong simplification effect since it allows economic operators to conduct their business on the basis of a single regulatory framework, rather than a 'patchwork' of 27 national laws.

The choice of a Regulation, however, does not mean that decision-making is centralised. Member States retain their competence for implementing the harmonised rules, e.g. as regards approval of clinical investigations, the designation of notified bodies, the assessment of vigilance cases, the conduct of market surveillance and enforcement action (e.g. penalties).

3.11. Fundamental Rights

In line with the Charter of Fundamental Rights of the EU, this proposal seeks to ensure a high level of human health protection (Article 35 of the Charter) and consumer protection (Article 38) by assuring a high level of safety of medical devices made available on the Union market. The proposal affects the freedom of economic operators to conduct business (Article 16) but the obligations imposed on manufacturers, authorised representatives, importers and distributors of medical devices are necessary to guarantee a high level of safety of those products.

The proposal sets guarantees for the protection of personal data. In respect to medical research, the proposal requires that any clinical investigation with participation of human subjects is conducted respecting the human dignity, the right to physical and mental integrity of the persons concerned and the principle of free and informed consent, as required by Articles 1, 3(1) and 3(2)(a) of the Charter.

4. BUDGETARY IMPLICATIONS

The budgetary implications of this proposal are as follows:

- Costs for the further development of the Eudamed databank (one-off costs and maintenance);
- Commission staff to organise and participate in 'joint assessments' of notified bodies;
- Costs for national assessors participating in 'joint assessments' of notified bodies in accordance with the Commission's rules on the reimbursement of expenses incurred by experts;
- Commission staff to provide scientific, technical and logistic support to the MDCG, to its sub-groups and to the coordinating Member States in the fields of clinical investigations and vigilance;
- Commission staff to manage and further develop the EU regulatory framework for medical devices (functioning of this Regulation and preparation of delegated/implementing acts) and to support Member States in ensuring its effective and efficient implementation;
- Costs for organising meetings of the MDCG and its sub-groups and of the Committee under Regulation 182/2011, including reimbursement of their members, appointed by the Member States, to ensure a high level of coordination between Member States;
- Costs for the establishment and management of the scrutiny mechanism in respect of conformity assessments by notified bodies for high risk devices, including the technical infrastructure for data-exchange;
- Costs for running EU reference laboratories when these are designated;
- Costs for participation in international regulatory cooperation.

Details of the costs are set out in the legislative financial statement. A thorough discussion on the costs is contained in the impact assessment report.

2012/0266 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[23],

Having regard to the opinion of the Committee of the Regions[24],

After consulting the European Data Protection Supervisor[25],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[26] and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[27] constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

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23 OJ C [...], [...], p. [...].
24 OJ C [...], [...], p. [...].
25 OJ C [...], [...], p. [...].
26 OJ L 189, 20.7.1990, p. 17.
27 OJ L 169, 12.7.1993, p. 1.

(2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.

(4) To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical investigations.

(5) For historic reasons active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than *in vitro* diagnostic medical devices.

(6) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as *in vitro* diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[28] should be amended to exclude medical devices from its scope.

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[28] OJ L 31, 1.2.2002, p.1.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[29].

(9) Products which combine a medicinal product or substance and a medical device, are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[30]. It should be ensured that appropriate interaction exists between the two legislative acts in terms of consultations during the pre-market assessment and exchange of information on vigilance cases occurring with combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements of the device part should be adequately assessed in the context of the marketing authorisation. Directive 2001/83/EC should therefore be amended.

(10) Union legislation is incomplete in respect of certain products manufactured utilising non-viable human tissues or cells that have undergone substantial manipulation and that are not covered by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004[31]. Whilst donation, procurement and testing of the human tissues and cells used for the manufacture of those products should remain within the scope of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[32], the finished product should come under the scope of this Regulation. Human tissues and cells that are not substantially manipulated, such as human demineralised bone matrix, and products derived from such tissues and cells, should not be covered by this Regulation.

(11) Certain implantable and other invasive products for which the manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation.

(12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain living biological substances of other origin are also not covered by this Regulation.

(13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of

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29 OJ L 342, 22.12.2009, p. 59.
30 OJ L 311, 28.11.2001, p. 67.
31 OJ L 324, 10.12.2007, p. 121.
32 OJ L 102, 7.4.2004, p. 48.