EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2011)

Opinion

Title **DG SANCO - Impact assessment on revision of the regulatory framework for Medical Devices**

(draft version of 23 August 2011)

(A) Context

Medical device products are intended to be used for human medical purposes, for example to diagnose, prevent or deliver therapy for a disease, injury or handicap. They are distinguished from medicinal products, or pharmaceuticals, because devices do not achieve their principal action by pharmacological, metabolic or immunological means. Many devices are available in the EU, from simple tongue depressors to complex X-ray machines, around 540,000 different kinds. "In vitro diagnostic" products are used in testing, so quality requirements for these differ and focus on predictive ability.

The EU regulatory framework involves three main directives - Council Directive 93/42/EEC on medical devices (MDD), Directive 98/79/EC on in vitro diagnostic medical devices (IVDD), Council Directive 90/385/ECC on active implantable medical devices (AIMDD). The last amendments to MDD and AIMDD were in 2007. All reflect the "new approach" to technical standards under which conformity assessment enables CE marking and free circulation on the internal market. Low risk devices can be self-certified by manufacturers, while independent Notified Bodies (NBs) are involved in assessing higher risk devices. NBs are supervised by national competent authorities.

(B) Overall assessment

The report provides a sufficient evidence base for decision-making, and generally makes good use of quantitative data. It should however be improved in various respects. Firstly, it should enable readers to compare options more easily to a baseline scenario. Secondly, the report 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. Thirdly, the report should better demonstrate the proportionality of applying IVD rules to all high risk "in-house" tests by better explaining its benefits. Fourthly, the report should clarify the expected impacts of moving to global standards for IVDs. Fifthly, further information on incidents should be added. Sixthly, competitiveness-related impacts on EU manufacturers particularly SMEs should be described. Also, the report should present a complete overview of the costs and benefits of the preferred option package.

(C) Main recommendations for improvements

(1) Enable readers to compare options more easily. Firstly, the report should more clearly explain the baseline scenario. The rules that would apply in the absence of EU legislative change and, where relevant, the scope for improving outcomes via better implementation should be very briefly summarised for each of the seven thematic problems. This could be done by adding a table to the current "no further EU action" baseline scenario section, or by adding new theme-specific baseline options to the various blocks of options. The report should clearly distinguish between policy options that mainly aim to (i) clarify existing legal provisions, (ii) improve their implementation and/or (iii) further harmonise the medical devices regulatory framework.

(2) Explain experiences with comparable controls on use of animal tissues to better justify the preferred option on ex ante controls of problematic devices. The significant choice between options 1E-1G on controlling risky or inconsistently-assessed devices merits a fuller explanation of the preferred option (NBs must send either 1E: nothing, 1F: preliminary assessment or 1G: notification of application; 1F and 1G enable checks). The report should use evidence, including expert views, about the somewhat comparable process that is in use for devices using animal tissues to inform its assessment where possible. Such evidence should particularly be used to better demonstrate the potential safety benefits of option 1G.

(3) Demonstrate the proportionality of applying IVDD rules to all high risk "in-house" tests. In discussing the impacts of options IVD-1B and 1C which apply more IVDD rules to "in-house" tests than under the current exemption, the report should better explain the safety rationale for involving Notified Bodies in assessment of high risk tests (class D). It should also attempt to explain whether any infrequently used class D tests could become unavailable instead of being made safer, notably those which are not commercially marketed at present. The report should better explain whether exemptions from provisions about conformity assessment or laboratory accreditation could be granted in emergency situations, to address stakeholder concerns on this point.

(4) Clarify the expected impacts of adopting global IVD standards. The likely impacts of adopting global standards for IVDs should be better presented and justified (option IVD-2B). The total extra costs should be more clearly presented, split by year to show the pattern of one-off and recurrent costs over time. The claim made about stakeholders' preference for this option should be better supported by quoting support statistics broken down for different groups, including the group of SME manufacturers. The source of the unit cost assumptions which drive the cost estimates should also be supplied.

(5) Provide more information on incidents and refer to this in assessing options on centralising manufacturers' reporting. The report should provide the Member State statistics on the number of reported incidents, sources of reports, and the proportion of these that result in corrective actions for recent years which DG SANCO has already collected. Such information could be annexed, but the problem section should at least give some examples of imposed restrictions to better illustrate the importance of tackling the relevant problems. The main text should also mention that many incidents will not require review (e.g. when caused by user error). When assessing option 2B and 4B on centralising manufacturers' reporting, the report should ensure the likely number of total annual reports is considered. The report should also mention whether the EU database

could store incident reports from sources other than manufacturers or could interact with other systems, given several States already collect reports from users and health services and might wish to continue this practice.

(6) Describe competitiveness-related impacts and their possible magnitude. The report should discuss the overall impact of the various proposed changes on EU manufacturers' ability to compete in European and third country markets, for SMEs in particular. When discussing major impacts on manufacturers' costs, it would also be useful to mention the potential for costs to be passed on to device purchasers and the possible magnitude of impact on their input costs.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The report and the executive summary should present a complete overview of the costs and benefits of the preferred option package, preferably in the form of a table.

(E) IAB scrutiny process	
Reference number	2008/SANCO/081 (MD), 2011/SANCO/036 (IVD)
External expertise used	No
Date of IAB meeting	Written procedure