

Evaluation of the EU blood and tissues and cells legislation – MedTech Europe comments to the roadmap –

14 February, 2017

MedTech Europe, on behalf of the European medical devices industry, supports the evaluation of the EU legislation on blood, tissues and cells to ensure a high level of human health and safety, while adapting to the rapid technological and scientific innovative progress that is a defining characteristic of the medical technology sector.

MedTech Europe notes the parallelism between the current EU regulatory framework for medical devices and the regulatory framework for blood, tissues and cells in the sense that both frameworks aim at ensuring the highest levels of safety in sectors which are subject to considerable scientific and technological developments. Another commonality between both current regulatory frameworks is that they both consist of Directives and, probably as a result of this, and more specifically for the blood Directives, substantial divergences in the interpretation and application of the rules have arisen.

As the Commission is aware, the current Directives on medical devices [e.g., Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Directive 93/42/EEC on Medical Devices (MDD), Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD)], have at various occasions been updated to scientific and technological developments, requiring high standards of quality and safety for medical devices for a high level of protection of health for patients, users and operators. Furthermore, one of the overall objectives pursued by the now ongoing revision of the regulatory framework for medical devices (upcoming Regulations on medical devices and in vitro diagnostic medical devices) is to ensure appropriate legal requirements that take into account technological, scientific and regulatory developments.

Similarly, we believe it is appropriate to update the legislation on blood, tissues and cells and increase the legally binding factors of these Directives. As the roadmap subject to this consultation recognises, “no evaluation of the main Directives has taken place since their adoption despite a considerable degree of scientific and technological development in the sectors” and of the “scientific and technological development resulting in the availability of new techniques for testing, processing and preservation, to name but a few”.

In the Explanatory memorandum to the Commission Proposal for the new Medical Devices Regulations, the Commission acknowledges that “In an internal market with 32 participating countries that are subject to constant technological and scientific progress, important differences in interpreting and applying the rules have emerged, thus undermining the legislation’s main objectives — the safety of devices and their free circulation within the internal market”.

This has also been the case of the implementation of the legislation on blood, tissues and cells, where the lack of harmonisation has raised concerns, as recognised by the Commission in the roadmap and different implementation reports, such as the one from April 2016 (“Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components”. COM (2016) 224 final).

MedTech Europe is of the opinion that two of the reasons behind the many different Member State approaches taken with respect to the implementation of the Directives on blood, tissues and cells are,

- (i) the existing pieces of legislation do not provide a basis for full harmonisation;
- (ii) the co-existence of various bodies (national, international, supranational) involved in the draft of provisions on blood safety (e.g., national legislation, EU legislation, publications from the Council of Europe and WHO, etc.).

In light of these considerations and by analogy to the Medical Devices sector, MedTech Europe is of the opinion that strong and binding EU legislation (similar to the soon-to be finalised Regulations for Medical Devices and In Vitro Diagnostic Medical Devices) is required also for blood and tissues and cells. Only then the EU will achieve a degree of harmonisation of safety and quality at Union level.