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PART I

COMMISSION STAFF WORKING DOCUMENT

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

Accompanying the documents

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. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The "recast" of Directives 90/385/EEC and 93/42/EEC and their amending directives was first envisaged in the Commission's Communication "Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment"[1]. However, a number of additional aspects have come into play which prompted the Commission to consider that not only a simplification was needed but also a strengthening of the whole legal framework for medical devices. Moreover, Directive 98/79/EC on in vitro diagnostic medical devices, which has not been substantially amended since its adoption, also needs to be revised. Its revision is addressed in the present impact assessment as well.

The revision of the regulatory framework for medical devices was mentioned in the Commission Work Programmes 2010[2] and 2011[3]. In both cases, the 'roadmaps' were published on the homepage of the European Commission's Secretariat-General[4].

1.1. Stakeholder consultation

1.1.1. Public consultations

In mid-2008, the Commission held a public consultation on the recast of the general regulatory framework for medical devices. The consultation was published on the Commission's website[5] and was widely announced to public authorities (European and third countries) and stakeholders (industry, Notified Bodies, healthcare professionals and patient and consumer groups). The Commission received 200 responses. A summary report of the responses (Appendix 1) as well as the individual responses (unless submitted confidentially) were published on 5 December 2008 on the Commission's website[6].

A second consultation on specific aspects related to *in vitro* diagnostic medical devices and the revision of Directive 98/79/EC was held in the second half of 2010. It was equally widely announced among interested parties and the public[7]. The Commission received 183 responses. A summary report of the responses (Appendix 2) as well as the individual responses (unless submitted confidentially) were published on 23 February 2011 on the Commission's website[8].

1.1.2. Further dialogue with stakeholders

During 2009, 2010 and 2011, the issues to be tackled in the context of 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

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1 COM(2005)535.

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 31 March 2010, COM(2010)135 final, Annexes II and III.

3 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 27 October 2010, COM(2010)623 final, Annexes II and III.

4 http://ec.europa.eu/governance/impact/planned_ia/planned_ia_en.htm

5 http://ec.europa.eu/health /medical-devices/documents/revision/index_en.htm

6 http://ec.europa.eu/health /medical-devices/documents/revision/index_en.htm

7 http://ec.europa.eu/health /medical-devices/documents/revision/index_en.htm

8 http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/ivd_pc_outcome_en.pdf

Identification (UDI)[9]. A special MDEG meeting was held on 31 March and 1 April 2011. Moreover, the Heads of Medicines Agencies (HMA) and the CAMD organised a joint workshop regarding the development of the legal framework for medical devices on 27 April 2011 and on 28 September 2011. A further special MDEG meeting 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, Commission's representatives regularly participated in conferences to present the ongoing work on the legislative initiative and discuss with stakeholders. Targeted meetings took place at senior level with representatives from industry associations and with Notified Bodies. Aspects linked to the appropriate regulatory framework were also discussed in the context of the "Exploratory Process on the Future of the Medical Device Sector" organised by the Commission from November 2009 to January 2010[10]. On 22 March 2011, the Commission and the Hungarian Presidency organised a high-level conference on innovation in medical technology addressing the role of the medical device sector in the context of Europe's healthcare challenges and the appropriate regulatory framework for this sector to meet the needs of tomorrow.

1.1.3. Conclusions of the Council of the European Union

The above-mentioned high-level conference was followed-up by Conclusions of the Council of the European Union on innovation in the medical device sector adopted on 6 June 2011 (Appendix 3)[11] which contain a number of recommendations as regards the issues to be addressed in the context of the revision of the medical devices directives.

1.1.4. Resolution of the European Parliament on defective silicone gel breast implants

As of end 2011, the existing regulatory framework for medical devices has 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 harm to thousands of women around the world. On 14 June 2012, the European Parliament adopted a Resolution of the Parliament[12], *inter alia*, calling on the Commission to develop an adequate legal framework to guarantee the safety of breast implants and medical technology in general and even to shift to a system of pre-market authorisation for certain categories of medical devices, including at least medical devices of class IIb and III.

1.2. Consultation of other Commission's services

At an early stage, a large number of Commission departments were invited to an inter-service coordination group meeting on 7 October 2008 to inform other services about the envisaged legislative initiative. After the transfer of responsibilities for the medical devices regulations from DG ENTR to DG SANCO as of 1 February 2010, an Impact Assessment Steering Group (IASG) was set up to which the following departments were invited: SG, LS, ENTR, COMP, EMPL, ENV, RTD, JRC, INFSO, MARKT, JUST, TRADE and BUDG.

The IASG met on 18 November 2010, 8 April 2011 and 14 July 2011.

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9 For an overview of the different working groups and their composition see http://ec.europa.eu/health/medical-devices/dialogue-parties/working-groups/index_en.htm

10 http://ec.europa.eu/health/medical-devices/competitiveness/exploratory-process/index_en.htm

11 OJ C 202 of 8.7.2011, p. 7.

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

1.3. Contacts with Third Countries

The market for medical devices is a global one. Since the early 1990s, regulators and industry representatives of the EU, the US, Canada, Japan and Australia have sought to bring about the convergence of their respective regulations in this sector in the context of the Global Harmonization Task Force (GHTF)[13]. The regulators of the other four GHTF members submitted comments on the 2008 and 2010 public consultations and the members of the GHTF were regularly informed about the progress of the legislative initiative. This revision will provide an opportunity to align EU regulations for medical devices with international guidelines developed by the GHTF.

Regular bilateral exchange of views took place with the US Food and Drug Administration (FDA) in the context of the annual meetings in the field of medical devices, medicinal products and cosmetic products.

The EFTA countries, Turkey and Croatia participated in the Medical Devices Expert Group meetings and targeted working group meetings where the changes to the regulatory system were regularly discussed.

After their adoption by the College, the proposals will need to be notified pursuant to Articles 2.9.2 and 5.6.2 of the WTO TBT Agreement.

1.4. External studies

For the preparation of this legislative initiative no specific external studies have been mandated. However, the following study was taken into account:

- Impact Assessment of Policy Options for Combating Counterfeiting of Medical Devices and for Developing Safer Distribution Channels for Parallel Trade in Medical Devices, Europe Economics, 2010.

1.5. Scrutiny by the Commission's Impact Assessment Board

The draft impact assessment was submitted to the Commission's Impact Assessment Board (IAB) on 23 August 2011. The IAB provided a favourable opinion on 23 September 2011 and made some recommendations. Those recommendations have been taken into account for the final version of the impact assessment report. In particular, the baseline option was better explained, the justification for a scrutiny mechanism allowing for an ex ante control of certain medical devices was further elaborated, the proportionality of the policy option to submit high risk 'in house' tests to the scope of the future regulations on IVDs as well as the impact of the alignment with international guidelines in the field of IVDs were better explained. Moreover, additional data regarding incidents reported in the context of the vigilance system were gathered and the competitiveness-related impacts on EU manufacturers were further elaborated.

Finally, the findings related to the defective PIP silicone breast implants which became known only at the end of 2011 and in the course of the first semester 2012 have been taken into account.

2. PROBLEM DEFINITION

2.1. Background

The main characteristics of the medical devices sector are:[14]

[13] http://www.ghtf.org/

[14] For more details see the 'fact sheet' about the medical device sector, Appendix 4.

- huge spectrum of products, from sticking plasters or wheelchairs to X-ray machines, scanners, pacemakers, drug-eluting stents or blood tests, but no exact data exist as regards the number of different types of devices on the market[15];
- EU market (2009): around €85bn[16], plus around €10bn for IVD[17], with growth even during the economic and financial crisis;
- extremely innovative[18], with trends towards more drug-device combination products, 'smart' implantable devices, telemedicine, artificial organs[19], neuroengineering (e.g. cochlear or retina implants), companion diagnostics for personalised medicine[20], use of tissues, cells or other biologics and nanotechnologies[21];
- high reinvestment rate in R&D, average 6-8% of the sales, for IVDs up to 10%;
- around 22,500 individual medical technology companies, more than 80% are SMEs (in the IVD sector 90%), employing around 500,000 persons in Europe[22];
- EU average percentage of total healthcare expenditure spent on medical devices (2009): 4.2%, for IVDs 0.8%.

The regulatory framework for medical devices is composed of three main directives:[23]

- 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).

The first two directives are very similar whilst the IVDD takes account of the specificities of the sector. The aims of all three directives are to ensure the functioning of the internal market and a high level of protection of human health and safety. Their main characteristics are:

- "New Approach" directives, based on the Treaty's 'internal market' article (now Article 114 of the Treaty on the Functioning of the European Union), to which the New Legislative Framework for the Marketing of Products applies[24];

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15 According to the WHO, estimates range from some 90,000 to 1.5 million in over 10,000 types of generic device groups, WHO, Medical Devices: Managing the mismatch, 2010, p. 1, http://whqlibdoc.who.int/publications/2010/9789241564045_eng.pdf; WHO fact sheet No 346, Sept. 2010, http://www.who.int/mediacentre/factsheets/fs346/en/index.html

16 Eucomed figures for EU 27, Norway and Switzerland, http://www.eucomed.org/medical-technology

17 EDMA Annual Report 2009, p. 11; http://www.edma-ivd.be/fileadmin/upl_documents/Annual_Report/2009/EDMA_2010-07-16_Annual_Report.pdf

18 According to information of the industry, the average life-cycle of medical devices are 18 months, even though this depends very much on the product. Heart valves or hip implants can remain unchanged during several years while other devices are constantly improved.

19 See report 360050011/2008 of the Dutch National Institute for Public Health and the Environment (RIVM) on artificial organs.

20 IVD (biomarker) are used to help predicting the outcome of a particular therapy for a given patient.

21 See AFSSAPS, Evaluation biologique des dispositifs médicaux contenant des nanomatériaux, rapport scientifique du 22.2.2011.

22 See http://www.eucomed.org/medical-technology/facts-figures.

23 For more details see also the 'fact sheet' about the EU regulatory framework for medical devices, Appendix 5.

24 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.

- essential requirements for the safety and performance of medical devices included in the directives;
- detailed product specifications laid down in harmonised standards;
- no pre-market authorisation by a regulatory authority;
- classification of devices in different risk classes:

Risk classification according to Annex IX of the MDD	class I (low risk)	class IIa (low to medium risk)	class IIb (medium to high risk)	class III (high risk)[25]
Examples	sticking plasters; corrective glasses	dental filling materials; tracheal tubes	X-ray machines; urethral stents	cardiovascular catheters; hip, shoulder and knee joint replacements
Risk classification according to the IVDD (NB: the review of the classification of IVD is addressed in Annex 2 to this impact assessment)	not listed in Annex II of IVDD (i.e. low risk)	not listed in Annex II of IVDD but intended for self-testing (i.e. low to medium risk)	listed in Annex II, List B, of IVDD (i.e. medium to high risk)	listed in Annex II, List A, of IVDD (i.e. high risk)
Examples	tests for the measurement of cholesterol level in blood	self-tests for the determination of pregnancy	reagents for evaluating the risk of trisomy 21	reagents for detection of HIV or hepatitis B, C and D infection

- for medium and high risk devices: conformity assessment by an independent third party, so-called "Notified Body";
- for low risk devices: conformity certified by the manufacturers themselves;
- once certified, devices bear the CE marking which allows them, in principle, to circulate freely in the EU/EFTA countries and Turkey.

The Member States have broad competences in respect to the implementation of the medical devices directives, such as for example the designation and monitoring of Notified Bodies, the supervision of clinical investigations, the investigation of vigilance cases and the surveillance of devices on the market.

2.2. Problem identification

The existing regulatory framework for medical devices 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 particular due to the PIP silicone breast implant scandal (see section 1.1.4) or problems occurring with certain metal-on-metal hip joint replacements. Several weaknesses which undermine the main objectives of the three medical devices directives, i.e. the safety of medical devices and their

[25] AIMD (e.g. pacemakers, implantable defibrillators) correspond to class III devices.

free circulation within the internal market were identified in the Commission's 2008 public consultation (see section 1.1.1). In the light of the envisaged revision of the EU regulatory framework for medical devices, the Commission's services analysed the PIP breast implant case ("stress test", Appendix 11). This analysis detected further shortcomings of the existing regulations in addition to the already identified weaknesses. The findings, however, do not suggest that the system for regulating medical devices is fundamentally unsound.

The present revision of the medical devices directives aims at overcoming the weaknesses, taking into account lessons learned from the PIP case, while maintaining the overall objectives of the legal framework. Its main part focuses on the systemic issues which are relevant for both the AIMDD/MDD and the IVDD. Issues that are relevant either only for the AIMDD/MDD or only for the IVDD, respectively, such as their respective scopes, clinical investigations (for MD), the review of the classification of IVD or clinical evidence (for IVD), are discussed in detail, respectively, in Annexes 1 and 2 to this impact assessment; the results are summarised in section 6 of this main part.

Besides the 27 EU Member States, the four EFTA countries and Turkey have also transposed the directives and participate in the European regulatory system for medical devices. A single market of 32 countries is a challenge to the uniform interpretation and implementation of the legal requirements as well as to the coordination of the activities of the national competent authorities in the area of their competences, both pre- and post-market. Due to imprecise legal requirements and different levels of expertise, human resources and powers of the competent authorities, the level of control exercised over Notified Bodies and over the medical devices placed on the market is fragmented.

This leads to an uneven level of protection of the patients, users and public health. Moreover, this lowers the confidence in the CE marking which should guarantee the free movement of devices within the EU and which is also recognised by several 3rd countries as proof of compliance with their own national safety requirements, often with the support of a certificate of free sale issued by the competent authority responsible for the exporting manufacturer.

Due to the absence of a central database regarding medical devices available on the EU market, stakeholders, in particular users, claim a lack in transparency in the regulatory process. This has prompted several Member States to impose registration systems in order to have an improved knowledge of devices put into service within their territory. Such national measures, however, do not give rise to a general overview of CE marked devices and create obstacles to the internal market.

Participation in the informal and non-statutory working groups which aim at the exchange of views and the coordination of activities of national authorities (e.g. Notified Body Operation Group, Compliance and Enforcement, Clinical Investigation and Evaluation, Vigilance WG, Medical Devices Expert Group on Borderline and Classification) and Notified Bodies (NB-Med) is voluntary and the guidance documents drawn up by them (MEDDEV, Manual on borderline and classification, NBOG-BPG, NB-Med Recommendation)[26] are not legally binding and are therefore not suitable to enforce a high level of patient safety and the functioning of the internal market.

2.2.1. Problem 1 – Oversight of Notified Bodies

Notified Bodies take responsibilities in areas of public interest and remain answerable to the competent authorities. The primary task of Notified Bodies is to carry out an assessment of

[26] http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm; http://www.nbog.eu/2.html; http://www.team-nb.org/index.php?option=com_docman&Itemid=38

the manufacturer's quality management system and/or the design of a device *before* those medical devices which require a third party certification are placed on the market. Currently 78 Notified Bodies are designated by 24 EU/EFTA states[27], Turkey[28] and Australia[29] under the AIMDD, MDD and IVDD[30] (August 2011). Authorities and manufacturers 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 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. Notified Bodies themselves acknowledge the differences[31], which ultimately lead to varying levels of protection of patients' and users' safety which, from a public health perspective, is an issue of concern. In addition, it distorts competition between manufacturers of similar products.

Example: The Commission received complaints from manufacturers of a new type of catheters as regards the quality and depth of the conformity assessment carried out by one Notified Body in respect of their competitor's devices. After a lengthy investigation of this issue, the designation of this Notified Body for the specific type of devices was withdrawn by the responsible Member State as the body did not demonstrate the necessary level of competence and expertise to conduct the conformity assessment for this type of products.

The competition between Notified Bodies must not be distorted by bodies which perform their tasks without having sufficient skills and expertise at their disposal. It is therefore crucial for the functioning of the system that the authorities responsible for the designation and monitoring of Notified Bodies exercise a close, independent and consistent control to ensure that Notified Bodies are designated only for the assessment of devices or technologies which correspond to their proven expertise and competence. The minimum requirements currently laid down in the medical devices directives, however, are very vague. The coordination group of Member States' competent authorities in the field of Notified Bodies (NBOG) issued a "Designating Authorities' Handbook"[32], but this Handbook does not have any legal status and adherence is at the discretion of the individual competent authority. In addition, there is currently no mechanism which ensures that competent authorities carry out supervision in accordance with commonly agreed criteria.

As regards the oversight of Notified Bodies, the Council of the European Union confirmed the need to improve the harmonised criteria for the designation of Notified Bodies and "*to ensure that they are designated only for the assessment of devices and technologies which correspond to their proven expertise and competencies*"[33].

2.2.2. Problem 2 – Post-market safety (vigilance and market surveillance)

The right and obligation of Member States to collect and analyse information about serious incidents occurring with devices and 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

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27 AT, BE, CH, CZ, DE, DK, ES, FI, FR, GR, HU, IE, IT, LT, LU, NL, NO, PL, PT, RO, SE, SI, SK, UK.

28 Under the EU-Turkey Customs Union Agreement.

29 Under the EU-Australia Mutual Recognition Agreement.

30 See also the NANDO database under http://ec.europa.eu/enterprise/newapproach/nando/. All 19 Notified Bodies designated under Directive 90/385/EEC and all 25 Notified Bodies designated under Directive 98/79/EC are also designated under Directive 93/42/EEC.

31 See section 8 of the Summary of responses to the 2008 public consultation (see above section 1.1.1).

32 http://www.nbog.eu/resources/da_handbook.pdf

33 Council Conclusions adopted on 6 June 2011, section 6, 8th indent, see Appendix 3.

has been illegally affixed to a product[34] is a central pillar of the regulatory system for medical devices in order to strike a reasonable balance between pre-market control of devices and their post-market surveillance.

Incidents within the meaning of the three medical devices directives are reported to the competent authorities of the Member States concerned. After assessment of the incident and the manufacturers' proposed field safety corrective action (FSCA), Member States must inform each other about measures taken or contemplated in order to minimise the recurrence of such incidents[35]. In 2010, Member States exchanged 748 National Competent Authorities Reports (NCARs), but the number differs hugely between Member States. While Germany accounts for roughly 40% of all NCARs, the UK for around 20% and Ireland for about 15%, other Member States submit very few or no NCARs (see statistics in Appendix 6a)[36].

NCARs represent only a share of the incidents which are originally reported to the competent authorities by manufacturers, users, patients or others. This is due to several reasons:

Firstly, the conditions for the exchange of NCARs are not clearly stated in the current directives. They were clarified by means of non-binding guidelines in December 2009 (MEDDEV 2.12-1 rev 6 – Guidelines on the Medical Devices Vigilance System) still leaving competent authorities with the discretion not to exchange NCARs when the manufacturer's corrective action is not considered to be essential to protect the safety of patients or users[37].

Secondly, many reported incidents do not require further action or measures by the competent authorities, for example when the incident was not due to the device but to the user. According to information of the German competent authority, the *Bundesinstitut für Arzneimittel und Medizinprodukte*, around 76% of the 22,428 incidents reported during the period 2005-2010 did not lead to further measures. According to information of the UK competent authorities, the *Medicines and Healthcare Products Regulatory Authority*, around 65% of reported incidents did not lead to further action.

Actually, there are no consolidated statistics regarding the total number of incidents reported in the 27 Member States. According to the public information made available on the websites of the four competent authorities who exchanged the largest number of NCARs in 2010, the numbers of reported incidents are around 10,000/year in the UK and France and around 6,000 in Germany (see Appendix 6b). But it should be noted that the criteria for the statistics published by the authorities are not harmonised.

This appears to show, firstly, that manufacturers do not report serious incidents to the competent authorities according to the same criteria since the obligations of manufacturers

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34 In terms of the directives "wrongly affixed CE marking". It is the case when the CE marking has been affixed unduly or is missing in violation of the directive.

35 Article 8(3) AIMDD, Article 10(3) MDD and Article 11(3) IVDD.

36 NCAR statistics are published at the Commission's website, http://ec.europa.eu/health/medical-devices/documents/vigilance-reports/index_en.htm.

37 The MEDDEV states: "*Information shall be disseminated between National Competent Authorities and copied to the Commission when:*
A) a FSCA is performed by the MANUFACTURER;
B) a National Competent Authority requires the MANUFACTURER to perform an FSCA or to make changes in an FSCA that the MANUFACTURER has already initiated;
C) there is a serious risk to the safety of patients or other USERs, but where no corrective action has yet been established, although measures are under consideration;
D) the MANUFACTURER does not provide a final report in a timely manner.
[…] National Competent Authorities should use their discretion where corrective action is taken by a MANUFACTURER which is not considered to be essential to protect the safety of patients or other USERs Under these circumstances a National Competent Authority Report may not be necessary."

(including the obligation to set up a post-market surveillance plan) are spelt out in the annexes of the directives only in general terms. Moreover, the NCAR statistics raise questions with regard to the criteria according to which Member States exchange information regarding reported incidents and measures taken to minimise the risk of recurrence. Furthermore, apart from the information exchange, no coordination is ensured between the competent authorities as regards the assessment of incidents and the corrective measures which have an impact on more than one Member State.

Examples for restrictions imposed by Member States on medical devices in the context of the vigilance system are:

- product withdrawal (recalls): certain infusion pumps, drug-eluting coronary stents, joint or breast implants, removed from the market for safety reasons;
- batch removal: removal of contaminated batches/lots of syringes or of swabs;
- reduced shelf life or stricter storage conditions of *in vitro* diagnostics following incident reports that demonstrated a lack of performance under certain circumstances;
- specific patients follow-up: strict instructions concerning the medical follow up of patients with certain implanted devices whose safety or performance is put into question after incidents were reported;
- stricter instructions for use of specific software used in radiotherapy or for radiodiagnostics.

Experience with the application of the vigilance system and other legal instruments available to the Member States (e.g. safeguard clauses, particular health monitoring measures, illegally affixed CE marking) has shown that national competent authorities react in different ways to the same problems. Whilst in some Member States the placing on the market or putting into service of a given device is banned or restricted, it may freely circulate in other Member States.

Example: After the report of an incident with an insulin pump, one Member State ordered the recall of the product while in other Member States the manufacturer was obliged simply to provide additional information to the health professionals.

This practice puts into question a harmonised level of protection of patients and users in the EU and also creates obstacles to the internal market[38].

2.2.3. Problem 3 – Regulatory status of products

The demarcation between the medical devices directives and the other regulatory frameworks applicable to e.g. medicinal products, biocides, food or cosmetics is not always clear. In the case of food and medical devices, the respective legislations are even overlapping. Since a decision on the regulatory status of a product falls within the competence of Member States, divergent interpretations in respect to "borderline" cases lead to the application of different legal regimes in the various Member States and lengthy discussions between authorities. This is especially the case for some ingested products (e.g. antacid products, simethicone containing products), osmotic laxatives, products containing micro-organisms or substances administered to the human body for which the principal mode of action often is not scientifically clearly determinable[39]. The difficulty of determining whether the principal mode of action is metabolic, pharmacological, immunological or not is likely to increase with the

[38] See Clinica, November 2010 p. 6, "EU device vigilance: scrutiny threatens radical change".

[39] Directive 2007/47/EC inserted in Article 1(5)(c) MDD that when deciding whether a product falls under the MDD or Directive 2001/83/EC, "particular account shall be taken of the principal mode of action".

development of new and more drug-device combination products which are an important area of innovation. Currently, a request for a preliminary ruling is pending before the European Court of Justice (C-109/12) relating to capsules containing living lactic acid producing bacteria for restoration of the vaginal bacterial flora which have been qualified as medicinal products by the authorities of a Member State. The same product, however, is available in some Member States as CE-marked medical device.

"Borderline" cases also exist between medical devices and IVD which need to be decided since the AIMDD/MDD and the IVDD currently are mutually exclusive.

Despite existing guidance documents, Member States take different positions with regard to the regulatory status of a product. This leads to the situation that a given product is considered a medical device in one or several Member States while, in other Member States, it is considered a pharmaceutical, a consumer product or something else. Different interpretations exist also with regard to the rules on the classification of a medical device (e.g. class I, IIa, IIb or III) which has an impact on the requirements applicable to the device.

Between 2006 and 2010, 114 borderline and classification problems have been circulated among the Member States through the so-called 'Helsinki procedure'[40]. Some of them are borderline cases with other legislations (e.g. qualification of products used in *in vitro* fertilisation procedures), others concern the classification of a specific medical device (e.g. classification of medical devices containing silver as an antimicrobial) and the majority of the cases concerns both aspects (e.g. qualification and classification of biofunctional textiles).

Around 50 particularly difficult ones, either resulting from an inconclusive 'Helsinki procedure' or on specific request from stakeholders, were discussed in plenary meetings of the informal Medical Devices Expert Group on Borderline and Classification[41] and consensus amongst the competent authorities could be reached. These consensus statements are published in the so-called Manual on Borderline and Classification which is publicly available. However, some controversial cases remain unsolved despite long discussions within the above mentioned Expert Group. The application of different regulatory regimes to the same product compromises both the protection of patient safety and the internal market.

Examples: Products against head-lice are regulated as medical devices, medicinal products, cosmetics or under specific national legislation depending on the Member State. Active coal solution or some heparin-containing products used for the rinsing of catheters are regulated either as medical devices or as medicinal products in the various Member States.

Moreover, even where a consensus is found, the consensus statements published in the Manual are not legally binding and competent authorities or national courts may decide at any moment not to follow them. This reduces the legal certainty and prompts criticism from stakeholders. The right of a Member State to submit a substantiated request to the Commission to adopt a Comitology measure as to whether a product falls within the definition of a medical device or not (or with regard to the classification of a device) has not been effectively used.

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40 The "Helsinki procedure" is a consultation procedure triggered by a Member State when this Member State wants to receive the other Member States' views on a specific qualification or classification problem. While this procedure has been useful to solve some issues, some limitations exist. In particular, the participation of Member States to this procedure is on a voluntary basis, its outcomes are not legally binding and the follow-up to be given (i.e. further discussion required in a plenary meeting of the Medical Devices Expert Group on Borderline and Classification) depends mainly on the initiating Member State.

41 See http://ec.europa.eu/health/medical-devices/documents/borderline/index_en.htm

Example: So far, the only substantiated request submitted by a Member State concerned a product (hygienic tampons containing lactic acid producing bacteria) *not* to be considered a medical device which would have left the question of the applicable regulatory regime unanswered.

The Commission itself cannot trigger the procedure on its own initiative and it would need further device-specific expertise to adopt an EU measure in a timely manner. The lack of uniform qualification (or classification) of a product across the EU creates a fragmentation of the internal market (as a manufacturer must follow different legal regimes in order to sell the same product in different Member States) and may put patient safety at risk.

2.2.4. Problem 4 – Lack of transparency and harmonised traceability

Transparency

No exact data exist as regards the number, the types and the approval status of medical devices on the European market. The European associations representing the medical technology industry give an estimate of around 500,000 different medical devices available[42] whilst the number of IVD is estimated to be around 40,000 by the European IVD manufacturers association. According to information provided by the Italian authorities, more than 320,000 medical devices (other than IVD) have been registered in the database established in 2007 by the Italian Ministry of Health[43]. In the newly set up Turkish database, more than 1.7 million medical devices are registered[44]. From a public health point of view authorities need to have at their disposal consistent information about medical devices on the market. Many interested parties, in particular patients, healthcare professionals[45], Health Technology Assessment (HTA)[46] bodies[47], insurers and third countries, consider the regulatory pathway of medical devices opaque and lacking in transparency since there is no access to key data regarding the characteristics, the clinical data and the conformity assessment path of certain medical devices, in particular implantable or other high risk devices.

The scope of the European databank for medical devices (Eudamed) is limited to information about class I device manufacturers and authorised representatives, certificates, vigilance reports and clinical investigations and it is not accessible to the public (patients, healthcare professionals etc.). Moreover, Eudamed as currently conceived requires the uploading of information by the 32 competent authorities (EEA countries, Switzerland and Turkey). This is burdensome for the Member States since they are required to set up their own systems for collecting the data to be entered into Eudamed.

In addition, for medical devices of classes IIa, IIb and III, for active implantable medical devices and for IVD listed in Annex II of Directive 98/79/EC and IVD for self-testing, the directives allow Member States to request to be informed of all data allowing for the

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42 http://www.eucomed.org/medical-technology

43 Information provided by the Italian Ministry of Health (state of play: April 2011).

44 Information provided by the Turkish Ministry of Health (state of play: July 2011).

45 *Alan G. Fraser et al*., Clinical evaluation or cardiovascular devices: principles, problems, and proposals for European regulatory reform, in: European Heart Journal 14.5.2011; *Deborah Cohen/Matthew Billingsley*, Europeans are left to their own devices, in: BMJ, 2011, 342:d2839.

46 Health Technology Assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic, and ethical issues related to the use of health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value, see http://ec.europa.eu/health/technology_assessment/policy/index_en.htm.

47 *Hulstaert, F. et al.*, The pre-market clinical evaluation of innovative high-risk medical devices, Belgian Health Care Knowledge Centre (KCE), 2011, KCE Report 158C; D/2011/10.273/31; Interview with Prof. Jürgen Windeler, director of IQWiG, in: Clinica, Jan/Feb 2011, p.23.

identification of these devices when they are put into service within their territory. Around 15 Member States[48] have made use of this right which means that a manufacturer of medium or higher risk devices, or his authorised representative, must notify the competent authorities of these Member States when the device is sold in their countries. 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.

Example: The introduction of a medical device databank by Italy with extensive information requirements and the levy of a fee prompted the European Commission to start an infringement procedure which resulted in an amendment of the Italian regulations.

Traceability

Traceability of medical devices is currently not regulated by the medical devices directives. This has prompted some European countries to impose traceability requirements on economic operators (manufacturers, importers, distributors, hospitals) at national (e.g. Turkey) or sometimes even at regional level (e.g. Spain) through a Unique Device Identification (UDI) mechanism. UDI is a series of numeric or alphanumeric characters that is created through a coding system. It allows the unambiguous identification of a specific product on the market and represents the "access key" to device related information stored in the UDI database. The UDI comprises the device identifier and the production identifier. The establishment of this code considerably enhances traceability even though the word "unique" does not imply serialisation of every single device, e.g. those devices marketed in lots and batches. Traceability contributes to enhance patient safety in cases where restrictive measures have to be taken on specific devices, such as a recall of products already placed on the market. It can also contribute to the fight against counterfeiting.

Example: According to information of the UK authorities it is envisaged that hospitals of the NHS need to require medical devices to bear a GS1 code when purchased by public procurement in order to enhance traceability and to increase efficiency.

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. Moreover, products or their packaging need to be adapted to the different sets of rules. In addition, the UDI mechanisms are often linked to databases so that manufacturers have to enter data in different national (or even regional) databases as already described in the preceding section, thus increasing their administrative burden and hampering the internal market.

2.2.5. Problem 5 – Access to external expertise

The medical devices directives currently do not make provision for a structured involvement of external experts (e.g. healthcare professionals, academics) in the regulatory process. Notified Bodies usually seek expert advice in the context of conformity assessment procedures but at EU level the dialogue on regulatory or safety issues usually takes place between regulatory authorities and manufacturers except in cases when a scientific opinion is sought from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[49] on specific issues.

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48 According to the results of an enquiry launched by the UK in 2009, 13 out of 22 EU/EFTA states which responded require a notification or a registration of devices when they are put into service in their respective territories.

49 The SCENIHR was established by Commission Decision 2008/721/EC of 5 August 2008, OJ L 241 of 10.9.2008, p. 21.

Regulators, medical societies and manufacturers have expressed the need to better involve scientific and clinical experts in the dialogue and make their advice available in the regulatory decision-making process to keep pace with the innovation of products. The Council thus suggested the promotion of "*early dialogue between manufacturers, scientific and clinical experts, competent authorities and, where appropriate, notified bodies, regarding 'new products' in particular, and their classification.*"[50]

2.2.6. Problem 6 – Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales

The obligations of manufacturers and/or authorised representatives are not bundled in the operative body of the directives but often need to be deduced from requirements mentioned within the annexes such as for example requirements relating to clinical evaluation and post-market safety/clinical follow-up. In the field of IVD, all manufacturers need to have a quality system (QS) in place whilst this is not clearly spelled out in the MDD for class I manufacturers. Some Member States require from the manufacturers established on their territory to supply a documentation of the QS when they inspect them but the practice is not harmonised.

As regards authorised representatives who, in principle, shall act instead of a non-EU manufacturer with regard to the latter's obligations under the directives, no minimum requirements exist. However, to fulfil this role authorised representatives need to be more than a mere mail-box but satisfy minimum criteria to contribute to the safety of devices of non-EU manufacturers placed on the EU market. Importers and distributors (including parallel traders and those selling over the internet) are currently not covered at all leading to different levels of protection of patient safety and to obstacles to the internal market.

Example: Member States enforce medical device regulations in different ways on parallel traders of medical devices since different opinions exist as to which requirements should be applicable to parallel trade in this field and as to whether activities usually performed by a parallel trader (e.g. repackaging or relabelling) would make this economic operator a manufacturer in terms of the directives.

Furthermore, uncertainties exist as to the application of the directives where (mainly) diagnostic devices, in particular IVD, are used by an economic operator to provide test results at a distance, either to a healthcare professional or directly to a consumer, without the diagnostic device itself being placed on the market or put into service in the EU. For example, in the field of IVD, laboratories offer to persons situated within the internal market to provide testing carried out on the basis of a body specimen which consumers may send per normal mail. Despite recital 11 and Article 9(13) of the IVDD it is not always clear whether IVD used in such a situation are subject to the directive. The problem is not limited to IVD but also exist with regard to diagnosis made on the basis of medical imaging devices. There are increasing concerns regarding the validity and the reliability of the results provided at a distance and their understanding by lay users.

Examples: Especially in the field of genetics or food intolerance, testing is offered to consumers/patients at a distance without that the tests themselves are paced on the market.

Concerns also exist as regards possible risks related to sales of medical devices over the internet, in particular as regards counterfeit products. Even though devices bought over the internet within the EU or from third countries are subject to the same requirements as devices sold in the 'traditional' way, enforcement is more difficult.

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[50] Council Conclusions adopted on 6 June 2011, section 5, 9th indent, see Appendix 3.

Examples: Counterfeit contact lenses and condoms[51] offered over the internet have been detected.

2.2.7. Problem 7 – 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. This holds true in particular in terms of identification of devices placed on the market, of designation and monitoring of Notified Bodies, of assessment of products, of vigilance and of market surveillance. In addition, there is no legal basis to ensure a gathering of expertise at EU level. This leads to a lack of uniform application of the rules and of common reactions in the European market. This compromises both patient safety and the good functioning of the internal market.

In the absence of a governance structure with a legal basis, the Commission and the Member States have taken steps to achieve a certain degree of harmonised implementation. They have set up informal working groups which usually meet in Brussels and are chaired by Commission or Member States' representatives (21 meetings were organised in 2010). However, in the absence of any reference in the directives to the management of the system at EU level, the informal working groups produce guidance documents which serve a good purpose but cannot address fundamental issues.

Moreover, there is no appropriate structure to ensure the sustainability and the efficiency of these activities. The Commission currently has less than 7 Full Time Equivalent (FTE) working on issues related to medical devices. There is a lack of

- administrative, technical and scientific support to the cooperation between Member States;
- solid IT tools to manage the system;
- consolidated scientific and clinical expertise.

Therefore, when deciding on the appropriate solutions to improve the current legal framework, it will be also necessary to decide "who" would be most suitable to provide the necessary input and structure to manage the system at EU level in a sustainable, efficient and credible manner.

The Council called for a "*European coordination mechanism founded on a clear legal basis and mandate in order to ensure efficient and effective coordination between national authorities while creating a level playing field. Synergies with existing bodies with relevant expertise should be explored when deciding on the mechanism for such coordination*"[52].

3. OBJECTIVES

3.1. Overall objectives

When addressing the problems described above, the following three overall objectives should be pursued:

- **Overall objective A: To ensure a high level of protection of human health and safety**

[51] See e.g. the Written Question E-007016/2011.

[52] Council Conclusions adopted on 6 June 2011, section 6, 10th indent, see Appendix 3.

The major objective pursued by the revision of the regulatory framework for medical devices is that the level of safety set by the medical devices directives is further enhanced and assured also for new and emerging device technologies which are being or will be developed. The Council stressed that "*future legislative actions in this area must […] specifically aim to increase patients' safety while at the same time creating a sustainable legislative framework favourable to medical device innovation that can contribute to a healthy, active and independent life*"[53].

- **Overall objective B: To ensure the smooth functioning of the internal market**

By adopting the 'Single Market Act', the European Commission reconfirmed its commitment to further deepen the internal market thus optimising its benefits for businesses and citizens[54]. The preceding 2010 Monti-Report[55] pleaded for a stronger single market and noted that the regulatory framework for goods needed regular updating in order to cope with ever-changing business and stem creeping obstacles at national level. The objective of this revision is to put in place a regulatory framework which is applied with consistency across the EU and which enhances the "*reliability, predictability, speed and transparency in decision-making*" as suggested by the Council in its Conclusions[56]. This will allow manufacturers and other economic operators, in particular SMEs which represent around 80% of the device industry (90% in the IVD sector) and are most affected by diverging national implementation of the medical device directives, to exploit the full potential of the internal market while ensuring a high level of health protection.

- **Overall objective C: To provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry**

The medical device industry is considered one of the most innovative sectors in Europe where innovative devices come to the market earlier than in other advanced jurisdictions. According to data provided by the European medical device industry, medical devices are available in Europe in average around 18 months earlier than in the US and more than two years earlier than in Japan where only around one-half of devices that are available in Europe reach the market[57]. Several studies or surveys conducted in the U.S. point to the faster pre-market assessment in Europe compared to FDA clearance of medical devices[58] whilst safety levels were considered equal[59]. The EU regulatory framework for medical devices today is considered innovation-friendly. These positive aspects should not only be maintained but further improved by means of simpler and more predictable, transparent and efficient

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53 Council Conclusions adopted on 6 June 2011, section 4, 6th indent, see Appendix 3.

54 Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions "Towards a Single Market Act", 27.10.2010, COM(2010)608final.

55 A New Strategy for the Single Market, Report to the President of the European Commission by Prof. Mario Monti, 9 May 2010, http://ec.europa.eu/bepa/pdf/monti_report_final_10_05_2010_en.pdf

56 See also Council Conclusions adopted on 6 June 2011, section 6, 1st indent, see Appendix 3.

57 The American Chamber of Commerce in Japan, 2008 Device Lag Study.

58 *Josh Makower et al.*, FDA impact on U.S. medical technology innovation, November 2010, http://www.eucomed.be/Home/portal/press/press_releases/2010/~/media/1030872F3DF84ABF97065607D3E9507C.ashx. The study was fiercely rejected by the FDA's CDRH Director Mr Jeffrey Shuren, see http://www.massdevice.com/news/update-cdrh-chief-shuren-blasts-stanford-study-medical-device-regulations. *PricewaterhouseCoopers*, Medical Technology Innovation Scoreboard, January 2011, http://pwchealth.com/cgi-local/hregister.cgi?link=reg/innovation-scorecard.pdf (visited on 3 March 2011); *California Health Institute and Boston Consulting Group*, Competitiveness and Regulation: The FDA and the Future of America's Biomedical Industry, February 2011, http://www.bcg.com/documents/file72060.pdf (visited on 3 March 2011).

59 *Boston Consulting Group*, EU Medical Device Approval Safety Assessment, January 2011.

regulations. It should support investment and dynamic growth in Europe, with particular attention to the needs and future potential of SMEs in the medical devices sector.

An example of the innovative developments in the sector is the trend towards more combination products. According to a survey, an estimated 30% of new products under development are such "combination products"[60].

The EUROPE 2020 strategy for smart, sustainable and inclusive growth[61] called for an 'Innovation Union' to improve the framework conditions for innovation[62]. The regulatory framework for medical devices should therefore be supportive of innovation so that users and patients have access to safe, innovative and effective devices. This also fits with the "Innovation Partnership for Active and Healthy Ageing" where medical technology plays an important role in allowing older people to live independently and be active in society. At the same time, the competitiveness of the European medical device industry should be further improved and secured over coming decades.

3.2. Specific objectives

These general objectives can be further detailed by the specific objectives set out below. Each of them contributes to the achievement of the overall objectives.

3.2.1. Objective 1: Uniform control of Notified Bodies

The aim is to ensure that the legal requirements concerning the pre-market evaluation laid down in the legal texts are applied and implemented effectively in all Member States in a consistent and efficient way. Concretely, this means

– that Notified Bodies are designated only for the assessment of devices or technologies which correspond to their proven expertise and competence;

– that the position of Notified Bodies vis-à-vis manufacturers is strengthened and that all follow the same high standards and criteria when they assess the conformity of medical devices.

3.2.2. Objective 2: Enhanced legal clarity and coordination in the field of post-market safety

In the post-market phase, the objective is to ensure complete information regarding safety issues and to enhance the coordination of competent authorities regarding incidents (so called vigilance) or regarding non-compliant products. The aim is to avoid duplication of work and inconsistent reactions to the same problem in different Member States.

3.2.3. Objective 3: Cross-sectoral solution of "borderline" cases

In order to determine the regulatory status of a given product or type of product, the scopes of the relevant legislations need to be clearly delimited from each other. Moreover, experts from different regulatory fields may need to discuss the question together. The aim is to set up a mechanism involving other relevant regulatory authorities (pharmaceuticals, biocides, food, cosmetics etc.) which would allow for the EU-wide determination as to which legislation is applicable to a given product or type of product.

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60 The combination can for example include medical devices incorporating a medicinal substance, medical devices incorporating a human blood derivative, medical devices using a material of animal origin, see *Richter S.*, Combination Products: Navigating Two FDA Quality Systems, www.pharmamanufacturing.com (visited on 11.8.2011).

61 Communication from the Commission of 3 March 2010, COM(2010)2020.

62 Communication of the Commission on Europe 2010 Flagship Initiative Innovation Union, 6.10.2010, COM(2010)546final.

3.2.4. Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability

The aim is to considerably enhance transparency by developing modern IT tools building on the Eudamed databank, which would meet the expectations of patients, healthcare professionals, hospitals and authorities regarding information on medical devices placed on the EU market. This would allow better tracking and tracing of certain devices in the interest of patient safety. Better traceability would help to contact users of devices when these devices need to be modified or taken off the market and to identify counterfeit devices.

3.2.5. Objective 5: Enhanced involvement of external scientific and clinical expertise

The objective is to have access at EU level to scientific and clinical expert advice to support decision-making, taking into account "real use" experience with devices and the needs of patients and users.

3.2.6. Objective 6: Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales

A clear and simple description of the obligations and responsibilities of the relevant economic operators (manufacturers, authorised representatives, importers, distributors) should make it easier for them to comply with the requirements and for competent authorities to enforce them, so ensuring that only safe products are placed on the EU market or put into service. In this context, clarification should be provided that devices used in the framework of commercial diagnostic services provided to the EU market fall within the scope of the legislation on medical devices. Addressing the issue of internet sales will enhance the safety of devices offered via the internet and contribute to the fight against counterfeit products.

3.2.7. Objective 7: Governance - efficient and effective management of the regulatory system

A well structured and result-oriented coordination between the national competent authorities as well as between them and the Commission is necessary to ensure a high level of patient safety and the good functioning of the internal market. Effective coordination and information exchange will lead to mutual trust in the action of the competent authorities. It will also allow sharing of resources and avoid duplication of action. To yield fruit, the tasks to be fulfilled at EU level (e.g. organisation of expert group meetings, document management, development and maintenance of IT tools, pooling of experts, central contact point for authorities and stakeholders, in particular manufacturers) need to be effectively and efficiently managed. At the same time, the governance model chosen needs to be financially sound and sustainable.

4. POLICY OPTIONS

Before presenting the different policy options to address the objectives pursued by this revision, some preliminary remarks should be made to set the frame for the discussion of the individual options.

4.1. "No EU action"

The baseline scenario consists in "no EU action", i.e. no change to the current regulatory framework. The option “no EU action at all” 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[63]. More importantly, no action would

[63] 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

mean that the problems described above would continue to exist, or even increase, putting public health at risk. The PIP breast implants scandal made it evident that "no EU action" is not a defendable policy choice.

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 Council of the European Union, in its conclusions of 6 June 2011, therefore recognised "*the need to adapt the EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent, and sustainable regulatory framework […]*"[64] and invited the Commission to address several issues when preparing future legislation.

The "no EU action" option has been taken as the baseline to measure the potential impacts of the policy options against the status quo. The impacts of the different policy options assessed later on in this report are illustrated with ('+') for positive, ('-') for negative or ('o') for neutral impacts. That means that all specific policy options are compared to the baseline option by describing its benefits and disadvantages compared to the 'no EU action'. It should be noted that the impact of the baseline option in most instances would not be neutral but negative in terms of public health/patient safety, internal market and/or economic costs for operators.

4.2. Fundamental change: marketing authorisation of medical devices

The option to transfer the responsibility for the assessment of the safety and performance of medical devices from Notified Bodies to a regulatory authority and to replace the CE marking by a marketing authorisation, such as exists in the field of pharmaceuticals, has also been discarded. Despite calls in the aftermath of the PIP breast implant scandal to shift to a system of pre-market authorisation (see Resolution of the European Parliament referred to in section 1.1.4), 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.

A *decentralised* marketing authorisation (done by Member States) would have a significant negative impact on the internal market for medical devices. In fact, the CE marking that automatically allows devices on which it is affixed access to the whole EU market would be replaced by the application of the mutual recognition of national marketing authorisations which would not offer automatic access to the market of other Member States. Under such a regime, a Member State could refuse a device authorised by another Member States access to its market because it considers that this device does not ensure an appropriate level of protection of health and safety. 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[65]. It would have enormous impact on the EU budget, on manufacturers in terms of costs and administrative

768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products. See also the legislative initiative for the alignment of 10 Directives with Decision 768/2008 under the lead of DG Enterprise and Industry.

64 Council Conclusions adopted on 6 June 2011, section 3, 7th indent, see Appendix 3.

65 The Centre for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA) employs around 1,380 staff (May 2011), of which around 380 are working in the Office of Device Evaluation and around 150 in the Office of In Vitro Devices.

burden and on innovation in terms of costs for regulatory compliance and time to market[66]. According to data provided by industry, the R&D costs to bring a new medicinal product to the market have significantly increased over time and are estimated at around 1bn€[67]. In contrast, the development costs for a significantly new medical device are estimated at up to 10m€[68]. The following tables focus on procedural aspects and indicate the average costs and approval times incurred by a manufacturer under the medicinal products and under the medical devices legislation. They show that costs for obtaining a marketing authorisation under the medicinal products legislation significantly exceed the costs for obtaining a CE marking under the medical devices legislation.

Medicinal products legislation

	Costs for market access (standard application for non-SME pharmaceuticals manufacturer)	**Costs for market access (standard application for SME pharmaceuticals manufacturer)**	**Compliance costs post-market**	**Time to market**
Scientific advice	76,300 €	7,630 € (max. -90%)		
Inspection	19,100 €	1,910 € (max. -90%)		
Marketing authorisation	254,100 €	254,100 € if success 0 € if failure		
Annual fee			91,000 €	
Time for marketing authorisation				210 days[69] (excl. stop the clock periods)
Total	**349,500 €**	**263,640 €**	**91,000 €/year**	**210 days (= 7 months)** **(excl. stop the clock periods)**

Medical devices legislation

(under the assumption of a classification as class III medical device)

	Costs for market	**Costs for market**	**Compliance costs**	**Time to market**

[66] See in particular the studies of *PricewaterhouseCoopers* and *Boston Conculting Group* quoted in Fn. 56 and 57, respectively.

[67] EFPIA, The pharmaceuticals industry in figures (2010), http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=9158; *DiMasia J.A./ Grabowski H.G.*, The Cost of Biopharmaceutical R&D: Is Biotech Different? Managerial and Decision Economics. 28: 469–479 (2007) http://www.manhattan-institute.org/projectfda/wiley_interscience_cost_of_biopharm.pdf.

[68] Eucomed, response of 3 July 2008 to the public consultation, Fn.1; BVMed Branchenbericht 2010 (2.12.2010), p. 5 http://www.bvmed.de/stepone/data/downloads/50/d8/00/branchenbericht10_12.pdf.

[69] So far, only one ATMP (ChrondroCelect, EMA product no. EMEA/H/C/000878) has been authorised under Directive 2001/83/EC. Its approval procedure lasted from 1 June 2007 to 5 Oct. 2009, i.e. 857 days.

	access (non-SME)	access (SME)	post-market	
Notified Body fee (initial certification of quality system and design dossier examination)	10,000€ - 30,000€	No specific SME regime; but costs for the assessment of the quality system usually lower the smaller the company is.		
Annual surveillance audit (quality system)			1,000€ - 3,300€ (around 33% of initial QS audit)	
Notified Body fee for renewal			6,600€ - 20,000€ every 5 years (around 66% of initial certification)	
Average time for pre-market assessment				In average 10-15 weeks assessment time by Notified Body [70] (for certain devices types, e.g. devices combined with a medicinal substance that has an ancillary action or devices manufactured utilising certain animal tissues, a consultation procedure prolongs the process)[71]
Total	**10,000€ - 30,000€**		**2,320€ - 7,300€/year**	**10-15 weeks (= +/- 3 months)**

A change towards a marketing authorisation would also have consequences on Notified Bodies which would have to cease their activity in the field of medical devices.

Such a fundamental change was widely rejected during the public consultation and the subsequent dialogue with competent authorities, manufacturers and most other stakeholders, even though there were also some voices of healthcare professionals, health insurance organisations and HTA bodies[72] who recommended a centralisation of the evaluation of high-

[70] See NB-Med response of 27 June 2008 to the public consultation. See also response of the VdTüV of 1 July 2008 which mentions 90 days as average assessment time.

[71] For drug-device combination products: 210 days consultation period of a national pharmaceuticals authority or EMA; for devices manufactured utilising certain animal tissues: 12 weeks consultation period of national competent authorities.

[72] *Alan G. Fraser et al*., Clinical evaluation or cardiovascular devices: principles, problems, and proposals for European regulatory reform, in: European Heart Journal 14.5.2011, p. 11 ("*Options would be for the divisions of NBs that assess medical devices to become the technical division of a new European medical devices agency, or they could remain decentralized while operating within an integrated system.*"); *Hulstaert, F. et al.*, The pre-market clinical evaluation of innovative high-risk medical devices, Belgian Health Care Knowledge Centre (KCE), 2011, KCE Report 158C; D/2011/10.273/31,

risk devices. However, in the absence of evidence which would support that a centralised evaluation by a regulatory authority[73] in order to achieve the objectives of this revision, such a radical shift in the regulatory system would be inappropriate.

4.3. Evolution: reinforcement of the current regime keeping the same legal approach

Between the two extreme scenarios described above in sections 4.1. and 4.2. it exists the possibility to build on the strengths of the "New Approach" on which the current regime is based while remedying the weaknesses identified. 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. The individual policy options developed below under section 4.4. are to be seen within this frame of a further evolution of the current regulatory regime. It has to be noted that some options are alternatives whilst others may be cumulative.

4.4. Policy options regarding Objective 1: Uniform control of Notified Bodies

The options to be discussed in this chapter concern

– the designation and monitoring of the conformity assessment bodies, i.e. the Notified Bodies, by the authorities (options 1A – 1D) and

– the conformity assessment carried out by these Notified Bodies (options 1E – 1G).

4.4.1. Policy option 1A: New minimum requirements for Notified Bodies

This option would require the amendment of the current Annex 8 of the AIMDD, Annex XI of the MDD and Annex IX of the IVDD which set the minimum criteria to be met for the designation of Notified Bodies. The criteria should be made clearer and more detailed in order to reduce the discretion of the designating authority during the evaluation of the conformity assessment bodies and to enhance their overall competence. The new minimum requirements would take account of Article R17 of Decision 768/2008/EC on a common framework for the marketing of products[74] but would in addition introduce sector-specific requirements.

4.4.2. Policy options 1B – 1D: Changes to the process of designation and monitoring of Notified Bodies

4.4.2.1. Policy option 1B: Designation and monitoring of Notified Bodies by an EU body

This option would transfer the responsibility for the designation and monitoring of Notified Bodies from the Member States to the EU. It would require that an EU body (e.g. the Commission or an agency) carries out the initial assessment of a candidate body and periodical surveillance assessments together with the authority of the Member State where the body is established. Such model exists in the field of ship inspections and surveys, where the Commission, assisted by the European Maritime Safety Agency, grants recognition to organisations which meet the minimum legal requirements[75].

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p. 19: ("*Instead of trying to streamline a very fragmented system of Notified Bodies and Competent Authorities, a more straightforward way to achieve the goals discussed above could be to centralise expertise. This could be realised under the EMA umbrella, […]*".

[73] See e.g. the report of *Boston Consulting Group*, EU Medical Device Approval Safety Assessment, January 2011 (above Fn. 57), that does not identify a lower safety level of devices in Europe compared to the US where a system of marketing authorisation applies to certain categories of devices.

[74] E.g. as regards legal personality, management, technical competence, capabilities, liability, confidentiality, subsidiaries and subcontrators.

[75] Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations.

4.4.2.2. Policy option 1C: Designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams"

This option would leave the ultimate responsibility for the designation and supervision of Notified Bodies with the Member States. However, the initial assessment of a candidate body, as well as regular surveillance assessments, would be carried out by a "joint assessment team" composed of assessors from the Member State where the body is established together with assessors of one or two other Member States and of an EU body (Commission or an agency). In addition, there should be the possibility to admit assessors of third countries which have concluded Mutual Recognition Agreements or other cooperation arrangements with the EU in the field of medical devices (e.g. US, Canada, Australia).

The designation by the responsible Member State should be based on the results of the recommendations of the "joint assessment team" to be submitted to a forum composed of experts designated by the Member States (MDEG, see below in section 4.10.1) which should also settle cases of divergent opinions within the joint assessment team. In addition, the designating Member State would have to submit annual reports to the MDEG regarding the periodic surveillance assessments carried out between the "joint assessments".

4.4.2.3. Policy option 1D: Designation and monitoring of Notified Bodies by Member States in accordance with the model provisions of Decision 768/2008/EC

This option would align the procedure for the designation and monitoring of Notified Bodies in the field of medical devices to the model provisions set out in Articles R13 to R26 of Decision 768/2008/EC. In brief, this option would leave the responsibility for the designation with the individual Member States, enhance the importance of accreditation of Notified Bodies and give Member States and the Commission the right to raise objections against the notification of a designated Notified Body within two weeks of this notification if the body was accredited or within two months where accreditation was not used.

4.4.3. Policy options 1E - 1G: Review of the conformity assessment process

4.4.3.1. Policy option 1E: No change to the conformity assessment process

This option would rely on the strengthened oversight of Notified Bodies (see policy options 1A-1D) as well as possibly corrective measures to be taken ex post to ensure that they apply equally high standards and criteria during their conformity assessments. No additional layer of scrutiny prior to the issue of certificates by the Notified Bodies would be added.

4.4.3.2. Policy option 1F: Systematic ex ante control of conformity assessment reports for specific device types

This option would oblige Notified Bodies to systematically submit their preliminary conformity assessment reports for certain devices or technologies to a forum composed of experts designated by the Member States (MDEG, see section 4.10.1) for scrutiny before a certificate could be issued.

On the basis of a number of criteria, the Commission could specify in a delegated or implementing act which device types would be submitted to a systematic prior scrutiny. The criteria to define those device types could be the following:

– new technology, i.e. a breakthrough technology which may have a significant clinical impact;

– "high risk" due to components or source material (e.g. tissues) or due to the impact in case of failure;

– increased rate of incidents;

– existence of significant discrepancies in the conformity assessment carried out by different Notified Bodies;

– existence of public health concerns regarding a specific device type or technology.

Within a predefined standstill period (e.g. three months)[76], the MDEG could raise concerns which would have to be taken into account by the Notified Bodies. A kind of precedent exists in the field of medical devices manufactured utilising animal tissues where a procedure was established in 2003 which requires a prior consultation of competent authorities before Notified Bodies can issue certificates[77].

4.4.3.3. Policy option 1G: Notification requirement regarding new applications for conformity assessment and possibility for ex ante control

This policy option would create the obligation for Notified Bodies to notify the competent authorities and the Commission of new applications for design-examination, including a description of the main features of the medical devices concerned. This obligation should be limited to high-risk devices (class III MD and class D IVD[78]). On a case-by-case basis, a forum composed of experts designated by the Member States (MDEG, see section 4.10.1) could then identify those devices or technologies for which they would require the Notified Body to submit to them a summary of its preliminary conformity assessment reports, wait during a predefined standstill period (e.g. 3 months) and take possible comments of the forum into account before issuing a certificate of conformity.

In addition, for devices of class IIa and IIb and IVD of class B and C[79], the Commission would be empowered, to determine by a delegated or implementing act certain device types for which a prior scrutiny of the preliminary conformity assessment by the forum would be temporarily required during a certain period of time (e.g. three to five years). The criteria for adopting such measure would be the same as the ones listed in policy option 1F.

4.5. Policy options regarding Objective 2: Enhanced legal clarity and coordination in the field of post-market safety

4.5.1. Policy option 2A: Clarification of key terms and of the obligations of the parties involved in the field of vigilance

This option would make provision to

– introduce the terms "field safety corrective action" (FSCA) and "field safety notice" (FSN) in accordance with international guidelines[80];

– clarify the obligations and the roles of competent authorities, Notified Bodies and economic operators in the field of vigilance and post-market safety.

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76 It should also be possible to reduce or waive the standstill period when the authorities do not have any concerns so that the process can be accelerated.

77 Commission Directive 2003/32/EC concerning detailed specifications as regards requirements laid down in Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin. Since its application (April 2004), around 130 consultations were carried out giving rise, in the majority of cases, to comments by national competent authorities regarding e.g. the clinical benefit of the use of animal tissues and the availability of suitable alternative synthetic products presenting lower risks; the country of origin (unsure BSE status); non-validated manufacturing process; traceability of animal tissues (state of play: September 2011).

78 Class D IVDs according to the GHTF classification of IVDs which is discussed in detail in Annex 2 to this impact assessment.

79 Class B and C IVDs according to the GHTF classification of IVDs which is discussed in detail in Annex 2 to this impact assessment

80 GHTF/SG2/N57R8:2006 - Medical devices post market surveillance: content of field safety notices.

4.5.2. Policy options 2B – 2C: Reporting of incidents and coordination of analysis

4.5.2.1. Policy option 2B: Central reporting of incidents and coordinated analysis of certain high risk incidents

This policy option would establish a vigilance data-processing network and vigilance database (possibly a module of Eudamed) allowing for the central reporting of incidents[81] by manufacturers to the competent authorities concerned. In addition, Member States would have to enter information about serious incidents they have identified after analysis of reports from other sources (e.g. healthcare professionals, patients). All national competent authorities concerned would have access to the information simultaneously. The analysis of certain incidents (e.g. in case of high risk incident, disagreement on FSCA, lack of resources at national level) should be coordinated under the lead of a coordinating competent authority. The findings, would lead, if needed, to a corrective action consistent in all Member States concerned and could also lead to the adoption of a regulatory measure applicable in the whole EU. If a reported incident led to a FSCA, the corresponding FSN would be publicly available via the EU-wide vigilance database. In addition, trends and signals would be analysed on the basis of the centrally reported incidents.

4.5.2.2. Policy option 2C: Decentralised reporting of incidents, but coordinated analysis of certain high risk incidents

This policy option would keep the current form of reporting of incidents to the individual national competent authorities and information sharing between them. But it would require that the analysis of certain incidents (e.g. in case of high risk incident, disagreement on FSCA, lack of resources at national level) be coordinated under the lead of a coordination competent authority. The findings would lead, if needed, to a FSCA consistent for all Member States affected and could also lead to the adoption of a regulatory measure applicable in the whole EU.

4.5.3. Policy option 2D: Promotion of cooperation of market surveillance authorities

Market surveillance is a core competence of the Member States. Regulation (EC) No 765/2008 strengthened the role of the national surveillance authorities and the coordination among them. Article 24 of this Regulation requires Member States to ensure efficient cooperation and exchange of information between their market surveillance authorities whilst Article 25 stipulates that the sharing of resources and experience may be set up by the Commission, in cooperation with the Member States concerned, in particular regarding actions for common projects, information campaigns etc. This policy option would build upon these rules and make some existing skills, knowledge and equipment, including those of designated reference laboratories, available to other Member States[82].

4.6. Policy options regarding Objective 3: Cross-sectoral solution of "borderline" cases

A precondition for a consistent definition of the regulatory status of a given product is a clearer delimitation of the respective scopes of the relevant legislations to the application of different regulatory frameworks to the same type of product in the various Member States.

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[81] Incidents is defined as: "Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health".

[82] The IMCO Committee of the European Parliament called for sharing of best practices between Member States, joint cooperation, pooling of know-how and co-funded joint market surveillance action, see report 2010/2085(INI) of 24.2.2011 on the revision of the GPSD and market surveillance.

4.6.1. Policy option 3A: Creation of a cross-sectoral advisory group on borderline issues

This option would set up, either in the revised MDD/IVDD or at a later stage by an autonomous act of the Commission, a multidisciplinary advisory group of national experts in the field of medical devices, medicinal products, food, cosmetics, biocides etc. to provide advisory opinions as regards the regulatory status of a given product or type of product.

4.6.2. Policy option 3B: Creation of a cross-sectoral advisory group on borderline issues and possibility to determine the regulatory status of products at EU level

In addition to the creation of a multidisciplinary advisory group (see policy option 3A), this option would empower the Commission to adopt implementing acts as to whether a given product or type of product falls within the scope of a specific legislation. This possibility already exists in the AIMDD/MDD as well as in legislation on certain foodstuffs[83]; it is also foreseen in the new Regulation […] on biocides[84]. Article 17 of Regulation 1394/2007 on advanced therapy medicinal products (ATMP) allows manufacturers to request EMA to deliver a scientific recommendation as to whether a tissue engineered product falls within the definition of an ATMP. But a provision that would allow for determining the regulatory status of a given product or category of products does not exist in the IVDD or in the EU legislation on medicinal products, cosmetics or general foodstuff with which potential borderlines exist. This policy option would thus require the amendment of the EU rules covering e.g. medicinal products, general foodstuff and cosmetics and introduce into them a provision enabling the Commission to adopt implementing measures regarding the regulatory status of a product.

4.7. Policy options regarding Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability

4.7.1. Policy options 4A – 4B: Registration of economic operators and listing of devices

4.7.1.1. Policy option 4A: Network of national databases

This option would build a network of national databases to make the data collected at national level available at EU level. This would require standardised data collection by the participating Member States which could either be those who decided to set up national databases or all, if so required by EU legislation. No requirements regarding traceability would be introduced.

4.7.1.2. Policy option 4B: Central registration of economic operators and listing of medical devices placed on the EU market

This policy option would develop the European databank for medical devices (Eudamed) into a central IT tool

– for the registration of EU manufacturers, authorised representatives, importers and certain distributors, and

– for the listing of medical devices which are placed on the EU market or put into service.

It would do away with multiple and divergent registration/listing requirements established by Member States.

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83 In some specific food legislation, provision is made that the Commission may determine whether a type of food or a given substance falls within the scope of that specific legislation or in a specific category of foodstuff, e.g. Regulation (EC) No 258/1997 on novel food; Directive 94/35/EC on sweeteners for use in foodstuff; Directive 94/36/EC on colours for use in foodstuff; Directive 95/2/EC on other additives than colours and sweeteners.

84 Article 3(3) of the Biocides Regulation (not yet finally adopted).

The IT tool should be publicly available as regards basic information about the manufacturers and the devices. The detail of information would depend on the risk class and, for devices belonging to a higher risk class (e.g. implantable devices and class III devices), would also include key clinical data (summary of safety and clinical performance data[85]). Other parts would only be accessible to competent authorities and/or Notified Bodies.

4.7.2. Policy option 4C: Requirement for the traceability of medical devices

This policy option would build upon Article R7 of Decision 768/2008 according to which economic operators shall be identified along the supply chain[86]. It would provide the legal basis for the later implementation in the EU of a system of traceability based on a globally compatible "unique device identification" (UDI) in line with international guidance developed by the GHTF[87] and with the UDI requirement currently being implemented by the US FDA[88].The implementation should be gradual, starting with class III devices (e.g. coronary stents) or devices for which a need to trace has been identified (e.g. devices with a high level of incidents). It would require manufacturers to obtain an UDI code, allocate it to the product and provide information to a UDI database.

4.8. Policy options regarding Objective 5: Enhanced involvement of external scientific and clinical expertise

4.8.1. Policy option 5A: Creation of a pool of experts

This option would provide that a pool of experts at EU level with proven knowledge in the field of medical devices/technology is set up. This pool of experts could be consulted on an ad hoc basis upon request by competent authorities, the Commission, manufacturers or Notified Bodies.

4.8.2. Policy option 5B: Designation of an expert panel and reference laboratories for specific areas in medical technology

This option would set up, either in the revised MDD/IVDD or at a later stage by an autonomous act of the Commission, an expert panel composed of clinicians and academics in various fields of medical technology and designate reference laboratories (especially in the field of IVD). Their role would be to provide expert advice in the pre-market and post-market phase of the life-cycle of a medical device to the Commission and to competent authorities regarding specific safety issues detected in the context of vigilance or post-market surveillance activities (e.g. safeguard clause procedures).

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85 Similar to the FDA Summary of Safety and Effectiveness Data (SSED).

86 Article R7 of Decision 768/2008/EC on a common framework for the marketing of products states: "*Economic operators shall, on request, identify the following to the market surveillance authorities, for … [period to be specified in proportion to the lifecycle of the product and the level of risk]:*
a) any economic operator who has supplied them with a product;
b) any economic operator to whom they have supplied a product."

87 GHTF/AHWG(PD2)/N2R2, final adoption foreseen by the end of 2011.

88 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm

4.9. Policy options regarding Objective 6: Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales

4.9.1. Policy option 6A: Alignment with Decision 768/2008/EC[89], additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services

This option would incorporate in the MDD and IVDD the model provisions of Articles R2-R7 of Decision 768/2008 regarding manufacturers, authorised representatives, importers and distributors. Whilst Decision 768/2008 defines an authorised representative and what it should be allowed to do, the Decision does not specify the minimum requirements an economic operator needs to fulfil in order to exercise the role of an authorised representative properly. Therefore, some sector-specific minimum requirements for authorised representative would be set up. In addition, it would be clarified that medical devices and IVD used in the context of a commercial diagnostic service provided in the EU need to be in conformity with the legal requirements.

4.9.2. Policy options 6B – 6C: Internet sales

4.9.2.1. Policy option 6B: Legislative measures regarding internet sales

This option would incorporate in the MDD and IVDD specific requirements regulating the sale of medical devices and IVD over the internet, contributing to address the problem of counterfeit products and to ensure the application of the legal obligations.

4.9.2.2. Policy option 6C: Addressing internet sales by soft-law action

This policy option would not foresee specific requirements relating to internet sales but address the problem by means of soft law such as information campaigns, voluntary portals and/or code of conducts for internet sellers. The Member States, possibly with support of the Commission, should coordinate such actions in the field of internet sales at EU level and with third countries, contributing to address the problem of counterfeit products and to ensure the application of the legal obligations.

4.10. Policy options regarding objective 7: Efficient and effective management of the regulatory system

4.10.1. Policy option 7A: Extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency

This policy option would extend the mandate of the EMA and transform it into a European regulatory agency for medicinal products and medical devices ("European Health Products Agency", name to be chosen).

As mentioned in the problem description and the objectives, enhanced coordination between national competent authorities is the cornerstone for achieving a more harmonised implementation of the regulatory framework for medical devices. Several of the policy options therefore suggest tasks for a forum composed of experts designated by the Member

[89] Decision 768/2008/EC on a common framework for the marketing of products which is part of the New Legislative Framework for the Marketing of Products.

States[90], for the purpose of this report called Medical Device Expert Group (MDEG)[91]. This MDEG would be given a legal basis in the new legislation[92].

Representatives of patient organisations, healthcare professionals, manufacturers and Notified Bodies could be invited to participate in the MDEG to provide additional expert views. The MDEG would be supported, where appropriate, by specialist multi-stakeholder subgroups for specific areas such as Notified Bodies, post-market safety, clinical investigations and evaluation built upon the current informal working groups of the Commission and involving patient organisations, healthcare professionals, manufacturers and Notified Bodies.

The MDEG would be established at the "European Health Products Agency" and the agency's secretariat would provide administrative, technical and scientific support for it as EMA's secretariat currently does for the scientific committees established at EMA. The European regulatory agency would also be entrusted with the tasks necessary to ensure a sustainable management of the regulatory regime for medical devices, such as organisation of the assessment of Notified Bodies, coordination in the field of post-market safety, management of an expert panel and a network of Reference Laboratories, and the setting up and management of IT infrastructure (see list of possible tasks in Appendix 8). This option would require the amendment of Regulation (EC) No 726/2004 concerning the establishment of the EMA[93] and a financial commitment of the Union budgetary authority for appropriate staffing of qualified personnel in the field of medical devices[94].

This option would not devolve decision-making power from Member States to the EU, but it would institutionalise the coordination between Member States and make available scientific and technical expertise to the Commission and the national authorities in the context of the fulfilment of their regulatory tasks. It would build on the existing "effective and efficient Community method" for which the EMA Secretariat and the network of competent authorities are known in the field of pharmaceuticals[95].

4.10.2. Policy option 7B: Creation of a new EU regulatory agency for medical devices only and of a Medical Device Expert Group at this agency

Instead of using an existing structure, this policy option would set up a new regulatory agency[96] specifically for medical devices. The MDEG would be established at this new agency which would provide it with administrative, technical and scientific support. The new

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90 The three EEA member states Liechtenstein, Iceland and Norway as well as Switzerland (MRA) and Turkey (Customs Union) apply the medical devices directives in their territories and participate in the EU medical device regulatory system. Participation of experts of these countries should also be ensured.

91 The possible tasks of a Medical Device Expert Group are set out in Appendix 7; in the legislative proposal, another name could be given to that group. The MDEG should not be confused with the current informal Commission's working group of the same name which forms a platform for advice to the Commission and the exchange of view between Member States' representatives and stakeholders.

92 The MDEG would need to be distinguished from a Committee to be established under the new 'Comitology' regime in accordance with Regulation (EU) No 182/2011.

93 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

94 In the Commission's report of January 2010 on the evaluation of the EMA, p. 93, it is stated that, at this stage, EMA is not suited to perform evaluation of all medical devices, http://ec.europa.eu/enterprise/dg/files/evaluation/final_report_emea_january_2010_en.pdf.

95 Commission's report of January 2010 on the evaluation of the EMA, p.15.

96 A Community agency is a body governed by European public law; it is distinct from the Community Institutions (Council, Parliament, Commission, etc.) and has its own legal personality. It is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task; see http://europa.eu/agencies/community_agencies/index_en.htm See also the Commission Communication on European Agencies – The way forward, COM(2008)135.

agency would also carry out the other tasks needed to ensure the EU governance of the system, such as organisation of the assessment of Notified Bodies, coordination in the field of post-market safety, management of an expert panel and a network of Reference Laboratories, and the setting up and management of IT infrastructure (see list of possible tasks in Appendix 8). The agency should have legal personality and staff qualified in the field of medical devices.

4.10.3. Policy option 7C: Management of the medical device regulatory system by the European Commission and creation of a Medical Device Expert Group supported by this institution

This option would mandate the European Commission to provide the necessary administrative, technical and scientific support to the MDEG. The Commission would also carry out the other tasks needed to ensure the EU governance of the medical device system mentioned in policy options 7A and 7B and listed in Appendix 8. The activities would mainly be performed by the Commission's Joint Research Centre (JRC)[97].

4.10.4. Policy option 7D: Creation of a Medical Device Expert Group managed by the Member States

This option would limit itself to create the statutory basis for a MDEG composed of the Member States' experts which would be managed by the Member States themselves. It would carry forward the Member States' initiative for a "Central Management Committee" set up in 2010[98]. The support staff could be allocated by the national competent authorities on a voluntary basis like for example for the Heads of Medicines Agencies network in the field of pharmaceuticals[99]. Alternatively or in addition, an EU body (EMA or the Commission) could be mandated to provide the secretariat like EMA does for the Co-ordination Groups for Mutual Recognition and Decentralised Procedures for human and veterinary medicines (CMDh and CMDv) in accordance with Article 27 of Directive 2001/83/EC and Article 31 of Directive 2001/82/EC.

5. ANALYSIS OF IMPACT AND COMPARISON OF THE POLICY OPTIONS

In this chapter, the likely economic, social and environmental (intended and unintended) impacts of the policy options as well as potential trade-offs and synergies will be assessed.

As a general remark it needs to be stated that the medical devices directives do not address environmental aspects linked to medical devices and the revision does not intend to extend their scope to issues related to the protection of the environment. The assessment will therefore address environmental impacts only when a specific policy option gives rise to consider them (e.g. reprocessing of single-use devices, see Annex 1). The focus, however, will lie on the economic impact (e.g. costs for industry and public budget) and on the social impact (e.g. patient safety and public health).

Moreover, the requirements laid down in the medical devices directives apply to European and third country manufacturers in the same way so that no distinction needs to be made as regards the impact on third countries.

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97 For more information about the JRC see http://ec.europa.eu/dgs/jrc/.

98 http://www.cmc-md.eu/index.html. See also Clinica (Jan/Feb. 2011, p. 27): "CMC out to prove it is the answer to consistent regulation in the EU".

99 http://www.hma.eu/index.html.

5.1. Impact of policy options 1A-1D (designation and monitoring of Notified Bodies)

5.1.1. Impact of policy option 1A (new minimum requirements for Notified Bodies)

The strengthening of the minimum requirements for Notified Bodies is not expected to have a noteworthy economic impact on those Notified Bodies that act in accordance with recognised professional conformity assessment standards in the field of medical devices as laid down in guidance documents and relevant international standards[100]. While the new minimum requirements would make them formally enforceable, it will not involve significant additional effort on the part of those Notified Bodies which are already complying with the spirit of the legislation other than the production of updated evidence.

Notified Bodies which currently do not meet the substantive requirements to carry out appropriate conformity assessment in the field of medical devices will either incur compliance costs to meet the new requirements or their designation would need to be limited or withdrawn.

The positive impact would be to ensure that only Notified Bodies with the necessary competence, experience and skills will be allowed to assess the conformity of medical devices. It will enhance the level of patient safety and public health and ensure a level playing field in the internal market.

5.1.2. Impact of policy option 1B (designation and monitoring of Notified Bodies by an EU body)

This option would lead to the transfer of competences from the Member States to the EU and would therefore have an impact on the EU budget. A NBOG report[101] indicates that competent/designating authorities in average have 3.5 assessors available which would mean that around 80 assessors are employed by national competent/designating authorities in the field of medical devices. In most cases, however, the assessors are either not exclusively responsible for Notified Bodies but also for other tasks related to medical devices, or not only responsible for Notified Bodies in the field of medical devices. No reliable figures exist as regards FTE responsible for the oversight of Notified Bodies at Member States' level in the field of medical devices.

Entrusting the tasks of designating and monitoring of Notified Bodies in the field of medical devices to a EU body would mean that new structures at EU level would have to be built up requiring in particular the recruitment of qualified staff who would assess (inspect) the Notified Bodies. Based on the current number of Notified Bodies (78 in August 2011) around 20 assessors (FTE) would need to be available at EU level to carry out the assessment.

Assessment activity	**Estimated amount of man-days per NB**	**Estimated amount of man-days for 78 NB**
Initial audit	9–15 man-days	702–1170 man-days
Surveillance audit with observed audit	9-15 man-days	702–1170 man-days
Preparation of assessment	9-15 man-days	702–1170 man-days
Follow-up of assessment	9-15 man-days	702–1170 man-days

[100] MEDDEV 2.10-2; NBOG Designating Authorities Handbook; EN ISO/IEC 17000 series.

[101] NBOG Report for the period 2005-2008 (May 2009).

Total (average)	**36 man-days**	**2808 man-days**

If the average amount of man-days is taken (936 man-days for initial audits, 936 man-days for preparation and 936 man-days for follow-up), a minimum of 2808 man-days would be required. 1 FTE is equal to around 220 man-days/year. Taking into account absences, training and travel times 20 FTE would be required to cope with the assessment of 78 Notified Bodies.

In addition to the EU assessors, 4 FTE would be needed for administrative support to ensure appropriate logistics and document management. The costs for human resources will be estimated in section 5.8. (management of the regulatory system). Travel expenses of roughly 200,000€/year would need to be added.

It would be crucial that sufficient and qualified assessors are available in the start-up phase of the implementation of such new process since Notified Bodies' oversight is the cornerstone of the medical device regulatory framework. It could be expected that the number of Notified Bodies will decrease as a consequence of more stringent requirements and their consistent enforcement so that the number of FTE assessors needed to perform this task could be reduced in subsequent years.

Member States could generate savings since they would be discharged of their responsibility to inspect Notified Bodies.

The advantage of a transfer of the Notified Bodies' oversight to the EU level would be that all Notified Bodies would be controlled by one authority which is independent of national interests. This would give a high assurance that the requirements would be implemented in a consistent way all over the EU. It would also lead to a world-wide high esteem of the European system of third party certification. Auditors of third countries which have concluded Mutual Recognition Agreements (MRAs) or other cooperation arrangements with the EU in the field of medical devices could be permitted to participate in the inspections which would facilitate a more effective and transparent implementation of these international agreements and thus support the global acceptance of CE marked medical devices.

A certain disadvantage would be that the day-to-day contact between Notified Bodies and "their" competent authorities which enables practical routine questions to be resolved would disappear. Several Member States expressed reservation when this change of the system was discussed with them. On the other hand, this could also be seen as an advantage since it would increase the independence of the inspectors. A disadvantage would also be that the implementation and full functioning of the new regime would require a relatively long period of time due to the need to recruit and train qualified inspectors at EU level and the high number of Notified Bodies to be assessed.

5.1.3. Impact of policy option 1C (designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams")

This option would mainly rely on existing resources at Member States' level. At EU level, the organisation of the 'joint assessments' (e.g. list of eligible assessors, composition of the assessment teams, document management, reimbursement) as well as participation in the onsite inspections would have to be ensured. This would require around 6 FTE for operative tasks and 3 FTE for support tasks.

In addition, the temporary 'secondment' of national auditors to 'joint assessment teams' would require the reimbursement of their expenses from the EU budget. The amount of man-days required to inspect the currently 78 Notified Bodies would be the same for this policy option as in option 1B. Taking into account that the above-mentioned 6 FTE would participate in the assessments and the national assessors would remain employed by their competent authorities

(absences, training etc. would therefore be at their charge) it would mean that around 2200 man-days (equivalent to 10 FTE) would need to be reimbursed by the EU budget. Applying the current daily allowance rate of 92€/day for experts, a sum of around 200,000€/year would need to be reimbursed; travel expenses of roughly 200,000€/year would need to be added (on the basis of average expenses of 650€ for intra-EU travels plus several travels to Notified Bodies' subsidiaries in third countries).

The advantage of this option would be that the existing structures would remain in place and that only the coordinating task would be transferred to the EU level. Furthermore, the participation of staff of the national designating/competent authorities would foster the exchange of best practices and lead to capacity building which would enhance the competence of national designating/competent authorities in all Member States. This will be helpful as these authorities would maintain the full responsibility for the regular surveillance audits to be documented in annual reports.

Like option 1B this option would also lead to a world-wide high esteem of the European system of third party certification; inspectors of MRA and other international cooperation partners could be admitted to participate in the joint audits.

Option 1C could probably be implemented relatively quickly since it would build on existing structures and human resources available at national level.

5.1.4. Impact of policy option 1D (designation and monitoring of Notified Bodies by Member States in accordance with the model provisions of Decision 768/2008/EC)

This last option would not have economic impacts and, as regards the designation of Notified Bodies, it would simply align the medical devices legislation with Decision 768/2008/EC on a common framework for the marketing of products.

It can, however, be predicted that this option alone would not significantly change the differences between Member States as regards their oversight of Notified Bodies. More than 80% of the Notified Bodies designated under the AIMDD/MDD/IVDD are accredited[102]. Therefore, in most cases, the 2-weeks objection period would thus apply during which a meaningful scrutiny by other Member States or the Commission could not be carried out. Moreover, the experience in other fields shows that when Member States and the Commission have been notified of designations from Member States which do not use accreditation[103], no objections or additional queries have been received from other Member States and the control exercised by the Commission was equally limited due to the scarcity of resources. It also needs to be noted that the other Member States and the Commission would only be notified after the designation decision had been adopted at national level. In conclusion, it cannot be expected that the scrutiny procedure foreseen by Article R23 of Decision 768/2008/EC alone would lead to a noteworthy improvement of the current situation as described in Problem 1.

Comparison of options 1A to 1D:

It should be recalled that in section 4.1. the 'no EU action' was discarded. Actually, no changes to the designation and monitoring of Notified Bodies would further reduce the level of protection of public health and patient safety and further impair the functioning of the internal market. Option 1A is complementary to any of the options 1B to 1D and would in any case be a necessary measure to provide a sound legal basis for the assessment of conformity

[102] The numbers of non-accredited Notified Bodies are 14 out of 78 (MDD), 3 out of 19 (AIMDD) and 6 out of 25 (IVDD) (state of play: August 2011).

[103] See Article 5(2) of Regulation (EC) No 765/2008.

assessment bodies by the authorities and therefore is a *condition sine qua non* for improving the oversight of Notified Bodies.

With regard to the three options in relation to the designation and monitoring process, option 1D is considered not sufficiently effective to remedy what has been identified as the weakest point of the current regulatory framework. It is therefore not the preferred option. But it could be combined with option 1C where the designation would remain the competence of the individual Member State. In this case, Option 1D would provide an additional safeguard that a Member State duly takes into account the findings of the 'joint assessment' and possible recommendations of the Medical Device Expert Group. In addition, the MDD and IVDD would incorporate the model provisions of Decision 768/2008.

The most effective option as regards improving the oversight of Notified Bodies would be option 1B. But it would also be the most costly one for the EU budget and it would likely require a longer implementation time than other options. Moreover, it might be met with reservation by Member States on grounds of the principle of subsidiarity. The effective implementation of option 1B would depend on setting up a strong management structure at EU level so that its choice is interrelated with the policy option to be chosen among options 7A-7D (see below section 5.8).

Option 1C would be the second most effective way of achieving specific objective 1. It would require less EU financing and could be implemented rather quickly. It would have the advantage over option 1B that it constitutes a cooperative approach building upon Member States' responsibilities and capacities and therefore would not raise concerns in terms of the subsidiarity principle. If chosen, it should be combined with option 1D.

For the above reasons, option 1A should be retained in any case. Option 1D, taken alone, is discarded. The choice between options 1B and 1C depends foremost on a political decision whether the EU should assume full responsibility for the assessment and designation of Notified Bodies in the field of medical devices or whether the ultimate responsibility shall remain at Member States' level. For this reason, in this impact assessment the choice between policy options 1B and 1C for the designation and monitoring process is left open.

	Minimum requirements for Notified Bodies	Designation and monitoring of Notified Bodies		
Impacts	**Option 1A**	**Option 1B**	**Option 1C**	Option 1D
Social impact (public health, patient safety, trust)	++	+++	+++	--
Economic impact (EU and national budgets, costs for NB and economic operators)	O	---	--	O

5.2. Impact of policy options 1E – 1G (conformity assessment procedures by Notified Bodies)

5.2.1. Impact of policy option 1E (no change to the conformity assessment process)

The improvement of the oversight of Notified Bodies would already be an important step towards more consistency in the conformity assessments performed by these bodies. During the regular surveillance audit, the assessors review the conformity assessment performed by the Notified Bodies and at that stage can identify discrepancies in the conformity assessment procedures. It could therefore be argued that it is not needed to review the conformity assessment prior to the delivery of certificates. In addition, the establishment of a voluntary "early advice" process with the involvement of external experts (see options 5A and 5B) could address concerns which might exist regarding genuinely new devices or technologies. Policy option 1E would therefore not change the conformity assessment process and would not have any impact compared to the status quo.

The option would, however, not allow a direct comparison of the performance of Notified Bodies and ensure the application of uniform standards, e.g. in respect to the assessment of the manufacturer's clinical evaluation. It would not enable public authorities either to be systematically informed at an early moment about new devices coming to the EU market for which accompanying measures regarding their use possibly would need to be adopted (e.g. prescription requirements or qualification requirements for users).

5.2.2. Impact of policy option 1F (systematic ex ante control of conformity assessment reports for specific device types)

The main negative economic and social impact of a systematic ex ante review of the Notified Bodies' preliminary conformity assessments for specific device types or technologies would be the slowdown of the procedure which would affect one of the most lauded aspects of the European system of pre-market evaluation of medical devices, i.e. rapid access to market and support of innovation. The impact would depend on the length of the review process; three months, as currently applicable to medical devices manufactured utilising animal tissues, would likely be the period of choice. This would mean that certain products would come onto the market up to three months later, leading to a delay in patients having access to an innovative device or technology and a certain loss of income for manufacturers. In practice, the delay would likely be longer if a "stop-the-clock" mechanism would be applied.

In addition, the submission of preliminary summary evaluation reports would generate administrative costs for the Notified Bodies for drawing up the necessary documentation and filing it to the MDEG.

This negative effect would not affect all medical devices or technologies but only those which have been determined by a Commission measure on the basis of the criteria set out in the legislation. A disadvantage of this option would be that it would take time until the Commission has adopted a measure defining the device type or technology subject to preliminary scrutiny of the Notified Body's assessment. Therefore, the reaction to a specific situation (e.g. increased number of incidents for a specific device) could be too slow.

The number of draft conformity assessment reports which would have to be submitted for review would depend on the categories of devices selected for the ex ante review and cannot be quantified since it depends on future developments in the sector as well as on findings regarding high risks, incidents rates or discrepancies in Notified Bodies' assessments. It could roughly be estimated that several hundreds of preliminary assessments could be subject to a systematic ex ante control mechanism per annum if applied. Such large numbers would be

difficult to manage and probably only a small part would actually require a substantial review of the Notified Body's preliminary assessment.

On the benefits side, it can be argued that a mechanism for an ex ante review would increase the level of protection for all European patients and users because it would ensure that high risk or novel devices are appropriately assessed before they reach the patient or user, and in particular that they have been submitted to an appropriate clinical evaluation. But it is not possible to quantify the number of possible cases where non-conformities would actually be identified so that the level of increase in the protection of patients and users against unsafe devices is not predictable either.

Other benefits would consist in establishing a level playing field between manufacturers because all Notified Bodies would be bound to apply the same criteria for their assessment. Furthermore, competent authorities would be informed at an early stage about high risk and novel devices in the pipeline for being placed on the European market and could intervene at an early stage from a public health perspective. This may lead to fewer restrictive measures by competent authorities in the post-market phase which would eventually have a positive impact on the functioning of the internal market.

To carry out a scrutiny diligently, the regulatory authorities would need to allocate appropriate staff to actually review the preliminary assessment reports of the Notified Bodies. Otherwise the submission and standstill would only be a bureaucratic hindrance without added value.

At EU level, the management of the review process would require additional human resources of at least 10 FTE. Besides this, it would generate administrative costs (translations, meetings, reimbursement of experts).

5.2.3. Impact of policy option 1G (notification requirement regarding new applications for conformity assessment and possibility for ex ante control)

Currently, no data is available at EU level as regards the exact number of medical devices, let alone a breakdown according to the different risk classes of devices. It can roughly be estimated that around 5-10% of the devices present on the market fall in the highest risk-class III or class D IVD[104]. In absolute terms this could be between 27,000 and 54,000 types of devices. The number of devices would have to be divided by 5 years (validity of certificates). Devices from the same manufacturer with similar characteristics could be included in the same conformity assessment.

There would be an economic impact related to the development and continuous maintenance of the IT infrastructure to be used by the Notified Bodies for the notification of applications. The IT should be set up by the EU body (Commission or agency) to ensure a consistent notification format and would need to be borne by the EU budget. The costs for IT will be part of the overall IT budget estimated below under 5.8.

Costs for Notified Bodies:

It can be estimated that the Notified Bodies altogether receive around 5,000 applications a year for design-dossier examination, including review of significant amendments. If the notification requirements only apply to new applications, roughly around 2,500 notifications with regard to design-dossier examinations for class III/D devices a year could be expected. If it was ensured that the electronic notification was based on a format used in any case by the Notified Bodies for their internal file management, the administrative costs would be very low

[104] Based on the data available for the Italian market and provided by the Italian Ministry of Health (state of play: May 2011).

and would probably require not more than one additional hour per notification. Cost for 1 hour can be estimated at 30€. The aggregate costs can therefore be estimated at **around 75,000€/year**.

Only a small percentage of the applications notified would actually concern genuinely "new" or problematic devices or technologies. In addition, due to limited capacities and strict deadlines the MDEG would need to make a selection of the cases for which it would request Notified Bodies to submit a preliminary assessment. A reliable estimation cannot be made but an expectation is that not more than 50 preliminary assessments/year should be submitted.

It can be estimated that 0.5 – 1 man/days would be needed for drawing up a summary of a preliminary assessment. Assuming that around 50 files would be selected, between 25 and 50 man/days would be spent by Notified Bodies. Costs for 1 man/day can be estimated at 250€ so that the aggregate costs can be estimated at **between 6,250€ and 12,500 €/year.**

In case of comments submitted by the MDEG, the Notified Body would need to analyse the comments and respond to them which may be estimated at 2 man/days. Assuming that in 50% of the submitted files comments are issued, 50 man/days would be spent on the follow-up. The aggregate costs can be estimated at **around 12,500€**.

Altogether, the administrative costs can be estimated at between **93,750 and 100,000€/year**.

Social impacts:

Like option 1F, also the present option would increase the level of protection for all European patients and users because it would ensure that high risk or novel devices are appropriately assessed before they reach the patient or user, and in particular that they have been submitted to an appropriate clinical evaluation. This option would also ensure a level playing field between manufacturers to the benefit of the internal market.

Moreover in some individual cases, the pre-market assessment procedure could be slowed down when the submission of the summary of the preliminary assessment is requested on a case-by-case basis. But in contrast to option 1F, the review process by a MDEG would only be triggered where these experts have identified possible concerns on the basis of the notification.

Required human resources:

The MDEG experts, between their meetings, would need to identify the critical cases for which submission of a summary of the preliminary conformity assessment is requested, and to review the summaries submitted.

At EU level, the management of the notification procedure and ad hoc review process would require additional human resources of at least 8 FTE. Besides this, it would generate limited administrative costs depending on the cases identified for review (translations, meetings, reimbursement of national and external experts).

Comparison of policy options 1E – 1G:

A comparison of the three options is inherent in the above description of the pros and cons. Policy option 1E would not contribute to the achievement neither of the specific objective 1 (uniform control of Notified Bodies) nor of the general objectives A and B (high level of protection of human health and safety; functioning of the internal market). On the other hand, it would be the option preferred by industry since it would not slow down the conformity assessment process and therefore be considered as the most suitable to ensure a supportive regulatory framework for innovation (overall objective C). Policy options 1F and 1G, on the contrary, would effectively achieve the overall objectives A and B (high level of protection of

human health and safety; functioning of the internal market) as well as specific objective 1 (uniform control of Notified Bodies).

However, option 1F would systematically slow down the regulatory pathway for certain devices coming to the market and possibly reduce Europe's advantage for ensuring rapid access to innovative medical technologies through a decentralised, flexible and timely pre-market assessment system. This may hamper realisation of overall objective C which is to provide a regulatory framework which is supportive to innovation.

Option 1G may also slow down the access of new products to the market but only case-by-case under the responsibility of the MDEG where it has identified a concern. It is therefore more flexible and more proportionate. Therefore policy option 1G is retained. It would however require that the review process does not lead to unreasonable delays and does not become the rule rather than the exception (see monitoring and evaluation).

The experience with Directive 2003/32/EC concerning medical devices manufactured utilising animal tissues (see section 4.4.3.2) supports the choice for option 1G. Even though the impact of the application of Directive 2003/32/EC cannot be measured in quantitative terms (and the Commission is not informed about the consultations under this piece of legislation), the feedback from several national authorities is that this mechanism has considerably improved the quality of manufacturers' risk analysis and management regarding devices manufactured utilising animal tissues and Notified Bodies' conformity assessments in this respect. Significant flaws were identified in the beginning when the consultation procedure came into application (April 2004) whilst the vast majority of summary evaluation reports submitted nowadays are considered fine. Scrutiny by competent authorities seems to have prompted manufacturers to shift to 'safer' source countries or higher quality starting material. It can be said that the process has contributed to increasing the safety of such devices and may have prevented some devices for which the manufacturer could not provide the required safety data from coming to the market.

At the same time, option 1G would also remedy shortcomings of the rather rigid process established by Directive 2003/32/EC since it would provide the flexibility to take account of developments which take place in the manufacturers' risk analysis and management regarding problematic devices and Notified Bodies' conformity assessment in this respect. Instead of forcing all devices of a specific type or category into a review process, competent authorities could select those which actually give rise for concerns on the basis of summary information provided by the Notified Bodies. This approach would ensure that any slow-down of the process is proportionate to the objective pursued. Moreover, the scrutiny would be carried out jointly by the competent authorities, thus allowing for work-sharing among them and avoiding that Notified Bodies are confronted with several opinions of individual authorities which may not necessarily be compatible.

Conformity assessment process

Impacts	Option 1E	Option 1F	**Option 1G**
Social impact (public health, patient safety, trust)	O	++	++
Impact on innovation	O	---	-
Economic impact (EU and national budgets, costs for NB, costs for manufacturers)	O	--	-

5.3. Impact of policy options 2A to 2D (enhanced coordination in the field of post-market safety)

5.3.1. Impact of policy option 2A (clarification of key terms and of the obligations of the parties involved in the field of vigilance)

The positive impact of this option would be to align the EU vigilance system with European and international guidance developed over the recent years and introduce into a legally binding text terms like "field safety corrective action" and "field safety notice" which are already in use in Europe by means of a guidance document[105]. There would therefore be no additional costs for manufacturers since most competent authorities already follow the guidelines in their application of the general and vague legal requirements in the field of vigilance.

The clarification of the legal obligations of manufacturers and Notified Bodies regarding post-market safety, some of them currently hidden in the annexes on conformity assessment, will enhance legal certainty. The current directives are silent in respect of the role of Notified Bodies in the vigilance system even though they are responsible for the (pre-market and continuous) assessment of the manufacturer's vigilance procedures and post-market surveillance plan (PMS). In practice, Notified Bodies are often required by the competent authorities to participate in the investigation of specific vigilance cases. As a result, it would be beneficial for all parties involved, in particular for the Notified Bodies, to clarify their role. Systematic information of Notified Bodies about incidents related to products for which they had performed the conformity assessment will provide added value for their assessment activity and may trigger a more timely decision as regards a suspension, restriction or withdrawal of a certificate they have issued.

All the above suggested amendments would not lead to significant costs but they would considerably enhance the legal certainty as regards the role and obligations of economic operators, Notified Bodies and authorities in the vigilance systems. This will increase the assurance that incidents are appropriately followed up and enhance the functioning of the internal market.

5.3.2. Impact of policy option 2B (central reporting of incidents and coordinated analysis of certain high risk incidents)

The costs for this option would consist in the establishment of the IT infrastructure for a central reporting of incidents and the recruitment of human resources necessary to ensure the coordination of the analysis of high risk and certain other incidents.

The costs for the development and maintenance of an IT infrastructure will be part of the overall IT budget estimated below under 5.8.

With the data available to the Commission, it is not possible to estimate with sufficient precision the number of incident reports to be entered by manufacturers. The competent authorities of the 'bigger' Member States receive around 5,000 incident reports from manufacturers (see Appendix 6b). But the available data does not allow identifying reporting of the same incident in several Member States; according to information from industry, a high percentage of reports are filed in several Member States to comply with the legal requirements. Roughly, it can be expected that at least 10,000 individual reports (possibly two or three times as much) would be notified by manufacturers. In addition to those report, Member States would enter information regarding serious incidents they have been made aware of by other sources. Based on the number of NCARs exchanged between competent

[105] MEDDEV 2.12-1 rev.6 of December 2009: Guidelines on a medical devices vigilance system.

authorities in recent years (e.g. 748 in 2010) and the fact that some Member States sent very few or no NCAR at all, it can be expected that every year around 1,000 or more incidents reported to the central database would in principle qualify for being checked to identify trends and signals[106], supported by specialised software. Moreover, it can be estimated that in 5-10% of those cases a more in depth coordinated analysis would be needed at EU level under the lead of the coordinating competent authority (due to the high risk of the incident or divergent options regarding the appropriate corrective action). Some of them possibly would need to be followed-up by the preparation of a measure to be adopted at EU level. Around 6 qualified FTE and 2 FTE support staff would be necessary to exercise these tasks.

The positive impacts would be manifold:

First of all, the same high level of safety would be ensured for all patients and users in the EU and distortion of the internal market would be avoided. All competent authorities that are concerned would be informed at the same time. An incident which justifies a recall of the product in one Member State to protect the safety of its citizens would, with all probability, justify the same action in another Member State where the product with the same failure is on the market.

Secondly, trends or signals could be identified more easily at EU level whereas for example an isolated analysis of a small Member State's market would not give rise to concerns. This would trigger the necessary consequences like e.g. extra controls of the Notified Bodies involved in the analysis of the devices with high incident rates. It would therefore also support the objectives of strengthening the Notified Bodies' oversight.

Thirdly, a coordinated approach would avoid duplication of investigations and analysis by several competent authorities. It would thus save resources deployed by the Member States.

And finally, the costs for the manufacturers would be reduced. A single central notification of incidents would replace multiple individual notifications. Moreover, a coordinated reaction to incidents would ensure that manufacturers are required to take corrective actions in a coherent way. It would thus avoid that a manufacturer would have to recall his product in one Member State whilst it would be required to provide 'only' a warning in another Member State or an updated version of the device in a third Member State. The coordination of the analysis of vigilance cases will generate significant savings for manufacturers. However, it is not possible to estimate the costs savings in quantitative figures because industry could not provide data as regards the cost of diverging vigilance systems in the various Member States. But especially for SMEs the savings would be relatively high since it would reduce their costs for dealing with different requests from several authorities.

5.3.3. Impact of policy option 2C (decentralised reporting of incidents, but coordinated analysis of certain serious incidents which have an impact on more than one Member State)

This option would not incur costs for an IT infrastructure since this would be left to the Member States. The coordination task would be limited to the coordination of vigilance cases which have an impact on more than one Member State and would require at least 3 FTE.

The positive impact would be limited to a coordinated approach regarding the analysis of certain serious incidents. Like option 2B, this option would avoid duplication of investigations and analysis by several competent authorities which would save resources

[106] This estimation is supported by the comparative analysis of medical device recalls 2005-2009 by the Boston Consulting Group (Jan. 2011) that found for the 5-years period some 5,000 records of field safety notices in the five Member States with the highest number of NCAR reporting.

deployed by the Member States and ensure that manufacturers are required to take corrective actions in a coherent way. However, unlike option 2B, there would be no positive impact related to a single central notification of incidents. Manufactured would therefore still be burdened by multiple notifications and Member States would need to manage their own incident reporting tools.

5.3.4. Impact of policy option 2D (promotion of cooperation of market surveillance authorities, including designated test laboratories)

For effective market surveillance in a single market, close cooperation between the national competent authorities is essential. The sharing of resources and experience would not lead to additional costs but rather to savings at national level where duplication of work would be avoided. Surveillance activities (e.g. coordinated checks, information campaigns) would become more effective so that the money is spent more efficiently. Moreover, often laboratories need to be involved for the analysis of samples of certain devices (e.g. sterile devices, IVDs). The laboratories should work in accordance with internationally approved procedures or criteria-based performance standards and use recognised methods of analysis. The designation of reference laboratories[107] with scientific and technical expertise within the field of medical devices can contribute to a high quality and uniformity of analytical results which would be the basis for coordinated surveillance measures throughout the EU.

To implement this option, 2 FTE would be needed at EU level. But it would not immediately create additional costs but only set the framework for the establishment of European Union Reference Laboratories and a network of national reference laboratories, possibly with the involvement of the Commission's Joint Research Centre. EU funding for the designated reference laboratories would need to be made available over time. But a recent evaluation of EU-RefLabs in the field of food and feed and animal health has concluded that the EU funding of a decentralised network of reference labs is cost efficient and provide good value for money[108]. The positive impacts are primarily an increased and equal level of safety of products in the market (in particular those which are not subject to a pre-market assessment by Notified Bodies) and savings at national level due to the avoidance of duplication of work.

Comparison of policy options 2A to 2D:

Policy option 2A is necessary for any effective implementation of the vigilance system as it would ensure legal certainty and facilitate uniform application of the rules. It should therefore be retained in any case as a *condition sine qua non* for improving the vigilance system.

A choice needs to be made between option 2B (central vigilance reporting) and option 2C (decentralised vigilance reporting). The additional costs required for implementation of option 2B appear justified as this option would provide a real EU added value in terms of protection of public health, functioning of the internal market, sharing of information and expertise between Member States and reduction of costs of manufacturers. Option 2B is therefore the preferred option, which would also be in line with the Council Conclusions requesting a further development of the vigilance system "*to allow a coordinated analysis and a rapid and EU-wide response to safety issues*"[109]. Option 2D is complementary and a sector-specific

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107 In the field of food and feed law (see Regulation (EC) No 882/2004), the Commission's Joint Research Centre hosts six European Union Reference Laboratory in support of a network of national reference laboratories to support the effective implementation of the legal requirements, http://ec.europa.eu/dgs/jrc/index.cfm?id=4070&lang=en

108 For the 26 EU-Ref-Labs in the area of food and feed and animal health, EU funding was less than 10 mio. € in 2010.

109 Council Conclusions adopted on 6 June 2011, section 6, 9th indent, see Appendix 3.

concretisation of the general policy on reinforcing market surveillance in the EU. Options 2A, 2B and 2D should therefore be retained.

	Clarification of key terms	Vigilance reporting and coordination of analysis		Market surveillance
Impacts	**Option 2A**	**Option 2B**	Option 2C	**Option 2D**
Social impact (public health, patient safety, trust)	++	+++	+	++
Economic impact (EU and national budgets, costs for NB and economic operators)	O	--	--	-

5.4. Impact of policy options 3A and 3B (cross-sectoral solution of "borderline" cases)

5.4.1. Impact of option 3A (cross-sectoral advisory group on borderline issues)

In the field of medical devices, this option would not cause additional costs since the Commission's Borderline and Classification Working Group has already been meeting regularly 3-4 times a year (plus meetings of sub-groups). Also in the field of cosmetics, regular meetings are held on borderline issues. Involvement of Commission services and national authorities from other sectors in an advisory group on borderline issues would likely lead to a certain increase of their workload including reimbursement of national experts. On the positive side would be an enhanced cross-sectoral voluntary coordination between authorities[110], based on a clearer definition of the scopes of the relevant legislations. This would create synergies by avoiding duplication of discussion in different fora. Controversial borderline cases could be settled ensuring the application of the appropriate regulatory control of a given product or type of products. It would therefore enhance the safety of citizens and reduce compliance costs for manufacturers who are subjected to different regulatory regimes in different Member States which often also causes costs for judicial litigation. However, there would be no legally binding decisions as regards the regulatory status of a product when it is considered a medicinal product, cosmetic, biocide or a general foodstuff which might reduce the benefits of an agreed solution in the longer term. The Commission would have only the possibility to launch infringement procedures on a case-by-case basis when it considers that the regulatory status of a product is not correctly determined in a given Member State, but the ultimate interpretation of Union law lies with the European Court of Justice.

5.4.2. Impact of option 3B (cross-sectoral advisory group on borderline issues and possibility to determine the regulatory status of products at EU level)

This option would bring the same benefits as option 3A but in addition it would provide enhanced legal certainty since an agreed solution on a given product or type of products could be made legally binding also in fields other than medical devices, for example in the legislation applicable to medicinal products or cosmetics. This would lead to an increase in workload for the Commission services preparing the legal measures as well as costs for the organisation of additional meetings of Standing Committees in the field of medical devices,

[110] See e.g. the joint Medical device – Medicinal product ad hoc working group on borderlines cases.

medicinal products, biocides, food and cosmetics. In the long-term, the legal clarity achieved by a binding measure would reduce the workload since discussions about cases would not be 're-opened'. A disadvantage in terms of procedure would be that EU legislation of other sectors would need to be amended which would make the legislative process more complex. Moreover, it can be expected that an introduction of the possibility to determine the regulatory status of a product at EU level would have the most significant impact in the sectors of medicinal products and food, and the delimitation between those two legislations. The evaluation of such impact goes beyond the scope of this report and would need to be assessed separately.

Comparison of policy options 3A and 3B:

In theory it appears desirable to choose option 3B and to introduce in other sectoral legislation provisions which would empower the Commission to decide whether a given product or category of products falls within the definition provided in EU legislation since it would significantly improve the functioning of the internal market at limited additional costs. The Council also called for setting up "*a simple and rapid mechanism […] for accelerated adoption of binding and consistent decisions […] on the determination of products […] in order to address the growing number of "borderline" cases between medical devices and other products subject to different regulatory frameworks*"[111]. However, in the fields of medicinal products and food such an amendment would have far-reaching impacts that cannot be assessed in this report. If considered appropriate, this question should rather be further examined in the context of future amendments of the medicinal products and/or food legislation.

The preferred option is therefore option 3B and should be retained for those sectors where the discussion of borderline questions is already well established (e.g. cosmetics). Option 3A could be seen as an intermediate solution for other sectors where the necessary amendments in the relevant legislation should not be introduced by the medical device package.

	Solution of "borderline" cases	
Impacts	Option 3A	**Option 3B**
Social impact (public health, patient safety, trust)	+	+++
Economic impact (EU and national budgets, costs for NB and economic operators)	-	--

5.5. Impact of policy options 4A to 4C (enhanced transparency regarding medical devices on the EU market, including their traceability)

5.5.1. Impact of policy option 4A (network of national databases)

In order to provide meaningful information about economic operators and medical devices on the European markets, a network of national databases would only make sense when all 32 countries that participate in the single market set up their own databases require the same type and amount of information from the economic operators established on their respective territories. More or less half of the Member States have already set up databases but the

[111] Council Conclusions adopted on 6 June 2011, section 6, 7th indent, see Appendix 3.

remainder would have to invest in such an IT infrastructure and bear the corresponding costs. At the same time Eudamed would have to be further developed as well to host the additional data to be uploaded from the Member States.

Such bottom-up IT infrastructure does not appear to be efficient resource spending since it would require multiple investments in IT tools which would need to be compatible with each other and the multiplication of management (human resources) and maintenance costs. Changes to the data to be collected would have to be introduced in the IT tools by all countries and at EU level.

More importantly, a network of national databases would not guarantee the desired level of transparency at EU level for the public, healthcare professionals and authorities since the accuracy of available information would primarily depend on the contribution of many different authorities.

5.5.2. Impact of policy option 4B (central registration of economic operators and listing of medical devices placed on the EU market)

IT development costs (EU budget)

The further development of Eudamed as a central registration and listing tool, which would also need to integrate a possible UDI database (see policy option 4C) and a more developed vigilance database module (see policy option 2B), would cost around 2mio.€/year over the first four years (costs for IT specialists included). The subsequent hosting, maintenance and support would require around 1.8mio.€/year (see also the table under 5.8.). At the same time, Member States would save costs spent for the management of registration at national level.

Impact on economic operators

It would also have an economic impact on economic operators subject to a new registration and listing requirement at EU level but globally these costs would be compensated by savings due to a single registration/listing instead of multiple ones in the various Member States.

In the case of manufacturers and authorised representatives of class I devices and of IVD other than those listed in Annex II of the IVDD and those intended for self-testing, a central registration would replace the current obligation in the MDD and the IVDD that they must register with the competent authorities of the Member States in which they have their registered place of business. For these economic operators, no additional obligation would be created and possible costs related to the move towards a central registration/listing database can be kept to a minimum if the transitional period is sufficiently long and existing data uploaded in Eudamed were used.

For other economic operators and devices, a central registration would be a new requirement at EU level. But it would do away with the right of every individual Member State to require notification according to its national law.

The calculation in the table below is based on the following parameters:

• around 540,000 different devices of all classes are on the EU market (data from Eucomed and EDMA, see above section 2.1.1.)
• around 226,000 devices are low risk devices (40% of 500,000 MD are class I MD, 65% of 40,000 IVD are neither listed in Annex II IVDD nor self-testing IVD)
• around 314,000 devices are medium and high risk devices (60% of 500,000 MD are classes IIa, IIb or III MD, 35% of 40,000 IVD are listed in Annex II IVDD or self-testing IVD)

•	time needed for registration/listing of one device for initial registration (preparation of file, login, data entry, validation etc.): 1 hour
•	tariff for one working hour of staff (category "clerk"): 30EUR[112]
•	average life-cycle of a medical device: 18 months (relevant for updating of information) and time needed for updating: 0.5 hour
•	around 50% of medium and high risk devices (i.e. 157,000) available in all Member States
•	'realistic' scenario: registration/listing requirements in 15 Member States regarding medium and high risk devices
•	'worst case' scenario: registration/listing requirements in all 27 Member States regarding medium and high risk devices

[112] According to the tariffs used as a basis for the calculation of administrative costs in the context of the Action Programme for reducing administrative burdens, provided by the Commission's Secretariat-General on the basis of ESTAT data for 2006, the EU27 average cost/hour was 14€ for a clerk. But the majority of manufacturers or authorised representatives are based in high-income Member States (e.g. Germany, UK, France, Italy, Ireland, Sweden) where the average cost/hour was well above 20€ for a clerk.

Costs and saving of a central registration and listing

	Baseline scenario: **Costs for registration/listing at Member States' level (in EUR); 'realistic' and 'worst case' scenario**	**Policy option 4B:** **Costs for central registration/listing at EU level (in EUR)**	**Savings (in EUR)**	**Rationale**
Initial registration				
Low risk devices (class I MD, IVD not listed in Annex II IVDD and not for self-testing ca. 226,000 devices	around 6.8mio	around 6.8mio	0	Single registration at national level replaced by single registration at EU level
Medium and high risk devices (class IIa, IIb and III MD, IVD listed in Annex II IVDD and for self-testing) ca. 314,000 devices	from around 70.6mio to around 127.2mio	around 9.4mio	between 61.2mio and 117.8mio	Multiple registrations at national level replaced by single registration at EU level
Updating				
Low risk devices (see above) ca. 226,000 devices	around 2.3mio	around 2.3mio	0	see above
Medium and high risk devices (see above) ca. 314,000 devices	from around 23.5mio to around 42.4mio	around 3.1mio	from around 20.4mio to around 39.3mio	see above
Total	**from around 103.2mio to around 178.7mio**	**around 21.6mio**	**from around 81.6mio to around 157.1mio**	**Single registration at EU level**

A central registration and listing tool at EU level would thus lead to around EUR 21.6mio costs for economic operators. These costs, however, would be compensated by savings of between around EUR 81.6mio and around EUR 157.1mio.

Besides the savings for economic operators, an enormous benefit would be achieved for public health by means of an increased transparency for patients, healthcare professionals, the public at large and authorities which would boost the confidence in the regulatory system, empower citizens to be informed about devices they are treated with, allow for a coordinated market surveillance and enable well informed decision-making. The EU database would be a a source of data for national databases established for intrinsically national purposes, such as reimbursement.

5.5.3. Impact of policy option 4C (traceability of medical devices)

In 2010, the European Commission established an ad hoc working group to discuss the traceability issues, the possible establishment of a European UDI and intermediate solutions to avoid an even further fragmented situation in the Member States which would jeopardize a future EU-wide system. This group has been open to Member States and stakeholders of the sector and until July 2011 met five times. It ensures also the interface to the discussions on UDI at GHTF level. Possible costs have also been addressed by the working group.

The introduction of a European system for the traceability of medical devices would have a significant economic impact for manufacturers, but it would at the same time hugely enhance the level of safety and public health protection. The costs for setting up such a system would be included in the costs estimated for the further development of Eudamed (see policy option 4B). For Member States, there would be no additional costs but rather a decrease since a European system would make the development of national systems redundant.

The costs for manufacturers can be broken down to the following aspects:

Attribution of UDI codes	**Labelling preparations for packaging lines**	**Providing information to UDI database**
Annual costs (e.g. membership fee in an organisation providing barcodes such as GS1) 500€ for small companies (few products) 10,000€ for big companies (numerous products)	Depending on complexity of production lines 500 – 5,000€ for manual production lines (small companies) 150,000€ for automated production lines (big companies)	Costs related to the upload of information to UDI database would be covered by central registration/listing (see policy option 4B)

The total costs cannot be estimated with sufficient reliability. According to information provided by industry associations more than 80% of the 22,000 medical device manufacturers are SME, but no data is available as regards how many of them are "small" and how many or "medium-sized" companies. More importantly, no information could be obtained as regards the number of different production lines which would determine the overall costs for adapting the labelling.

Still, the costs for labelling adaptations will be high. But they need to be put into perspective with the benefits for patient safety and public health, with the costs for 'no EU action' and with the synergies achieved by a globally compatible traceability system.

Benefits for patient safety / public health:

The main goal of a UDI system is to enhance patient safety by enabling tracking and tracing of devices through their supply chain. This would considerably enhance the effectiveness of the post-market safety due to improved incident reporting, targeted Field Safety Corrective Actions and better monitoring by the competent authorities. It can also reduce medical errors by reducing possible mix-up of devices. The establishment of a UDI system can also contribute to the fight against counterfeit devices.

Surveillance of the market as well as purchase and stock-management by hospitals will also become more efficient since UDI would become the 'access key' to different databases (by means of clearly identifying the same type of device).

Benefits for the internal market:

Without the development of a European UDI, there will be a fragmentation of the internal market, with negative consequences for public health and for the competitiveness of the sector. As indicated in the problem description, some European countries (or regions) have already started, and more Member States are likely to develop their own UDI systems. Therefore, the costs would be higher than with a European UDI as they would be multiplied by the number of different systems. Manufacturers would need to adapt their product lines according to the different types of UDI systems chosen and enter the data in various databases. In such a scenario, the costs would not be compensated by an enhanced level of patient safety at EU level because traceability would not be ensured EU-wide.

Synergies with international actions:

The US FDA is in the process of implementing a UDI system. FDA is actively involved in the development of guidance on UDI by the GHTF so that their system will likely be compatible with international 'best practice'. Since most of European medium size and big manufacturers sell their medical devices also to the US market[113], they will need to adapt to the forthcoming US FDA requirements.

To keep implementation costs limited, it would therefore be important to mirror as closely as possible the UDI system implemented in the US based on GHTF guidance (see also below under chapter 8 - Monitoring and Evaluation). This would also allow traceability of devices, and thus their enhanced post-market safety, at international level and in particular with the US. It would also likely pave the way towards a global UDI with other jurisdictions adopting the same UDI system.

Comparison of policy options 4A to 4C:

Option 4A would be neither an effective nor an efficient means to enhance transparency at EU level as regards economic operators and medical devices available on the EU market. This option is therefore discarded.

Options 4B and 4C, on the contrary, would effectively achieve the specific objective 4. They would contribute to patient safety and would lead to considerable cost savings for economic operators due to the reduction of obstacles to the internal market. The options are linked to each other and are complementary and should both be retained. Eudamed and the UDI database would need to be merged. The aim is to have only one database at European level in order to enhance transparency and traceability whilst decreasing costs for manufacturers. UDI will give the opportunity to overcome some negative aspects of the current Eudamed because

[113] According to Eucomed, more than 90% of its members selling equally to the US and to the European market.

it would identify every medical device by using a unique code at the EU level. Multiple entries in the database for the same product would be avoided. They would also be in line with the request of the Council that a "*modern IT infrastructure for a central and publicly available database must be further [developed] with a view to providing key information about medical devices, relevant economic operators, certificates, clinical investigations and field safety corrective actions. In this context, the possibility of introducing a system to improve traceability of devices, thus enhancing safety, should be studied*"[114]. The impacts are compared to the 'no EU action'. If Eudamed was not to be developed into a central databank for the registration of all devices, costs for economic operators would increase because of the multiplicity of national registrations whilst keeping the level of transparency regarding products on the EU market as limited as it is today.

	Registration and listing		Traceability
Impacts	Option 4A	**Option 4B**	**Option 4C**
Social impact (public health, patient safety, trust)	-	+++	+++
Economic impact (EU and national budgets, costs for NB and economic operators)	--	++ (due to savings compared to baseline scenario)	++ (due to savings compared to baseline scenario)

5.6. Impact of policy options 5A – 5B (enhanced involvement of external scientific and clinical expertise)

5.6.1. Impact of policy option 5A (creation of a pool of experts)

In order to be meaningful, a pool (i.e. a list) of experts, who could be consulted on an ad hoc basis by the Commission or competent authorities would need to be extensive. Whilst the economic impacts would be limited (i.e. reimbursement of experts for their services), the management of such a pool (such as publication of call for expression of interest, selection, keeping up-to-date, verification of absence of conflict of interests) would be a challenge. 2-3 FTE would be needed at EU level to accomplish this task. Compared to the current situation, a pool of experts with specific knowledge in the field of medical devices available to Commission, competent authorities, Notified Bodies or manufacturers would bring some benefits in terms of well-informed and science-based decision-making but the issue of conflict of interests would rather speak against an extensive pool of experts to be consulted on an ad hoc basis.

5.6.2. Impact of policy option 5B (designation of an expert panel and reference laboratories)

Like option 5A, also this option would bring benefits in terms of well-informed and science-based decision-making. The establishment of an expert panel composed of scientific and clinical experts of various medical disciplines, either as a stand-alone body or within a broader structure of a scientific committee, and the designation of reference laboratories would also have only limited economic impacts in terms of costs or administrative burden. 2-3 FTE at EU level would be needed for the management of the expert panel and the reference

[114] Council Conclusions adopted on 6 June 2011, section 6, 5th indent, see Appendix 3.

laboratories. Compared to a mere pool of experts, a panel with experts in key areas of medical technology and reference laboratories would have the advantage that their involvement in the decision-making process would become more stable so that there would be a steady exchange of knowledge between experts and regulators. Also the issue of conflict of interests could be better monitored with a panel than with a 'loose' pool of experts.

Comparison of policy options 5A and 5B:

Option 5B is superior to option 5A because the creation of an expert panel would provide a greater guarantee that independent external expertise is continuously available to the interested parties, including for the regulatory decision-making process, at no significant additional cost.

	External expertise	
Impacts	Option 5A	**Option 5B**
Social impact (public health, patient safety, trust)	+	+++
Economic impact (EU and national budgets, costs for NB and economic operators)	-	-

5.7. Impact of policy options 6A – 6C (clear obligations and responsibilities of economic operators, including in the field of diagnostic services and internet sales)

5.7.1. Impact of policy option 6A (alignment with Decision 768/2008/EC, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services)

As indicated in the impact assessment regarding the proposal to align 10 product harmonisation directives to Decision 768/2008[115], the specification of obligations of economic operators, including those offering diagnostic services to the EU market, is not expected to increase their overall costs because most of the obligations codify the normal practice of responsible and compliant companies, in particular those who have already a quality management system in place which is the general rule among medical device manufacturers on the basis of the EN ISO 13485 standard[116].

The additional requirements would concern authorised representatives which have a particular role under the AIMDD/MDD/IVDD as representatives of non-EU manufacturers in the EU. Also in this respect, no increase of the overall costs is expected for those authorised representatives who already comply with the spirit of the legislation.

The positive impact will be an increased legal certainty as regards the obligations of the different economic operators in the supply chain of medical devices. This will bring more safety as regards devices on the market and improve the functioning of the internal market. Eventually it will also lead to a reduction of costs of compliant economic operators who currently have to fight against unfair practices of non-compliant competitors.

115 Reference no. of DG ENTR's impact assessment not yet available.

116 EN ISO 13485:2003: Medical devices - Quality management systems – Requirements for regulatory purposes.

5.7.2. Impact of policy option 6B (legislative measures regarding internet sales)

No figures exist as regards the volume of internet sales in the field of medical devices. Since most devices are sold to hospitals or healthcare professionals through 'controlled' distribution chains, it can be assumed that the volume is not very high and especially not comparable to the sale of pharmaceuticals over the internet. Nonetheless, a market certainly exists especially for devices purchased directly by consumers (e.g. contact lenses, condoms). However, so far there is little evidence that dangerous or counterfeit devices are offered over the internet in significant numbers. Specific mandatory requirements regarding internet sales therefore appear disproportionate and would probably not be an effective tool to address the issue since 'rogue' traders, especially those outside the EU, would not be deterred by specific obligations. In reality, it is more an issue of enforcement by authorities and awareness of the buyers for which hard-law regulation is not the most appropriate instrument.

5.7.3. Impact of policy option 6C (addressing internet sales by soft-law action)

Coordinated monitoring and information campaigns as well as a possible portal on which internet vendors that adhere to a voluntary code of conduct can register would not have an economic impact on economic operators or buyers. It would, however, lead to some expenditure at EU and national level to finance and monitor the necessary tools (awareness campaigns, setting up a portal). Some national authorities appear to finance campaigns as regards safety of products purchased over the internet, e.g. UK internet safety campaign (£9mio). Coordination between national authorities, including EU wide campaigns and cooperation with third countries, would likely be more cost-efficient since the problems linked to internet sales are not limited to national territories. The actual costs would depend on the medium and the scope of any soft-law action and would not immediately be triggered by the new legislation but on a case-by-case basis on the concrete coordinated market surveillance activities.

Comparison of policy options 6A and 6C:

The alignment with Decision 768/2008 in respect to the obligation of economic operators, including those offering diagnostic services to the EU market, as well as additional requirements concerning authorised representatives (policy option 6A) should be retained due to the positive impact on the safety of products throughout the supply chain and the enhanced legal certainty for economic operators whilst causing no or very limited costs. In addition, policy option 6C (soft-law action on internet sales), due to its flexibility, efficiency and cost-effectiveness is the preferred option to address concerns regarding internet sales of medical devices and should also be retained.

	Clarification of obligations/responsibilities of economic operators	Internet sales	
Impacts	**Option 6A**	Option 6B	**Option 6C**
Social impact (public health, patient safety, trust)	+++	O	++
Economic impact (EU and national budgets, costs for NB and economic operators)	O	-	-

5.8. Impact of policy options 7A – 7D (management of the regulatory system)

The management of the future EU regulatory system will generate costs relating to (1) the human resources needed to perform at EU level the tasks necessary to implement the regulatory framework; (2) the development and maintenance of the IT infrastructure; and (3) the organisation of meetings of the MDEG (and its subgroups).

Under the assumption that the preferred policy options will eventually be retained, between **35 and 50 FTE** at EU level would be needed to fulfil the tasks. The difference between 35 and 50 results from the choice between option 1B (oversight of Notified Bodies by an EU body) or option 1C (coordination of 'joint assessments') which is left to a political decision. The costs for the 35-50 staff for operational and support tasks will depend on the choice between option 7A-7D and will be estimated for each of the options.

The results of the negotiations on the Multiannual Financial Framework (MFF) 2014-2020[117] and their impact on staffing in case of new tasks assigned to an EU body would need to be taken into account for any of the four options discussed.

[117] The Commission's proposal for the MFF 2014-2020 is not yet adopted. But the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A Budget for Europe 2020" defines some core elements, COM(2011)500 final.

Summary of required HR (operational staff, excl. IT)

Tasks	Estimated required HR
Oversight of Notified bodies - Option 1B: Oversight by an EU body *or* - Option 1C: 'joint assessments'	 20 FTE (assessors) and 4 FTE (support staff) or 6 FTE (assessors) and 3 FTE (support staff) (and reimbursement of national assessors)
Mechanism for an ex ante scrutiny of draft conformity assessment reports	6 FTE (engineers, clinical experts) and 2 FTE (support staff)
Coordination of post-market safety issues (vigilance and market surveillance)	8 FTE (vigilance experts) and 2 FTE (support staff
Management of external scientific and clinical expertise	2 FTE (scientific or medical experts) and 1 FTE (support staff)
Coordination of assessment of multinational clinical investigations (special MDD issue, see Annex 1, option MD-3B)	4 FTE (clinical experts) and 1 FTE (support staff)
Total	In case of option 1B (Notified Body oversight by an EU body): **50 FTE (operational and support staff)** In case of option 1C (Notified Body oversight through "joint assessments"): **35 FTE (operational and support staff)**

Approximate costs for IT development, support and maintenance

The costs can be estimated as shown in the table below. This estimation is considered to remain unchanged whichever of the options 7A to 7D is chosen.

Areas for IT development	Estimated costs
Development of Eudamed as central registration and listing database, incl. UDI database Development of vigilance module and data-processing network for a central reporting of incidents (plus business intelligence tools for statistical analysis of data for signal detection) Single submission of certain applications for multi-national clinical investigations Notification of applications received by Notified Bodies for certain conformity assessments and submission of summary evaluation report, incl. follow-up Depository of outcome of the assessment of Notified	Development phase 2014-2017: EUR 2 mio/year in average (10 FTE, i.e. IT developers and analysts, software licences) Implementation and maintenance phase as of 2018: EUR 1.8 mio/year in average (7 FTE, i.e. IT developers and IT support, hosting, plus developers of statistical analysis tools)

Bodies	

Approximate costs for meetings of Medical Device Expert Group

Medical Device Expert Group (MDEG) 8 meetings/year (2 days each) with experts from 27 Member States (EUR 17,555/day)	EUR 280,800year
MDEG sub-groups max. 32 meetings/year of max. 8 sub-groups (2 days each) with experts from 27 Member States (EUR 17,555/day)	EUR 1,123,200year
Total	**EUR 1,404,000year** (maximum)[118]

The reimbursement of the travel expenses of the experts designated by the Member States for meetings of the Medical Device Expert Group and its sub-groups would amount to max. EUR 1.4mio/year. Compared to the costs currently spent for the reimbursement of national representatives attending the informal working groups (budget forecast for 2011: EUR 526,500) the increase is justified by an enhanced frequency of meetings to achieve stronger coordination. This estimation is considered to remain unchanged whichever of the options 7A to 7D is chosen.

The question is "*who*" should be mandated to perform the new tasks at EU level which are needed to implement the regulatory framework. This question is addressed in the following paragraphs evaluating the impacts of the policy options regarding the management of the regulatory system.

5.8.1. Impact of policy option 7A (extension of the responsibility of the European Medicines Agency (EMA) to medical devices and creation of a Medical Device Expert Group at this agency)

This option would build on the existing "effective and efficient Community method" for which the EMA Secretariat and the network of competent authorities is known in the field of pharmaceuticals[119] and establish it also as the pivotal EU body to coordinate activities in the field of medical devices and actively promote the communication about the regulatory requirements.

The essential positive impacts of this model are the consistency in the implementation of the legal requirements of the EU regulatory framework for medical devices whilst generating synergies where an overlap exists between the regulatory frameworks for pharmaceuticals and for medical devices (i.e. drug-device combination products, tissue engineered products, personalised medicines, borderline products). This would first of all establish an equal and high level of patient and user safety in the EU. It would also reduce compliance costs as well as the regulatory risk and burden for economic operators doing business in more than one Member State which currently are subject to inconsistent yet contradictory measures in the different Member States. Regulatory consistency would thus strengthen the functioning of the internal market to the benefit of patients and users and medical device manufacturers.

It would not change the system of formal decision-making in the EU. The Members States would remain responsible for decisions to be taken at national level for the implementation of

[118] It is not expected that all Member States participate in all meetings so that the real costs will be less.

[119] Commission's report of January 2010 on the evaluation of the EMA, p.15.

EU regulations; their coordination would take place within the Medical Device Expert Group, composed of experts designated by the Member States. The Member States' authorities would be the main beneficiary of the administrative, technical and scientific support to be provided by the new structure. The Commission would adopt, where needed, delegated or implementing acts in accordance with Articles 290 and 291 TFEU and obtain as well technical input from the new agency and the Medical Device Expert Group. Therefore, this option would not raise concerns in terms of the subsidiarity principle.

A further positive impact of this option would be the creation of a central contact point for manufacturers, Notified Bodies and competent authorities (EU and from third countries) to provide technical advice and exchange information under the auspices of the Commission.

Finally, the allocation of competences for pharmaceuticals *and* medical devices under the same roof would mirror the situation in 19 of the EU Member States where the competences for medical devices and for pharmaceuticals are united in the same national agency[120].

Option 7A would have budgetary implications since the tasks of the new "European Health Products Agency" related to medical devices would require an annual subsidy from the EU budget or a re-deployment from the existing EMA budget. Contrary to the tasks of the EMA in the field of pharmaceuticals, the medical device part of the future new agency, at least at the beginning, could only be financed to a small part by fees, since the major role would be the coordination between the authorities of the Member States for which, in principle, an economic operator should not be liable to pay fees (the issue of fees is addressed in section 6.6 "Financing").

"European Health Products Agency" – medical device related tasks: costs for staff The costs for staff, their offices and office equipment are estimated on the basis of current staff costs at EMA, i.e. 1 AD: EUR 161,708/year; 1 AST: EUR 90,091year (2011 prices)[121] + 14% overhead costs for administrative or cross-cutting tasks[122].	
35 FTE (26 AD + 9 AST)	4,204,408€ + 810,819€ = 5,015,227€ +14% overhead = **5,717,358€**
50 FTE (40 AD + 10 AST	6,468,320€ + 900,910€ = 7,369,230€ +14% overhead = **8,400,922€**

There may also be a number of risks and possible negative impacts. Whilst some interested parties (e.g. European Cardiology Society, the Belgian HTA body KCE), expressed their support for an extended role of EMA in the field of medical devices, the majority of stakeholders (in particular industry and Notified Bodies) as well as national competent authorities voiced concerns against the possible extension of the role of the current EMA to medical devices in response to the 2008 public consultation and subsequent discussions. They

120 AT, BE, BG, CZ, DE, DK, ES, FR, GR, IE, LU, LV, PL, PT, RO, SI, SK, SE, UK (in DE, the responsibility for Notified Bodies' oversight in the field of medical devices is entrusted on a different authority; in BE a separate agency is responsible for IVD). In the remaining eight Members States (CY, EE, FI, HU, IT, LT, MT, NL) either other national agencies or the ministries are the competent authorities for medical devices.

121 EMA has a relatively high premise cost index (168 compared to average =100), but a low travel cost index (58 compared to average =100), Evaluation of the EU decentralised agencies in 2009, Final Report Vol. II, p. 98-99.

122 EMA has a ratio of 14% for administrative staff, see Evaluation of the EU decentralised agencies in 2009, Final Report Vol. II, p. 95.

expressed the fear of a creeping "take-over" of the smaller medical device part by the pharmaceuticals part which would influence the elaboration and application of requirements in the field of medical devices with a "pharmaceuticals mindset" and eventually lead to the application of procedures which would not be appropriate to the device sector. They also pointed to the fact that EMA currently has no expertise in medical devices and feared that a possible new medical device part of the agency would not be appropriately staffed but remain the under-staffed 'poor relation' of the larger pharmaceuticals part.

In fact, EMA currently employs more than 700 staff and the agency already manages six committees in the field of pharmaceuticals with a seventh committee to be set up in 2012[123]. This considerable size of EMA which may further increase with the implementation of the revised pharmacovigilance legislation raises questions as regards the manageable size of a regulatory agency for which the Commission assumes responsibility and therefore needs to exercise control.

These concerns would need to be allayed by appropriate provisions in the amending EMA-Regulation and a financial commitment of the EU budget strictly targeted at the financing of the tasks related to the medical devices. This issue is also addressed in chapter 8 of this impact assessment on "Monitoring and evaluation".

5.8.2. Impact of policy option 7B (creation of a new EU regulatory agency for medical devices only and of a Medical Device Expert Group at this agency)

Option 7B would have basically the same positive impacts as option 7A but it would not create synergies in the field of drug-device combination products and borderline products. In terms of budget, the costs for human resources and meeting organisations would also be the same but additional costs would be related to the setting up of a new agency (new seat agreement, costs for setting up and maintaining a new infrastructure etc.).

This option would have the advantage that the concerns of the medical device sector with regard to a 'take-over' of their sector by a pharmaceuticals regulator would be addressed. The disadvantage, however, would be that synergies could not be achieved, both in terms of costs (e.g. use of an existing infrastructure) and in terms of expertise. The latter is likely to be more important with a view to the growing number of drug-device combination products and of borderline cases between pharmaceuticals and medical devices.

Moreover, it is questionable whether a separate medical device agency would have the 'critical mass' in terms of cost efficiencies since smaller agencies tend to have a relatively high share of administrative staff that is not directly involved in delivering the services for which the agency has been set up. In an evaluation report of EU agencies mandated by the Commission it was therefore suggested that the minimum size for an agency should be around 100 staff[124]. The report stated that on average agencies have a share of 30% administrative staff which increases to 37% for small agencies (<75)[125] which would need to be added as overhead costs.

New EU body for medical devices only: costs for staff

The costs would depend on the location chosen. In the absence of such decision, the average staff costs for the Commission are taken as a basis of the calculation, i.e. EUR 127,000/year for one

123 CHMP, CVMP, COMP, HMPC, PDCO and CAT; the PRAC (Pharmacovigilance Risk Assessment Committee) will be set up in 2012.

124 Evaluation of the EU decentralised agencies in 2009, Final Report Vol. II, p. 16, 97. On the other side, the recently set up BEREC Office is planned to have only 28 staff.

125 Evaluation of the EU decentralised agencies in 2009, Final Report Vol. II, p. 95.

AD/AST (2011 prices) + 37% overhead costs.	
35 FTE (AD/AST)	4,445,000€ +37% overhead = **6,089,650€**
50 FTE (AD/AST)	6,350,000€ +37% overhead = **8,699,500€**

5.8.3. Impact of policy option 7C (management of the medical device regulatory system by the European Commission and creation of a Medical Device Expert Group supported by this institution)

This option would constitute a modified 'status quo' in the sense that the Commission would continue to provide support for the coordination of the implementation of the EU regulatory framework, a solution favoured by many Member States and stakeholders (notably industry). But the MDEG would obtain a statutory basis and the Commission would need to dedicate considerably more resources to this task. Moreover, the Commission would need to dedicate resources to the other tasks needed to ensure the management of the regulatory system.

If it could be assured that the Commission services responsible for the management of the regulatory system would be appropriately staffed, this option would basically have the same positive impacts as option 7A, except for the synergies with pharmaceuticals which would only be achievable to a lower degree. But it would require that the Commission allocates permanently an additional 35-50 FTE to its department(s) in charge of medical devices. An advantage would be that, contrary to options 7A and 7B, no additional overhead costs would incur since administrative or cross-cutting tasks would be provided by the existing Commission resources.

Commission: costs for staff The costs are estimated on the basis of current average staff costs of the Commission, i.e. EUR 127,000/year for one AD/AST (2011 prices)	
35 FTE (AD/AST)	**4,445,000€**
50 FTE (AD/AST)	**6,350,000€**

There would also be no need for the Commission to dedicate resources to the oversight of an agency. On the other side, it may be argued that it is not part of the Commission's core competences to undertake tasks of primarily administrative, technical and/or scientific nature, such as the development of well-functioning IT tools, the organisation of meetings and joint assessments of Notified Bodies. Whilst this may indeed be true for most policy-oriented Commission services, the JRC has proven technical and scientific expertise in several fields and could extend this to the field of medical devices. In particular as regards improving the quality of the results of conformity assessment carried out by Notified Bodies, it was agreed by the Commission, EFTA and national competent authorities to make accessible, where appropriate, to the European Co-operation for Accreditation (EA) competences available at the JRC, in particular its Institute for Reference Materials and Measurements[126].

[126] General Guidelines for the Cooperation between the European Co-operation for Accreditation and the European Commission, the European Free Trade Association and the Competent National Authorities, OJ C 116, 21.5.2009, p. 6.

5.8.4. Impact of policy option 7D (creation of a Medical Device Expert Group managed by the Member States)

This option would depend on the willingness of Member States to cooperate and coordinate among themselves in the Medical Device Expert Group and its sub-groups. It is therefore questionable if this option would actually achieve the objective of an effective and efficient management of the regulatory system. Other tasks such as the development of an IT infrastructure or access to external scientific or clinical expertise would unlikely be performed by the Member States themselves.

This option would not require financing by the EU budget, but - if appropriately done – it would consume financial and human resources of the Member States' competent authorities. Due to the financial and economic crisis, many Member States have reduced the financing and workforce of their respective authorities responsible for medical devises. It is therefore unlikely that Member States would be able to allocate resources to appropriately staff and support a Medical Device Expert Group under their management. If, alternatively or in addition, the Commission or EMA was mandated to provide the secretariat, around 4 FTE (2 AD and 2 AST) would be required to fulfil the secretarial functions[127], i.e. 508,000€/year (Commission) or 503,598€/year (EMA).

Besides the uncertainty of the success of a self-managed coordination by the Member States, this option would also lack an internal market dimension which could only be guaranteed either by the Commission or another independent EU body.

Comparison of policy options 7A-7D:

Option 7D should be discarded because it would not be an effective means to achieve the objectives of this revision. Of the remaining three options, option 7B would be the least preferable since the creation of a new agency would not be efficient compared to the possibility of extending the mandate of the existing EMA.

Options 7A and 7C would both provide an effective and efficient tool for a consistent implementation of the medical devices regulations provided that the necessary resources are allocated either to EMA or to the relevant Commission's services. The synergies which could be gained in the field of drug-device combinations products and borderline products would be stronger for option 7A while they are not excluded for option 7C either. The possibility to maintain policy-making and implementation within the Commission and an enhanced involvement of its departments which fall within the "innovation" portfolio could be seen as a strong commitment for the Commission's innovation agenda. The absence of the need to dedicate resources to the oversight of an agency would be an additional advantage for option 7C.

The choice between both options requires a political decision and cannot be taken in this impact assessment on the basis of only technical criteria.

	Management			
Impact	Option 7A (EMA)	Option 7B (new agency)	Option 7C (Commission)	Option 7D (Member States)
Enhanced coordination	+++	+++	+++	-

[127] For the secretariat of the CMDh EMA provides around 2 FTE and for the CMDv around 1.25 FTE.

Synergies	+++	O	+	O
Costs for EU budget	--	---	-	O
Acceptance by stakeholders	-	+++	++	-

6. OVERVIEW OF PREFERRED OPTIONS, LEGAL FORM AND OVERALL IMPACTS

6.1. Overview of preferred policy options

The following table gives an overview of the preferred policy options with regard to the systemic problems and the objectives pursued by the revision of the regulatory framework for medical devices:

General 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	
Specific Objectives	**Preferred Policy Options**
Problem 1: Oversight of Notified Bodies	
Objective 1: Uniform control of Notified Bodies	**Policy option 1A:** New minimum requirements for Notified Bodies, ***and*** *either* **Policy option 1B**: Designation and monitoring of Notified Bodies by an EU body *or* **Policy option 1C**: Designation and monitoring of Notified Bodies by Member States with involvement of "joint assessment teams" ***and*** **Policy option 1G**: 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 in the field of post-market safety	**Policy option 2A:** Clarification of key terms and of the obligations of the parties involved in the field of vigilance ***and*** **Policy option 2B:** Central reporting of incidents and coordinated analysis of certain high risk incidents

	and **Policy option 2D:** Promotion of cooperation of market surveillance authorities
Problem 3: Regulatory status of products	
Objective 3: Cross-sectoral solution of "borderline" cases	**Policy option 3B:** Creation of a cross-sectoral expertise on borderline issues and possibility to determine the regulatory status of products at EU level in certain legislation (not medicinal products and food)
Problem 4: Lack of transparency and harmonised traceability	
Objective 4: Enhanced transparency regarding medical devices on the EU market, including their traceability	**Policy option 4B:** Central registration of economic operators and listing of medical devices placed on the EU market ***and*** **Policy option 4C:** Requirement for the traceability of medical devices
Problem 5: Access to external expertise	
Objective 5: Enhanced involvement of external scientific and clinical expertise	**Policy option 5B:** Designation of an expert panel and 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	**Policy option 6A:** Alignment with Decision 768/2008, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services ***and*** **Policy option 6C:** 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*** **Policy option 7A:** 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*** **Policy option 7C:** 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 table gives an overview of the preferred policy options in relation to the specific issues in the field of medical devices (other than IVD) which are discussed in more detail in Annex 1:

Specific Objectives	Preferred Policy Options
Problem MD-1: Scope - regulatory gaps or uncertainties	
Objective MD-1: Covering of legal gaps and loopholes	**Policy option MD-1B:** Regulate products manufactured utilising non-viable human cells and tissues as medical devices ***and*** **Policy option MD-1C:** Regulation of certain implantable or other invasive devices without a medical purpose within the MDD ***and*** **Policy option MD-1F:** 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	**Policy option MD-2B:** 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	**Policy option MD-3A:** Introduction of the term "sponsor" for clinical investigations and further clarification of key provisions in the field of clinical evaluation and investigations ***and*** **Policy option MD-3B**: Coordinated assessment of multi-national investigations by the competent authorities of the Member States where the investigation is performed

The following table gives an overview of the preferred policy options in relation to the specific issues in the field of in vitro diagnostic medical devices which are discussed in more detail in Annex 2:

Specific Objectives	Preferred Policy Options
Problem IVD-1: Scope – regulatory gaps or uncertainties	

Objective IVD-1: Covering of legal gaps and loopholes	**Policy option IVD-1C:** 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*** **Policy option IVD-1F:** Amendment of the legal definition of an IVD to include tests providing information "about the predisposition to a medical condition or a disease" ***and*** **Policy option IVD-1G:** 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	**Policy option IVD-2B**: Adoption of the GHTF classification rules and adaptation of the conformity assessment procedures to the relevant GHTF guidance ***and*** **Policy option IVD-2C**: Batch release verification for high risk IVD by the manufacturer under the control of a Notified Body and 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	**Policy option IVD-3B:** Legislative clarification of the requirements for the clinical evidence for IVD ***and*** **Policy option IVD-3E:** Clarification of the legal requirements in respect to point-of-care or near-patient IVD medical devices ***and*** **Policy option IVD-3G:** Alignment to the MDD where appropriate

The major costs for the EU budget generated by the preferred policy options are linked to the effective management of the future regulatory framework, and in particular to human resource requirements (35 to 50 FTE depending on the option eventually chosen), to the development and management of the IT infrastructure (e.g. Eudamed, ca. EUR 2mio/year) and to meetings between national experts (ca. EUR 1.4mio/year). For more details see under Section 5.8. For industry, the major costs will be related to the implementation of an UDI system (however compensated by a harmonised approach that is compatible with international guidelines) and, especially for the IVD sector, the introduction of a new classification system based on international guidelines. In addition, the scrutiny mechanism will lead, in certain cases, to a delay as regards access to market. Higher compliance costs for industry, however, are

expected to be overcompensated by avoidance of divergent rules in the different Member States in areas not yet harmonised and different enforcement practices. In particular due to the establishment of a central registration tool, industry will be able to reduce administrative costs of up to 157mio. Also an EU vigilance portal with central reporting of serious incidents instead of multiple reporting will reduce administrative costs. It is not expected that the preferred policy options have an impact on the prices of medical devices and the public health budgets. To the contrary, tightened and uniform controls to ensure compliance with the legal requirements and enhanced traceability of the products will lead to higher safety standards and therefore lower the impact of faulty or non-performing devices on patients and on society.

A complete overview of the estimated costs and benefits of the preferred policy options is provided in Appendix 9. The overall impact on the competitiveness of the European medical device industry cannot be quantified in absolute figures. A more robust and predictable regulatory framework that improves the functioning of the internal market and reduces administrative costs will support the competitiveness and innovativeness of the European medical device industry, including SMEs. It will enhance the confidence of third countries in the CE marking for medical devices and thus facilitate the export of European products to third country markets. At the same time, the status of Europe as a place for research and innovation in the field of medical technology will be confirmed which may contribute to attract investment in the medical device industry. By aligning EU legislation with guidelines adopted at international (i.e. GHTF) level, Europe will contribute to global convergence of medical device regulations to the benefit of industry in terms of market access abroad, and of patients and users in terms of raising the bar for globally recognised safety standards.

SMEs will have to comply with the same requirements as regards the safety and performance of medical devices as any other manufacturers because the quality and safety of devices cannot depend on the size of the manufacturing company. Such regime would also be prejudicial to small or medium-sized manufacturers since their products would risk being stigmatised if less stringent requirements were applicable to them. Should certain activities under the future regulations be subject to fees, the interests and special needs of SMEs, and in particular micro-enterprises would be taken into account.

It is not expected that the preferred policy options would have a significant impact on the prices of medical devices to be paid by the users and/or health security systems, even though this cannot be totally excluded for individual devices. Overall, however, an enhanced level of medical device safety would eliminate the costs which are caused by unsafe devices to be born either by the individual patients (in addition to the harm caused to their health) or by the collective insurance systems.

6.2. Legal form

Active implantable medical devices and other medical devices (other than IVD), which currently are subject to two separate pieces of legislation (i.e. the AIMDD and the MDD) should be regulated within one legislative act. There are historic reasons for separate acts but this is no longer justified. The provisions of the AIMDD and the MDD should therefore be merged and AIMD be classified as class III devices as it is already the case in several Member States and at international level by the GHTF. Where necessary, specific provisions regarding AIMD could be maintained. The legislation on IVD, however, should be kept separate from other medical devices to reflect the specificities of the products and the IVD sector which is rather homogenous with few overlaps to the other medical devices. This approach was broadly supported by stakeholders and Member States during the two public consultations.

As regards the legal form of the two legislative proposals, the above mentioned preferred options would justify the adoption of either directives or regulations. An analysis of the pros

and cons in light of Article 296 TFEU leads to the conclusion that a regulation in terms of Article 288(2) TFEU would be the more appropriate legal form since it would create a single EU regulatory framework for medical devices and thus better support the objectives pursued by this revision, i.e. the uniform interpretation and implementation of the legal requirements and thus a high level of protection of human health and safety throughout the EU.

A more detailed analysis regarding the choice of the legal form is provided in Appendix 10.

6.3. Synergies

The preferred options will provide a robust regulatory framework with clearer rules, favour a high level of consistency in their implementation by national authorities and ensure an efficient management by an EU body. In the case of extending the mandate of the EMA, synergies would be created between the future medical device part of the new structure and EMA's existing pharmaceuticals part, which already is involved in the assessment of certain aspects of some drug-device combination products. Some synergies may also exist to a certain extent if the Commission was entrusted with the coordination of the new system.

The positive aspects of the current system (flexibility, speed and low costs) 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 of 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. All in all, 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.

At international level, either the new "European Health Products Agency" or the reinforced medical device department of the European Commission will be a recognised partner for 3rd country regulators (FDA, Health Canada etc.) in the field of medical devices.

6.4. Administrative costs

Administrative costs are defined as "*the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties*".[128]

Five of the preferred policy options (i.e. policy options 1G, 2B, 4B, 4C and IVD-2B) will lead to administrative costs: (1) the obligation of Notified Bodies to notify new applications for conformity assessment and, if appropriate, to submit their preliminary evaluation for certain devices to the Medical Device Expert Group before the delivery of a certificate; (2) the central reporting of incidents; (3) the development of Eudamed to a central European databank for medical devices with information about the economic operators (manufacturers etc.), medical devices and UDI, (4) the labelling requirements regarding UDI, and (5) the adoption of a rules-based risk classification for IVD and the corresponding conformity assessment procedures.

To determine the administrative costs the EU Standard Cost Model is used.

$$\sum P \times Q$$

where P (for price) = tariff x time

Q (quantity) = number of business and frequency

[128] Impact Assessment Guidelines (SEC(2009)92, Part III, page 45.

6.4.1. Administrative costs for a notification mechanism with possibility for an ex ante control of conformity assessment reports (policy option 1G)

The price is determined by the cost for a Notified Body to notify application for conformity assessment of 'high risk', new or problematic devices and to submit, where requested, a summary of its preliminary conformity assessment and to assure the follow-up. The administrative costs are detailed above in section 5.2.3 (impact of policy option 1G).

- **Altogether, the administrative costs can be estimated at between 93,750 and 100,000€/year.**

6.4.2. Administrative costs for the central reporting of incidents (policy option 2B)

Since the adoption of the MDD, manufacturers are obliged to report serious incidents to the competent authority. However, the directives do not specify to which authority the manufacturer shall report. In MEDDEV 2.12-1 rev. 6 it is stated that in general, the report shall be addressed to the competent authority of the Member State where the incident has occurred unless specified differently.

A central reporting of incidents would therefore not create any additional administrative burden since it would do away with the reporting to the individual Member States. Since an incident currently can prompt multiple reporting, a centralisation of this obligation would therefore lead to a net reduction of administrative costs of manufacturers.

6.4.3. Administrative costs for the registration of economic operators, the listing of medical devices and upload of UDI-related information in a central European databank for medical devices (policy options 4B and 4C)

As regards the registration in a further developed Eudamed (which would integrate a UDI database), the preferred options 4B and 4C will create new obligations at EU level, in particular for class IIa, IIb and III devices. It is important to underline that the central registration and listing database and the UDI database would be merged so that costs for the collection of data and their upload would be required only once for both aims.

The price is determined by the cost for a manufacturer to upload the required information in Eudamed. The administrative costs are detailed in section 5.5.2. and show that the costs generated at EU level will be largely compensated by savings due to the replacement of multiple registrations at national level by a single registration at EU level.

- **New administrative costs at EU level: around EUR 21.6mio**
- **Savings due to reduction of administrative costs of the same nature at national level between around EUR 81.6mio and EUR 157.1mio**

The savings exceed by far the new administrative costs and therefore contribute to the Commission's action programme for reducing administrative burdens[129].

6.4.4. Administrative costs related to the indication of the UDI on the label (policy option 4C)

Labelling requirements are considered administrative costs. The introduction of a UDI system in Europe (option 4C) would require that the UDI data carrier (linear bar code, 2D matrix code, RFID) appears on the label of the product (on the device itself and/or on the packaging).

As mentioned above, the costs for adaptation of the labelling will depend on the complexity of the products and the production lines. For manual production lines, the costs can be

[129] Communication of 22.10.2009, COM(2009)544.

estimated at 500 – 5,000€. For automated production lines, the costs are far higher and can be estimated at 150,000€.

No data is available on the number of manual and/or automated production lines of European and international manufacturers. In any case, savings due to the fact that the multiplication of different systems could be avoided and more precise data would be available when the European UDI would be implemented by means of a delegated or implementing act.

6.4.5. Administrative costs related to the adoption of GHTF classification for IVD and corresponding conformity assessment procedures (policy option IVD-2B, see Annex 2)

The change of the classification system and the corresponding consequences on the conformity assessment of a large number of IVD (most class B and C IVD) may have an overall economic impact estimated at around **EUR 170mio**. A large part can be considered as administrative costs because they are related to the preparation of documentation for the assessment by a Notified Body and adaptation of the labelling (indication of Notified Body number).

6.5. Simplification potential

As mentioned in the beginning of this impact assessment, the "recast" of Directives 90/385/EEC and 93/42/EEC was first mentioned in the Commission's 2005 Simplification Strategy and has been maintained in Annex III (simplification items) of the Commission's Work Programmes 2010 and 2011.

6.5.1. Codification, merger of AIMDD and MDD, and transformation into regulations

The most obvious simplification aspect of this revision exercise is the transformation of the existing three main Council or Parliament and Council directives[130], their three amending directives and two Commission implementing directives[131] into two regulations of the European Parliament and of the Council. The regulations will be directly applicable and therefore make national transposition laws redundant. On the one hand, this will reduce administrative and legislative work at the level of Member States and, on the other hand, divergences due to late or incorrect transposition will be avoided so that economic operators will not need to adapt to (slightly) different national laws.

Moreover, the merger of the current AIMDD and MDD as well as the parallel revision of the current IVDD, both combined with the clarification of obligations of economic operators, will eliminate overlaps and redundancies and will increase the clarity and consistency of Union rules in the field of medical devices.

6.5.2. Co-regulation

The envisaged proposals will maintain the regulatory approach to set the essential requirements in the legal text and use standardisation for detailed technical specifications. Moreover, the use of conformity assessment procedures, which are streamlined and simplified by the current proposals, will further ensure that the intervention by public authorities prior to the marketing of products is kept at an appropriate level. By strengthening the authorities' control of Notified Bodies, this regulatory approach is reinforced and made fitter for future challenges in the sector of medical devices.

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130 Council Directive 90/385/EEC, Council Directive 93/42/EEC, Directive 98/79/EC of the European Parliament and of the Council, Directive 2000/70/EC of the European Parliament and of the Council, Directive 2001/104/EC of the European Parliament and of the Council, and Directive 2007/47/EC of the European Parliament and of the Council

131 Commission Directive 2003/12/EC and Commission Directive 2005/50/EC.

6.5.3. Central reporting of incidents and central registration and listing of economic operators and devices

The creation of a central European databank with interconnected electronic systems for the registration of economic operators and medical devices and for the central reporting of incidents by manufacturers will substitute the multiple registration and reporting requirements at national level by a one-stop-shop process at EU level. Within this process, the European UDI system, replacing diverging national systems, would play a key traceability role. This future IT architecture will not only reduce the administrative costs for economic operators but also provide European citizens and policy makers with a modern IT tool which informs them about the medical devices available on the Union market.

6.6. Financing

With the adoption of the proposals by the Commission scheduled in the first semester 2012, an adoption of the legislative acts by the co-legislator can be expected by the end of 2013 so that credits for its implementation would need to be foreseen as of 2014 which would go hand in hand with the start of the next Multiannual Financial Programme (MFF) 2014-2020.

Estimated budgetary needs

Human resources – EMA or – Commission (with involvement of JRC)	– between EUR 5.7 mio/year (for 35 FTE with overhead) and EUR 8.4 mio/year (for 50 FTE with overhead) – between EUR 4.4 mio/year (for 35 FTE with overhead) and EUR 6.3 mio/year (for 50 FTE with overhead)
IT system development, maintenance, support and infrastructure	– 2014-2017: EUR 2 mio/year in average – 2018 et sqq.: EUR 1.8 mio/year in average
Meetings	– 1.4 mio/year
Reimbursement of experts – National assessors for 'joint assessment teams' (daily allowance and travel expenses) – Clinical and scientific experts	– 0.4 mio/year (only needed if policy option 1C is chosen) – 0.1 mio/year
Miscellaneous (publications, communication, translations, travel expenses etc.)	– 0.6 mio/year
Total	– **EMA: between EUR 10.2 and 12.5 mio/year (2014-2017), between EUR 10 and 12.3 mio/year (2018 et sqq.)** – **Commission/JRC: between EUR 8.9 and 10.4 mio/year (2014-2017), between EUR 8.7 and 10.2 mio/year (2018 et sqq.)**

If option 7A (EMA) was chosen, the costs linked to the tasks conferred to a new "European Health Product Agency" in the field of medical devices would need to be approved within EMA's annual budget by the budgetary authority. If option 7C (Commission/JRC) was

chosen, the costs for staff would be booked either on the administrative budget line of the Commission or as operational costs of the lead Directorate-General and be transferred to the JRC in the context of an internal service agreement. As stated above, the results of the negotiations on the MFF 2014-2020 would need to be taken into account for any of the two options.

Operational expenses regarding the implementation of the AIMDD, MDD and IVDD have so far been charged on the "internal market" budget line (BL 02 03 01). Since Article 114 TFEU will remain the legal basis for the revised directives, this budget line should continue to provide funding for the implementation. With the extension of the legal base to public health (Article 168 TFEU), also the next public health programme "Health for Growth" (BL 17 03) should provide funding. Financing the implementation of the (future) legislation on medical devices is foreseen as one of the options to be presented in the impact assessment for this programme which covers the period 2014-2020.

Part of the operational expenses (e.g. IT development, 'joint assessment' of Notified Bodies) may be recaptured by fees for the registration of economic operators and listing of devices and the assessment of Notified Bodies. The legal basis for the levy of fees (as well as a decision whether there should be a refund to Member States) should be included in the legislative act to be adopted by the co-legislator. However, the amount cannot be predicted at this stage since the level of fees and, if applicable, the amount of the refund to the Member States' competent authorities[132] are not yet defined; it necessitates a specific impact assessment but it can be predicted that the level of fees would be considerably lower compared to those applied for pharmaceuticals.

7. SUBSIDIARITY AND PROPORTIONALITY

The use of Union competences is governed by the principles of subsidiarity and proportionality (Article 5 TEU). The application of these principles is further specified in Protocol No 2 to the TEU and TFEU which needs to be taken into account for the preparation of the Commission proposals. The preferred options for EU action suggested in this impact assessment will respect the principles of subsidiarity and proportionality.

Legislation in the field of the internal market (Article 114 TFEU) and regarding common safety concerns in public health matters (here: high standards of quality and safety of medical products, Article 168(4)(c) TFEU) is a shared competence between Union and Member States (Article 4(2)(a) and (k) TFEU).

The current EU legislation on medical devices is based on Article 114 TFEU (ex-article 95 TEC) and its aim is to ensure a high level of protection of human health as well as the proper functioning of internal market. According to this legislation, medical 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 on the internal market.

Several of the preferred policy options (e.g. mechanism to settle borderline and classification issues; central registration and listing, including traceability; enhanced coordination regarding post-market safety) are explicitly geared at addressing threats to the single market, while

[132] The aspect of refund is of special importance to contribute to the funding of national competent authorities as regards the fulfilment of the tasks allocated to them by the EU legislation.

enhancing the level of protection of public health in the EU. Also indirect threats are addressed with the reinforcement of the control of Notified Bodies which is needed to ensure the confidence in the CE-marking and to avoid negative repercussions on the free movement of devices due to restrictive national measures (e.g. based on the safeguard clauses).

Harmonised rules and procedures allow manufacturers, especially SMEs, to reduce costs related to national regulatory differences, while ensuring a high and equal level of safety for all European patients and users.

The majority of policy options suggested in this impact assessment leave the ultimate responsibility for the implementation of the harmonised rules at the level of Member States. The coordination among them as well as certain technical tasks (e.g. IT infrastructure, consolidated expertise), however, can only be ensured appropriately at EU level.

Only option 1B (designation and monitoring of Notified Bodies by an EU body) could give rise to being questioned on the ground of the subsidiarity principle, if it was chosen instead of policy option 1C (designation and monitoring of Notified Bodies by Member States with the involvement of 'joint assessment teams'). But the choice of this option would be justified by the high level of effectiveness in ensuring a uniform oversight of Notified Bodies which is a cornerstone for the functioning of the entire EU regulatory system for medical devices.

8. MONITORING AND EVALUATION

The successful implementation of the future regulatory framework for medical devices will depend on several factors. The following monitoring and evaluation tools could be envisaged:

8.1. Alignment of national legislations to the future EU regulatory framework for medical devices

The new EU regulations will be directly applicable in all Member States. But since all Member States currently have their own legislation regarding medical devices based on the existing AIMDD, MDD and IVDD, they would be required to repeal their existing national regulations in the field of medical devices. The European Commission would need to monitor this process. Member States should therefore be required to communicate all national measures falling within the scope of the new EU regulations and identify those which are repealed in order to align with these regulations. The Commission would need to verify that Member States correctly align with the new EU framework. Indicator of success will be the absence of infringement cases for violation of the new regulations.

8.2. Oversight of Notified Bodies

At the latest three years after entry into force of the new legislation, on the basis of a roadmap set up by the Commission and the Member States, all existing Notified Bodies should be assessed and designated according to the new requirements and designation process and the mechanism for notification by Notified Bodies of certain conformity assessment applications should be established.

Indicator for success of combined policy options 1A and 1B or 1C will either be the number of Notified Bodies designated under the MDD/IVDD which might decrease due to the new requirements and process and/or the level of diversification of the Notified Bodies' designation scope which is expected to increase. It should be emphasised that the reduction of the number of Notified Bodies is not as such an objective pursued by the revision even though it may be a consequence. The objective that Notified Bodies are designated in accordance with their proven expertise and competences may also be achieved by more specified designation scopes.

Indicator for success of policy option 1G will be the number of preliminary assessment reports submitted to the MDEG and the number of comments made by this group on these reports. The number of times that MDEG would make use of its "right of evocation" should be reasonable. Even though it is difficult to predict how many notifications would justify the submission of a preliminary assessment report, the number should probably not exceed 50 a year so that the system remains workable and does not overly slow down the assessment process. It should therefore be monitored that the implementation of this policy option does not lead to an unreasonable increase in time to market.

A further indicator of success of the revision of the entire regulatory framework (stronger oversight of Notified Bodies, 'early advice' process with external experts etc.) will be a decrease over time of the number of comments emitted by MDEG and an increased recognition of the Notified Bodies by third countries.

8.3. Post-market safety

Annual statistics should be drawn up to indicate the number of incidents reported to the central vigilance database and the number of cases where a coordinated analysis led to a uniform Field Safety Corrective Action (FSCA). Indicator of success for the combined policy options 2A, 2B and 2D will be the number of cases where divergent positions exists with regard to FSCA or restrictive measures taken in the context of market surveillance which should be low and decreasing over time.

8.4. Cross-sectoral solution of borderline cases

Indicator of success for policy option 3B will be, on the one hand, the number of meetings of a cross-sectoral advisory group on borderline issues and the number of cases solved by consensus by this group or by a legally binding measure adopted by the Commission, and, on the other hand, the decrease of cases in which different regulatory regimes are applied to the same product or type of products in various Member States.

8.5. Enhanced transparency and traceability

The timely deployment of a performing and interoperable IT infrastructure will be key to achieve an enhanced transparency of the regulatory system for medical devices, and in particular to implement policy options 4B and 4C (central registration and listing database combined with UDI for traceability). The operational services would need to work closely with the IT specialists to conceive the development of Eudamed that meets the needs of the users. A roadmap should be set up which defines deployment progress. Indicator of success will be that 5 years after entry into force of the new legislation, a clear picture will be available at EU level as regards the economic operators and medical devices on the EU market and the key clinical data supporting the assessment of high risk devices.

As regards UDI, the indicator of success will be that, after full implementation of UDI (ca. 10 years after entry into force of the revised legislation), the possibility exists to track and trace all devices subject to the UDI requirement. An additional success indicator will be that the US and EU UDI systems (as well as possibly other UDI systems based on the GHTF guidance on UDI) are fully compatible and allow traceability between the respective jurisdictions. Close cooperation with international partners, in particular with the US FDA in the context of the regular bilateral cooperation, would be important in order to keep the impact on economic operators as low as possible.

8.6. Enhanced involvement of external scientific and clinical expertise

With regard to the enhanced role of external experts, strict enforcement of the rules on disclosure of possible conflicts of interests will be key to ensure the independence of advice

given to decision-markers as well as a high level of transparency as guarantee for trust in the system.

Indicator of success will be the number of opinions given by external scientific and clinical experts, including reference laboratories, in particular in the context of an 'early advice' procedure available to manufacturers and Notified Bodies. In order to justify the costs, around 10 opinions should be delivered per year.

8.7. Clear obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales

The number of coordinated actions regarding internet sales of medical devices could be taken as indicator of effective implementation as well as their impact on the quantity of counterfeit devices on the EU market. Regarding diagnostics services offered at a distance in the EU, a survey should reveal the extent to which the devices used in the context of such services comply with the EU requirements.

8.8. Effective and efficient management of the regulatory system

Immediately after adoption of the new legislation, the Commission would need to prepare the new governance model. If option 7A (extension of the mandate of EMA) was chosen, the amendment to Regulation (EC) No 726/2004 would need to be implemented by the Commission in close cooperation with the management of EMA. Qualified staff would have to be recruited in time and the infrastructure for hosting the Medical Device Expert Group would have to be set up. Within the Commission a task-force should be set up to assist EMA that the necessary arrangements are put in place to ensure the transition to a new "European Health Products Agency". The Management Board of EMA would have to ensure that national agencies that do not have a shared competence for medicines and medical devices are adequately represented.

If option 7C (fulfilment of tasks by the Commission) was chosen, the Commission would need to decide about the distribution of tasks between its services. This would require a decision on the redeployment of the necessary staff and the recruitment of qualified personnel.

8.9. Consultation and reporting

The current informal Commission's Medical Device Expert Group , which shall be given a statutory mandate by this revision, as well as the special working groups will provide a regular platform to discuss issues related to the implementation of the new regulatory framework. The further monitoring of the implementation will continue to be done in close cooperation with the future statutory Medical Device Expert Group.

Seven or ten years after the implementation, the Commission should report to the European Parliament and to the Council about the achievements of the 'medical device package'. The report should address the impact of the new rules in respect of public health and patient safety, internal market, innovativeness and competitiveness of the medical device industry (with special attention to SMEs). The Commission should consult competent authorities and stakeholders (healthcare professionals, patients, manufacturers, Notified Bodies) when preparing its report.

9. LIST OF ACRONYMS AND ABBREVIATIONS USED IN THE IMPACT ASSESSMENT

AIMD	Active implantable medical devices
AIMDD	Active Implantable Medical Devices Directive (Directive 90/385/EEC)
ATMP	Advanced Therapies Medicinal Product
CAMD	Competent Authorities for Medical Devices
CAT	Committee on Advanced Therapies
CI	Clinical investigation
CIE	Working Group on Clinical Investigation and Evaluation
COCIR	European Coordination of the Radiological and Electromedical Industry
COEN	Compliance and Enforcement Group
EDMA	European Diagnostic Manufacturers Association
EFTA	European Free Trade Association
EMA	European Medicines Agency
EU	European Union
Eucomed	European Medical Technology Industry Association
Eudamed	European databank for medical devices
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
FTE	Full Time Equivalent
GHTF	Global Harmonization Task Force
GMDN	Global Medical Device Nomenclature
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
IVD	*In vitro* diagnostic medical device
IVDD	*In Vitro* Diagnostic Medical Devices Directive (Directive 98/79/EC)
JRC	Joint Research Centre

MD	Medical device
MDD	Medical Devices Directive (Directive 93/42/EEC)
MDEG	Medical Device Expert Group
MEDDEV	Guidelines relating to the application of the medical devices directives
MRA	Mutual Recognition Agreement
NB-Med	Co-ordination of Notified Bodies Medical Devices
NBOG	Notified Body Operations Group
NBOG-BPG	Notified Body Operations Group - Best Practice Guidance
NCAR	National Competent Authority Report
NET	New and Emerging Technologies Working Group
PoC/NP	Point of care/Near-patient
QS	Quality system
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SMEs	Small and medium-sized enterprises
SUD	Single-use device
TEC	Treaty Establishing the European Community
TFEU	Treaty on the Functioning of the European Union
UDI	Unique Device Identification
WHO	World Health Organization
WTO/TBT	World Trade Organization/Technical Barriers to Trade