EUROPEAN PARLIAMENT

IMPA Impact Assessment

Initial appraisal of a European Commission Impact Assessment

European Commission proposals on medical devices and in vitro diagnostic medical devices

Impact Assessment on the Revision of the Regulatory Framework for Medical Devices
(SWD (2012) 273, SWD (2012) 274 (summary))
accompanying the Commission Proposals on Medical Devices (COM (2012) 542)
and on In Vitro Diagnostic Medical Devices (COM (2012) 541).

• Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's Impact Assessment accompanying the Commission proposals on Medical Devices and on In Vitro Medical Devices (MDs and IVDs):

- Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009;
- Proposal for a Regulation of the European Parliament and of the Council on in vitro medical devices.

The Commission's proposals, strengthening the legal framework for medical devices, including in vitro medical devices, 'aim to ensure that patients, consumers and healthcare professionals can reap the benefits of safe, effective and innovative medical devices'.[1] The existing regulatory framework, having been in place for twenty years, a revision is needed to fill in gaps following technological development of medical devices.

Following the scandal of defective breast implants (PIP), the European Parliament adopted a Resolution in June 2012, calling on the Commission, inter alia, 'to develop an adequate legal framework to guarantee the safety of breast implants and medical technology in general'[2].

The market for MDs is characterised by the very broad range of products, 'from simple tongue depressors to complex X-ray machines'. It is a growing and highly innovative market, with a high investment rate in R&D.

• Identification of the issue at stake

According to the Commission, the present regulatory framework for MDs is not fundamentally unsound, but analysis of some problem cases (of which the PIP silicone breast implant scandal has attracted the most public attention) has shown that there are weaknesses and shortcomings, identified in the IA as **systemic** types of problems:

[1] Commission Press Release of 26 September 2012.
[2] Resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP, P7_TA-PROV(2012)0262.,

Problem 1 – Oversight of Notified Bodies;
Problem 2 – Post-market safety (vigilance and market surveillance);
Problem 3 – Regulatory status of products;
Problem 4 – Lack of transparency and harmonised traceability;
Problem 5 – Insufficient access to (independent) external expertise;
Problem 6 – Unclear and insufficient obligations and responsibilities on the part of economic operators, including in the fields of diagnostic services and internet sales;
Problem 7 – Management of the regulatory system.

In addition, the IA also identifies some more specific issues, such as regulatory gaps or uncertainties with regard to certain products, or the classification of IVDs.

• Objectives of the legislative proposal

The Commission proposal attempts to advance **three overall objectives:**

- to ensure a high level of protection of human health and safety;
- to ensure the smooth functioning of the internal market; and,
- to provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry.

In addition, seven **specific objectives,** directly related to the seven 'systemic' problems identified, contribute to the achievement of the overall objectives:

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

The Commission presents a very clear and comprehensive overview of the proposals' objectives, and logically links these with the identified problems.

However, Objective 1 could be criticised as being too specific. It has the effect of narrowing the scope of possible policy options, indicating from the start the direction in which the Commission intends to go. Objective 1 is apparently based on the premise that the system of Notified Bodies is maintained and precludes from the outset a serious assessment of any policy options that would more radically change the current regulatory framework. Furthermore, if the system of Notified Bodies is to be maintained, then Objective 1 might better have been 'effective control' whereas 'uniform control' could be a possible means for achieving this objective.

• Range of the options considered

Three main policy options are discussed in the IA:

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

First option

The first main option of 'no EU action' - namely that no further legislative EU action is taken and the current set of directives remains the legislative framework - is discarded in the IA because the problems listed above would continue to exist 'putting public health at risk', as made evident by the PIP breast implants scandal (IA p.26). The IA uses the 'no EU action' as baseline scenario for assessing the detailed options within the third main option 'evolution reinforcement'. The second reason for discarding the 'no EU action' option is that the Commission has to align the existing directives to the New Legislative Framework for the Marketing of Products. However, the IA could have assessed the impacts of EU action limited to this legislative alignment only.

Furthermore, the IA did not assess in how far actions needing no 'EU legislative action on MD and IVD' could face the problems identified. Such actions could be, for example:

- applying the existing instruments and controls more seriously[3];
- creating a culture in which warnings from individual experts and consumers could be reacted upon more timely and more seriously;
- improving the quality of risk assessment and generalisation of the application of the precautionary principle[4];
- generalise protection of disclosure of information in the public interest (like the British Public Interest Disclosure Act PIDA of 1998).

The impact assessment should at least consider whether these types of action could help avoid the problems faced and that they could be necessary and useful complements to the options identified under the third main option (namely, the reinforcement of the current regime).

Second option

The second main option ('Fundamental change: marketing authorisation of medical devices'), which would basically abandon the current system of Notified Bodies, was discarded as well, for several reasons.

First, a decentralised marketing authorisation by Member States would easily generate cases of one MS refusing a medical device authorised by another MS. Second, a central marketing authorisation at EU level would require a new EU body and 'it would have enormous impact on the EU budget, on manufacturers in terms of costs and administrative burden, and on innovation in terms of costs for regulatory compliance and time to market'. This conclusion is based on information from consulting groups and industry. Medicinal products legislation and Medical devices legislation are compared (p.27/28), with the latter seen as cheaper for 'cost for market access' and 'compliance cost post-market', whilst the 'time to market' is shorter. However, for the latter, the data basis was not sound (cf. footnote 69 of the IA), and the cost indicated was not presented in relation to the average market volume of the product.

The IA refers to the wide rejection of the 'fundamental change' option by most stakeholders, 'even though there were also some voices of healthcare professionals, health insurance organisations and HTA bodies who recommended a centralisation of the evaluation of high-risk devices'. It concludes: 'However, in the absence of evidence which would support that a

[3] EP Resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP called "6. for the introduction and implementation of essential and immediate specific measures on the basis of the current legislation on medical devices" and proposed several specific possible measures,
[4] See, for example, ERF study "The Precautionary Principle" www.riskforum.eu, October 2011.

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

Given the fact that the EP Resolution of 14 June 2012 on defective silicone gel breast implants expressly called on the Commission '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' (at paragraph 7), it would have been desirable for this option to have been considered more fully.

Third option

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

The IA distinguishes the following **options per detailed policy objectives** (all are within the third main option 'Evolution: reinforcement of the current regime keeping the same legal approach'), - first the options for the **general** objectives common to MD and IVD, and then the options for the objectives **specific** to either MD or IVD.

These detailed options per policy objective are listed in the Annex to this Initial Appraisal.

Despite the apparent level of detail, some of these options leave considerable scope for further specification.

Listing all 'hidden' options, not discussed in the IA, but proposed by the Commission, would exceed the scope of this 'Initial Appraisal'. The electronic systems foreseen by the proposals include information from manufacturers and Member States but very limited or no information from health practitioners, patients and patients' groups, in contrast to what was requested by the European Parliament in its Resolution of 14 June 2012.

• Scope of the Impact Assessment

According to the IA (p.37), the focus lies 'on the economic impact (e.g. costs for industry and public budget) and on the social impact (e.g. patient safety and public health)', whereas 'The assessment will ... address environmental impacts only when a specific policy option gives rise to consider them (e.g. reprocessing of single-use devices, see Annex 1)', as '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'.

This argument does not seem very convincing as most of the mentioned policy options have the potential to impact differently on environmental issues. Nevertheless, the IA has occasionally considered environmental issues.

Furthermore, the social impacts considered could have included, beyond patient safety and public health, for example:

- the safety and health of the staff and other people applying the devices;
- the well-being of people living close to the patients;
- employment in the medical devices sector.

The IA does not seem to have considered in any detail impacts on life and health insurance schemes.

The precautionary principle (which would opt in favour of devices the safety of which have been proven, and which would discard devices the safety of which has not yet been established sufficiently) is mentioned only once in the IA, and then only marginally (p. 21).

The IA checked the regulatory options in the light of the principles of **subsidiarity and proportionality** in general terms (on p.75-76). No national parliament has issued a reasoned opinion challenging the two proposals on grounds of subsidiarity.

- **Budgetary or public finance implications**

The implications for the EU budget are set out in the legislative financial statement annexed to the proposal on MD, and expressly declared valid also for the IVD proposal. Impacts on Member-State public finances and health insurance schemes have not been analysed.

- **SME test**

According to the IA (p.12), the MDs sector in the EU comprises 'around 22,500 individual medical technology companies, more than 80% are SMEs (in the IVD sector 90%), employing around 500,000 persons in Europe'. In view of this specific feature of the sector, the IA could have paid more attention to the expected impacts on SMEs, even if, admittedly, 'the quality and safety of devices cannot depend on the size of the manufacturing company'[5].

- **Simplification and other regulatory implications**

The fact that three directives are to be replaced by two regulations in itself can be an important move towards regulating in a more simple way the medical devices sector, currently marked by heterogeneous implementation in the Member States.

The well structured and modular composition of the proposed two legal texts could be seen as exemplary. However, the common core of the MD and the IVD proposals is repeated in each one of the two legislative proposals, which results in duplication of legal texts and bears the risk that even the common, duplicated, parts of the two legal texts, might start their own separate legislative lives. As reasons for presenting separate proposals for MD and IVD, Appendix 10 of the IA puts forward the preference of the industry concerned and a general trend at international (GHTF) level to separate the two issues.

- **Relations with third countries**

Interactions with third countries and international organisations or bodies have been considered, e.g. Global Harmonization Task Force GHTF (IA p. 11).

- **Stakeholder consultation**

The IA, throughout the report, refers to the outcome of various stakeholder consultations, addressed to "industry, Notified Bodies, healthcare professionals and patient and consumer groups" (IA p.9) and included also national regulators (ministries and agencies).
In 2008, the Commission held a public consultation on the recast of the general regulatory framework for MDs. 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.

[5] IA, p.70

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. 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.

- **Quality of data, research and analysis**

The IA does not have a very ample recourse on quantitative data. In particular the data put forward for discarding the second main option, 'fundamental change' (replacing the current system of Notified Bodies), had been prepared by 'industry' and consulting groups and could not be checked independently (p. 27 IA). The 'time to market' figure was based on only one case (footnote 69 IA) and the 'costs for market access' and 'compliance costs' have not been put in relation to the (average) market volume of the product in question.

The result of the comparison of the detailed options for the different criteria has been presented in a qualitative way, using the range of ---, --, -, 0, +, ++, +++, underpinned by justification in the text. However, this qualitative presentation provides only limited transparency, open to the subjective views of its author(s).

The Commission consulted external experts only in the framework of the stakeholders consultation.

For the preparation of this legislative initiative **no specific external studies** have been commissioned. 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 (IA p. 11).

- **Commission Impact Assessment Board**

The Commission's IA Board considered a draft version of the IA in written procedure on 23 September 2011. Its overall assessment was that the IA provides a sufficient evidence base for decision-making, and that it generally makes good use of quantitative data. However, some critical remarks were made, inter alia, that the IA should better justify its preferred option on ex ante controls of problematic devices by referring to the comparable controls in place for use of animal tissues as a way to show the likely safety benefits, that the IA should clarify the expected impacts of moving to global standards for IVDs, and that competitiveness-related impacts on EU manufacturers, particularly SMEs, should be described. Also, the IA should present a complete overview of the costs and benefits of the preferred option package. These comments have partially been given follow-up in the final version of the IA. E.g., the 'complete overview of the costs and benefits of the preferred option package' is given as Appendix 9.

- **Coherence between the Commission's legislative proposal and IA**

The IA seems to largely correspond to the proposals.

Author: Helmut Werner

Impact Assessment Unit
Directorate G for Impact Assessment and European Added Value
Directorate General for Internal Policies of the Union (DG IPOL)
European Parliament.

This note, prepared by the Impact Assessment Unit for the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) analyses whether the principal criteria laid down in the Commission's own Impact Assessment Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work. This document is also available on the internet at: http://www.europarl.europa.eu/activities/committees/studies.html

To contact the Impact Assessment Unit, please e-mail: impa-secretariat@ep.europa.eu

Manuscript completed in January 2013
Brussels © European Union, 2013.

ISBN 978-92-823-4086-8
DOI 10.2861/31029
CAT BA-30-13-231-EN-C

ANNEX: POLICY OPTIONS
IA on Medical Devices and In Vitro Medical Devices

(the IA's preferred options are shown in italics)[6]

- **Options for general (systemic) objectives:**

Policy options regarding Objective 1: Uniform control of Notified Bodies

Policy option 1A: New minimum requirements for Notified Bodies;

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

Policy option 1B: Designation and monitoring of Notified Bodies by an EU body[7]*;*

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

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

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

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

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

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

Policy options regarding 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;

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

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

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

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

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

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

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.

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

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

Policy option 4A: Network of national databases;

---

[6] Please note the different options for each objective are not necessarily exclusive, e.g. for objective 1 the options 1A; 1B-1D and 1E-1F could be combined, e.g. 1A+1C+1F.

[7] Here, the IA prefers "either 1B or 1C", based only on consideration of social and economic impacts. The IA could have arrived at a more precise recommendation by considering additional criteria like efficiency or coherence with Decision 768/2008/EC (the common framework for the marketing of products). Both Commission proposals chose option 1C.

Policy option 4B: Central registration of economic operators and listing of medical devices placed on the EU market;
Policy option 4C: Requirement for the traceability of medical devices.

Policy options regarding Objective 5: Enhanced involvement of external scientific and clinical expertise
Policy option 5A: Creation of a pool of experts;
Policy option 5B: Designation of an expert panel and reference laboratories for specific areas in medical technology[8].

Policy options regarding 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/EC, additional requirements for authorised representatives and clarification of obligations in the field of diagnostic services;
Policy options 6B – 6C: Internet sales;
Policy option 6B: Legislative measures regarding internet sales;
Policy option 6C: Addressing internet sales by soft-law action.

Policy options regarding objective 7: Efficient and effective management of the regulatory system
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[9]*;*
Policy option 7B: Creation of a new EU regulatory agency for medical devices only and of a Medical Device Expert Group at this agency;
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;
Policy option 7D: Creation of a Medical Device Expert Group managed by the Member States.

- **Options for the specific objectives in view of (non-in vitro) Medical Devices**[10]

Policy options regarding objective MD-1: Covering of legal gaps and loopholes

Products manufactured utilising non-viable human cells and tissues
Policy option MD-1A: Regulate products manufactured utilising non-viable human cells and tissues as medicinal products;
Policy option MD-1B: Regulate products manufactured utilising non-viable human cells and tissues as medical devices.

Implantable or other invasive products without a medical purpose
Policy option MD-1C: Regulation of certain implantable or other invasive products without a medical purpose within the MD;

[8] Further options are imaginable, more liberal and open approaches could nevertheless enhance access and use of independent expertise, e.g. "peer" reviews, enhanced transparent documentation requirements of applications of new devices.
[9] Here, the IA prefers either 7A or 7C; Whereas Option 7A is clearly providing for better 'synergies', Option 7C is put at an equal level because of its 'better acceptance by stakeholders'. Both Commission proposals choose option 7C.
[10] Cf part II of the IA.

Policy option MD-1D: Regulation of certain implantable or other invasive products without a medical purpose outside the legislation on medical devices.

Reprocessing of single-use medical devices
Policy option MD-1E: Prohibition of the reprocessing of single-use medical devices;
Policy option MD-1F: Harmonized regulation of the reprocessing of single-use medical devices;
Policy option MD-1G: Minimum criteria for the reprocessing of single-use medical devices.

Policy options regarding objective MD-2: Appropriate legal requirements taking into account technological, scientific and regulatory developments
Policy option MD-2A: No legislative action;
Policy option MD-2B: Review of the classification rules and essential requirements regarding specific devices or technologies.

Policy options regarding 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.

Policy options MD-3B – MD-3C: Assessment of multi-national investigations
Policy option MD-3B: Coordinated assessment of multi-national investigations by the Member States where the investigation is performed;
Policy option MD-3C: Voluntary cooperation among the Member States where the clinical investigation is performed.

- **Options for the specific objectives in view of In Vitro Medical Devices**[11]

Policy options regarding objective IVD-1: Covering legal gaps and loopholes

"In-house" tests
Policy option IVD-1A: Delete the exemption for "in-house" tests;
Policy option IVD-1B: Clarify the scope of the exemption for "in-house" tests and require a mandatory accreditation for "in-house" tests manufacturers;
Policy option IVD-1C: Clarify the scope of the exemption for "in-house" tests, require a mandatory accreditation for "in-house" tests manufacturers and subject high risk (class D) "in-house" tests to the requirements of the IVDD.

Genetic tests
Policy option IVD-1D: No legislative change and clarification by guidance;
Policy option IVD-1E: Amendment of the legal definition of an IVD to include all tests providing information "obtained by analysis of the genetic material", with a negative list of genetic tests excluded from the IVDD;
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".

[11] Cf part III of the IA.

Companion diagnostics in personalized medicines
Policy option IVD-1G: No legislative change regarding companion diagnostics;
Policy option IVD-1H: Regulation of companion diagnostics within the framework of the legislation on medicinal products.

Policy options regarding objective IVD-2: Appropriate and robust classification and conformity assessment of IVDs

Classification
Policy option IVD-2A: No change to the classification of IVDs;
Policy option IVD-2B: Adoption of the GHTF classification rules and adaptation of the conformity assessment procedures to the relevant GHTF guidance.

Batch release verification
Policy option IVD-2C: Batch release verification for high risk IVDs by the manufacturer under the control of a Notified Body (legislative clarification);
Policy option IVD-2D: Systematic batch release verification for high risk IVD by an independent laboratory.

Policy options regarding objective IVD-3: Clear and updated legal requirements for enhanced safety and performances of IVDs

Clinical evidence
Policy option IVD-3A: No legislative change regarding clinical evidence;
Policy option IVD-3B: Legislative clarification of the requirements for the clinical evidence for IVDs;
Policy option IVD-3C: Legislative clarification of the requirements for the clinical evidence for IVDs and demonstration of the clinical utility.

Point-of-care or near-patient IVDs
Policy option IVD-3D: No change regarding point-of-care or near-patient IVDs;
Policy option IVD-3E: Clarification of the legal requirements in respect to point-of care or near-patient IVDs.

Alignment with the MDD where appropriate (e.g. medical software)
Policy option IVD-3F: no alignment with the MDD;
Policy option IVD-3G: Alignment to the MDD where appropriate.