

Evaluation and Transparency. These areas have suffered in terms of coherence and uniformity in the interpretation and implementation of the legal requirements.

3. New and emerging technologies have challenged the current framework, highlighting gaps or pointing to potential loopholes including the scarcity of expertise needed to independently assess such technologies. The framework needs to fill these gaps and be made more robust to future technologies.
4. The New Approach itself has undergone a substantial revision which requires all sectoral legislation to be reviewed and revised accordingly.
5. Furthermore, uniform implementation of the Directives has been hampered by national variation such as in the areas of borderline and classification, i.e. the determination of the regulatory status of a given product or type of products as medical device or not, including the classification of medical devices, national registration procedures and requirements for traceability. This variation threatens not only the smooth functioning of the internal market, but, in this case, also the health and safety of patients.

The medical devices market is a global one, with our major trading partners increasingly aligning their legislation to the Global Harmonisation Task Force for Medical Devices (GHTF) model. To keep European industry competitive, the European legislation also needs to further converge on this model.

Who will be affected by it?

The conformity assessment bodies which are involved in the evaluation of medical devices and the manufacturers' quality system ("Notified Bodies") and the medical device industry will be affected. There may also be an impact on public authorities but enhanced coordination and possibly centralisation of certain procedures could create synergies, allow for work-sharing and reduce duplication of tasks at the level of the individual Member States. The strengthening of the regulatory systems will enhance the safety of devices coming on the market and will therefore positively impact the safety of citizens (patients) and healthcare professionals.

At the international level, EFTA countries, Turkey and other candidate countries will be concerned due to necessary changes of their respective regulations. But modification of the EU regulatory framework for medical devices will have a significant impact also on industry in the main markets notably the USA, Japan, Canada and China. It will also be widely considered by the authorities of the other GHTF members (USA, Japan, Canada, Australia), the members of the Asian Harmonization Working Party (e.g. China, India and ASEAN) and Latin American countries (e.g. Brazil).

- (i) Is EU action justified on grounds of subsidiarity?
- (ii) Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? (Necessity Test)
- (iii) Can the EU achieve the objectives better? (Test of EU Value Added)

The proper functioning of the single market in the European Union requires common rules for the safety and performance of medical devices. Action at Union level prevents varying product regulations emerging across Member States which results in fragmentation of the internal market and imposition of unnecessary barriers to intra-EU trade. Through harmonised rules it is possible to reap the economies of scale as production series can be made for the whole European market, while ensuring a high level of safety for patients and users throughout Europe.

B. Objectives of the initiative

What are the main policy objectives?

The proposals shall contribute to a high level of safety for the patient and user, delivering a transparent system whereby citizens can be confident in the safety of medical devices. They shall also ensure the good functioning of the internal market for medical devices. Moreover, their objective is to provide a simple and easily-understandable regulatory environment for medical devices that is supportive of innovation and the competitiveness of the European medical device industry.

Do the objectives imply developing EU policy in new areas?

No, this area has been the subject of Union legislation since the 1990ies.

C. Options

- (i) What are the policy options being considered?
- (ii) What legislative or 'soft law' instruments could be considered?
- (iii) How do the options respect the proportionality principle?

1. No EU action

2. Legislative measures

Any change to the Medical Devices Directives would require legislative measures in form of binding legal acts. They would be accompanied by a Communication of the Commission elaborating on how the medical device sector provides innovative solutions in the diagnosis, prevention, monitoring and treatment of diseases and explain how the legislative measures will allow support full exploitation of this rapidly growing potential, where safe and responsible innovation meet the needs and expectations of patients, consumers and healthcare professionals. The following options for legislative measures may be envisaged:

a) Fundamental change: marketing authorisation of medical devices

This option would imply a departure from the "New Approach" on which the current regime is based and the transfer of the responsibility for the assessment of the safety and performance of medical devices from Notified Bodies to regulatory authorities and the replacement of the CE marking by a marketing authorisation.

b) Evolution: reinforcement of the current regime keeping the same legal approach

This option would build on the strengths of the existing directives based on the "New Approach" while remedying the weaknesses identified. It would imply a revision of all three main directives, their codification with subsequent amendments, a merger of Directives 90/385/EEC and 93/42/EEC and keeping the regulation of IVDs separate from other medical devices. This policy choice is further detailed by a number of individual policy options to address the weaknesses identified. The elements which are considered for 2.b) are:

Scope, legal form and alignment with other legislation

- Transforming the current directives into regulations
- Extending the scope of the EU legislation on medical devices to cover:
 - products manufactured utilising non-viable tissues and cells of human origin;
 - certain implantable, injectable or otherwise invasive products for aesthetic purposes;
- Addressing the issues of genetic tests and "in-house" tests in the EU legislation on IVD;
- Addressing the issue of reprocessing of single-use medical devices;
- Addressing the issue of "borderline" cases and diverging determination of the regulatory status of a given product and type of products by Member States;
- Alignment, where appropriate, to the New Legislative Framework for the Marketing of Products (Regulation (EC) No 765/2008 and Decision 768/2008/EC), in particular as regards the obligations of economic operators;

Pre-market phase

- Strengthening and harmonising the oversight of notified bodies in terms of demonstration of competence, impartiality and transparency;
- Simplifying and streamlining the conformity assessment procedures;
- Ensuring uniform high standards and criteria for the conformity assessment by notified bodies, in particular as regards the assessment of the manufacturer's clinical evaluation and in the field of new technologies;
- Coordination of Member States' approvals regarding multi-centre clinical investigations;
- Clarifying basic concepts related to clinical investigation and evaluation;
- Alignment of the classification of IVDs with GHTF guidance;

- Clarifying the concept of clinical evidence in the EU legislation on IVD;

Post-market phase

- Developing a tool for the central reporting of incidents by manufacturers and improving the coordination of authorities in the areas of vigilance and market surveillance;
- Clarification of key concepts in the field of post-market safety;
- Regulating the distribution and traceability of medical devices with a view to address counterfeiting and device identification (e.g. UDI);
- Centralising the registration process for manufacturers/authorised representatives and medical devices in the European Union (further development of Eudamed);

Management of the system

- Introducing a legal basis for a Medical Device Expert Group (MDEG) to be composed of experts designated by the Member States and to be established at an EU body (e.g. agency or Commission)
 - to ensure a consistent application of the regulatory framework for medical devices throughout the EU;
 - to enhance the coordination between national competent authorities in the field of post-market safety and multi-national clinical investigations;
- Mandating an EU body to provide administrative, technical and scientific support to the MDEG to ensure a sustainable management of the regulatory regime and, among others,
 - to organise and participate in the assessment of Notified Bodies;
 - to manage an expert panel and a network of Reference Laboratories;
 - to develop, maintain and manage the IT infrastructure.

In particular option 2.b) is respecting the principle of proportionality.

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

Benefits and costs of the options will be described in the impact assessment.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

Strengthening the requirements regarding the pre-market assessment of certain (high risk) medical devices may add costs to manufacturers. On the other hand, enhanced coordination between Member States and possibly centralisation of certain procedures will bring benefits to the functioning of the internal market and do away with additional national requirements, leading overall to a reduction of the administrative costs.

The medical devices market is a global one, with our major trading partners increasingly aligning their legislation to the Global Harmonisation Task Force for Medical Devices (GHTF) model. To keep European industry competitive, the European legislation also needs to further converge on this model. Hence international alignment will be a feature of the proposal which may have a positive impact on international trade and the implementation of Mutual Recognition Agreements with the USA, Canada and Australia.

(i) Will an IA be carried out for this initiative and/or possible follow-up initiatives? (ii) When will the IA work start? (iii) When will you set up the IA Steering Group and how often will it meet? (iv) What DGs will be invited?

An inter-service coordination group (registered in the SG database on inter-service coordination groups) had its first meeting in October 2008 to give other interested services a first overview of the envisaged initiative. Work on the impact assessment started in the second semester 2010. In

accordance with the new Impact Assessment guidelines, an Impact Assessment Steering Group (IASG) has been set up to which, besides DG SANCO, the following services have been invited: SG, LS, DGs ENTR, COMP, EMPL, RTD, JRC, INFSO, ENV, MARKT, JUST, TRADE and BUDG. The IASG met on three times (Nov. 2010, April 2011 and July 2011). The draft impact assessment was sent to the IAB by the end of August 2011 and received a favourable opinion of the IAB by the end of September.

- (i) Is any of options likely to have impacts on the EU budget above €5m?
- (ii) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial regulation? If not, provide information about the timing of the ex-ante evaluation.

A transfer of administrative, technical and scientific tasks to an EU body in respect to key areas and for certain medical devices, if part of the final proposal, would impact the EU budget in terms of human resources, IT development, maintenance, support and infrastructure, meeting arrangements and reimbursement of national experts, building & equipment, etc. The extent of the financial impact has been estimated as part of the impact assessment.

E. Evidence base, planning of further work and consultation

- (i) What information and data are already available? Will existing impact assessment and evaluation work be used?
- (ii) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?
- (iii) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?
- (iv) Is any particular communication or information activity foreseen? If so, what, and by when?

Data gathered prior to the last revision (e.g. the Study on Competitiveness in the European medical device sector, July 2005, and the results of industry's survey on barriers to competitiveness, June 2007) need considerable update. An external study on distribution channels of medical devices (addressing also the issue of counterfeiting) was finalised in March 2010. Regarding the reprocessing of medical devices, the SCENIHR issued a scientific opinion in April 2010 which has been followed up by a report from the Commission to the European Parliament and the Council of 27 August 2010 on the issue of reprocessing of medical devices in the EU, in accordance with Article 12a of Directive 93/32/EEC, COM(2010)443. The public consultation launched in May 2008 did not provide sufficient socio-economic data regarding the impact of the possible policy options. National competent authorities, Notified Bodies, industry, medical professionals, patients and other interested stakeholders have therefore been requested to submit information and data on the impact of the envisaged measures through targeted consultation. As regards specific aspects related to the IVD sector, a public consultation from June – September 2010 invited interested parties to provide data to prepare the revision of the IVD Directive.

An external contractor has not been used.

The adoption of the proposal should be accompanied by a press release.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

A public consultation regarding the general features of the possible recast of the Medical Devices Directives was launched in May 2008; the result of the 200 responses was published in December 2008.

An additional public consultation regarding specific aspects related to the revision of the IVD Directive was launched in June 2010; the result of the 183 responses was published in February 2011.

The outcome of the two public consultations is available at http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index_en.htm.

Continuous consultation with stakeholders takes place through the Commission's "Medical Device Experts Group" (MDEG) - an informal expert group with representatives from Member States, industry, notified bodies, European standards bodies and other stakeholders in this area – and its working groups. Furthermore, targeted bi- and multi-lateral consultations, particularly with national

competent authorities, industry federations and medical professionals are being held.

Discussion in the context of the "Exploratory process on the future of the medical devices sector" (Nov. 2009 – Jan. 2010) also highlighted possible adjustments of the current regulatory framework to enhance the innovativeness and competitiveness on the medical devices industry.

A high-level conference was organised in March 2011 which brought together regulatory authorities, healthcare professionals, patients, industry, academics and other interested parties to discuss specific aspects concerning the regulatory framework for safe and innovative medical devices. This conference was followed up by Conclusions of the Council of the EU on innovation in the medical device sector, adopted on 6 June 2011.