

ROADMAP

- 1. Proposal for a Directive/Regulation (*to be determined*) of the European Parliament and of the Council on the approximation of the laws of the Member States relating to medical devices and repealing Directives 90/385/EEC and 93/42/EEC (recast);**
- 2. Proposal for a Directive/Regulation (*to be determined*) of the European Parliament and of the Council on the approximation of the laws of the Member States relating to in vitro diagnostic medical devices and repealing Directive 98/79/EC (recast)**

Lead DG/contact person: SANCO/B2

Expected date of adoption of the initiative: 2nd semester 2011

Initial IA screening & planning of further work

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Medical devices are used in the diagnosis and treatment of patients each day and are critical to the high protection of health of EU citizens.

Based on the New Approach, rules relating to the safety and performance of medical devices were harmonised in the EU in the nineties, beginning in 1990 with Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices and later followed in 1993 by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and in 1998 by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. These three legal texts form the core legal framework. Directives 90/385/EEC and 93/42/EEC have been supplemented over time with a number of modifying or implementing Directives, the latest being Directive 2007/47/EC which shall be implemented as of March 2010. Directive 98/79/EC on in vitro diagnostic medical devices (IVDs) has not been substantially amended since its adoption.

What are the main problems identified?

In recent years a number of drivers have come into play that necessitate an urgent simplification and strengthening of the legal framework.

1. In its continued commitment to simplification of legislation, the Commission in its Communication to the European Parliament and Council, COM(2005) 535, committed itself to recast (in a Regulation) Directives 90/385/EEC, 93/42/EEC, 2000/70/EC and 2001/104/EC. Currently, with three main Directives and five modifying or implementing Directives, the framework has been criticised as being too fragmented and difficult to follow, particularly for micro, small and medium enterprises or third country manufacturers and trade partners. The texts need to be consolidated and significantly simplified.
2. The key elements to the framework are Market Surveillance, Vigilance, Notified Bodies, Clinical Evaluation and Transparency. Experience has shown that the current system is shaky. These areas have suffered in terms of coherence and uniformity of approach due to the lack of efficient and effectively coordinated controls.
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 definition of a medical device, national registration

procedures, classification and interpretation of guidance. This variation threatens not only the smooth functioning of the internal market, but, in this case, also the health and safety of patients.

6. 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.

Is EU action justified on grounds of subsidiarity?

The proper functioning of the single market in the European Union requires common rules for the safety and performance of medical devices. Action at Community level prevents varying product regulations emerging across Member States which results in fragmentation of the internal market and imposition of unnecessary barriers to intra-Community 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.

B. Objectives of EU initiative

What are the main policy objectives?

The proposal 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. Its objective is also to ensure a simple and easily-understandable regulatory environment for medical devices to ensure the efficient functioning of the internal market.

Does the objective imply developing EU policy in new areas or of strategic importance?

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

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

1. Do nothing

2. Legislative measures: Any change to the Medical Devices Directives would require legislative measures. Therefore the instrument being considered would be a binding legal act. Three options may be envisaged:

a) Recast of two main Directives (see Commission Communication on simplification [2005] 535): This option would restrict itself to an editorial simplification through the merger of the two main Directives 90/385/EEC & 93/42/EEC and their codification with their subsequent amending Directives 2000/70/EC, 2001/104/EC and 2007/47/EC. It would not address the revision of the IVD Directive.

b) Revision of the entire legal framework, including the IVD Directive: This option would allow for more than editorial changes, merging and codifying the two main directives on (active implantable) medical devices and their modifying or implementing Directives in one single text and addressing the challenges in this sector which are lying ahead (cf. above, A.) (horizontal and vertical recast). A separate legislative proposal would address the fundamental revision of the Directive 98/79/EC on IVDs (ideally also in a recast).

Possible elements which may be considered for 2.b) are:

- Turning the Medical Device Directives into a Regulation (NB: the Legal Service of the Council has put into question the possibility to turn a directive into a regulation in the form of a recast);
- Adapting, when appropriate, to the revised New Approach model;
- Extending the scope to cover devices manufactured utilising non-viable tissues and cells of human origin and/or invasive or implantable devices for aesthetic purposes.
- Addressing the issues of genetic tests, diagnostic services provided at a distance and "in-house" tests in the IVD Directive;
- Addressing the issue of reprocessing of single-use medical devices;
- Regulating the distribution and traceability of medical devices with a view to address counterfeiting and device identification;
- Strengthen the notified body assessment in terms of demonstration of competence, impartiality and transparency, providing for timely and uniform action in the areas of vigilance and reinforced market surveillance, using when appropriate, elements of the review of the New Approach;
- The setting up of a coordination body at a European level tasked with ensuring uniformity and a high level of health protection in the key areas and the provision of expertise;
- Introduction of more binding rules where guidance needs to be mandatory rather than recommended.
- Simplifying procedures for updating the technical annexes;
- Strengthening and clarifying the basic concept of the clinical evidence, including technical data, that needs to exist to demonstrate the safety and performance of a device;
- Introducing the concept of clinical validity in the IVD Directive;
- Centralising and simplifying the registration process for medical devices in the European Union (further development of Eudamed);
- Tackling known issues previously not covered by the Directives such as environmental issues, animal health (sourcing and testing) and 'orphan medical devices';
- Setting minimum requirements for exports of medical devices to countries without medical device regulations;
- Adaptation and robustness to new technologies;
- Fine-tuning of the delineation to other Community legislation (e.g. pharmaceuticals, machinery, personal protective equipment, biocides)
- International alignment.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

There are impacts on other community legislation regarding e.g. pharmaceuticals, machinery, personal protective equipment (DG ENTR) and biocides (DG SANCO). These are dealt with within the current legislation and may be further refined in the proposal. Should environmental issues be tackled, there may also be an impact on the scope of environmental legislation such as REACH, RoHS and WEEE. Consideration may also be given to the inclusion of aspects of biological risks in relation to the animal by-products, currently dealt with in Regulation 1774/2002 on animal by-products (DG SANCO).

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The various policy options are likely to affect the target of the continued high level of protection of health and simplification. Moreover, the European citizen will be affected as medical devices are used to diagnose, treat and even sustain the lives of European citizens.

1. No policy change: This option would mean that the regulatory framework for medical devices is not reviewed as required by the revision to the overarching legal framework, the New Approach. Also the Commission would be reneging on its commitment to simplify legislation in this area. Furthermore, the current legal framework would be vulnerable to challenges, both technical and political, in the future.

2. Legislative measures:

a) Recast of the two main Directives and its amending Directives as mentioned in the Commission Communication on Simplification (2005)535: This legislative measure would restrict itself to a simplification through codification of the Directives on medical devices and active implantable medical devices as well as the four modifying Directives. It would not address substantial issues such as the modifications necessary due to the revision of the new Approach legislation, nor to substantial simplification and strengthening the legislation for future challenges. Since it would lead to the adoption of a new legislative act it would nevertheless require the adaptation of the documentation related to the current legislation (certificates, declarations of conformity, guidelines etc.) by industry, Notified Bodies and authorities without adding value to public health and the competitiveness of the industry. This policy option (as originally considered in 2005) would not embrace the revision of the IVD Directive despite the need to adapt it to technological progress and the development of international guidelines in this field.

b) Revision of the entire legal framework, including the IVD Directive: This policy option would require two legislative proposals, one for the recast of Directives 90/385/EEC & 93/42/EEC and their amending Directives and one for the revision of Directive 98/79/EC. The measures would go beyond a codification and allow for modifications of the texts. These modifications would seek to ensure the appropriateness of the regulation of medical devices for future developments in this sector. The revision of, on the one hand, Directives 90/385/EEC and 93/42/EEC and, on the other hand, of Directive 98/79/EC in parallel would allow for keeping the provisions applicable to both areas aligned. Recast would lead to a more consistent and clearer text which would facilitate the application of legislation by the economic operators. In addition, the specificities of IVDs would be reflected by keeping them separately regulated in a revised Directive 98/79/EC.

All options are going to be thoroughly considered in the impact assessment which will test the safety/cost implications of the different policy scenarios.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

A centralisation of EU expertise in respect to the key areas and for certain medical devices, in particular those utilising non-viable human tissue, if part of the final proposal, may impact the budget in terms of human resources, meeting arrangements, building & equipment, IT development & maintenance etc. The extent of the impact would be estimated as part of the impact assessment.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

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. On the other hand, strengthening the requirements regarding the pre-market assessment of certain (high risk) medical devices may add costs to manufacturers. Further centralisation of certain procedures, however, will bring benefits to the functioning of the internal market and do away with additional national requirements.

Who is affected?

Within the EU, 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 a centralisation of certain procedures could create synergies 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 and the accession 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).

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

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. A study on distribution channels of medical devices (addressing also the issue of counterfeiting) was finalised in March 2010. Regarding the reprocessing of medical devices, a scientific opinion of the SCENIHR is expected by April 2010 which will allow the preparation of a report of the Commission on this issue to be sent to the Parliament and the Council by September 2010. The merger of Directives 90/385/EEC and 93/42/EEC and their

respective amending acts will enhance the clarity of the legal provisions and eliminate incoherencies. The establishment of a central European database with information concerning economic operators and medical devices on the EU market will do away with multiple national reporting information requirements and thus reduce administrative burden.

The public consultation launched in May 2008, however, has not provided 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 will therefore be requested to submit information and data on the impact of the envisaged measures through targeted consultation. It is currently not envisaged to use an external contractor.

Which stakeholders & experts have been/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 consultation regarding specific aspects related to the revision of the IVD Directive should be launched by April 2010.

Continuous consultation with stakeholders will take place through the Commission's "Medical Device Experts Group" (MDEG) - an informal expert 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 will be 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.