



SUBJECT: ROADMAP EVALUATION AND FITNESS CHECK OF UNION REGULATION ON BLOOD, TISUES AND CELLS – SHC 9411

The roadmap dated 17/01/2017 has been discussed at the meeting of the Working Group on Organs, Tissues and Cells of human origin of the Belgian Superior Health Council.

The experts of the Working Group agree that a comprehensive assessment of the current Union regulation on blood, tissues and cells might be useful, but on the other hand they had a number of remarks.

As pointed out in the text, ethical aspects have not been taken into account in the European regulation. These aspects fall under the responsibility of the Member States, but they have not been addressed to the same extent by all Member States. In Belgium, ethical aspects have been included in the national legislation. In this way Belgian legislation has safeguarded the not-for-profit character of the allogeneic donation and contributed not only to the quality and safety of tissues and cells, but also to the availability of human body material. Therefore, the Working Group of the Belgian Superior Health Council would advice to include ethical aspects in the revision of the European directives, at least to a certain level.

The explicit citation of “commercialization” of human cellular and tissue products in the text, although clear and transparent, also raises questions. Commercialization can be considered as a risk to availability, quality and safety. Indeed, it is not impossible that some valuable transplants that do not have commercial interest (not profitable) would no longer be available for the patients who need them. On the other hand, as commercialization is about profit, it could be that cells or tissue won't be available for some patients due to the price of the product. This risk must be taken into account in the revision of the Directives. The term 'commercialization' should also be clarified.

In the same way, cost aspects also have an impact on safety and quality. Therefore, if audits and inspections are still increased and when GMP would be imposed for all tissues and cells (although it is not proven that this enhances safety and quality), these extra requirements are very expensive and this means money which is not available for other healthcare costs.

Additionally, a number of more detailed remarks, related to a specific chapter have been added.

B. Content and subject of the evaluation

(B.1) Subject area

In the current roadmap text, the focus lies on risks related to infectious diseases transmitted from the donor and from cross-contamination during processing.

As mentioned above, there are also risks for public health, related to the non-availability of certain types of tissues and cells, due to the entry of private (commercial) operators on the market and/or due to the implementation of higher level (and expensive) technical requirements for the preparation and preservation of the human body material.



C. Scope of the evaluation/FC

(C.1) Topics covered

As mentioned above, ethical issues (which can lead to quality and safety issues and can impact the entire field) , as well as pricing and reimbursement issues should be addressed by the European directives and no longer be the responsibility of Member States.

(C.2) Issues to be examined

1.b. Whether it was the initial intention of the EU or not, it is a fact that Directive 2004/23/EC paved the way for the commercialization and internationalization of human cell and tissue products. In practice, human cell and tissue products (substantially manipulated or not) are commercialized and part of an international market.

D. Evidence base

(D.2) Previous evaluations and other reports.

The statement “The directives have not been subject to any previous formal evaluations or impact assessments” is not entirely correct. Indeed, as it is only since 2005 that the current formal impact assessment (IA) process became mandatory of all major EU policies, the IA of the Directive 2004/23/EC proposal was non-exhaustive and limited to the evaluation of its impact on business with special reference to SMEs. The main conclusion of the IA was that the requirements of this Directive could increase the cost for starting materials used by business. In addition, there have been a number of consultations with competent technical experts and representatives of the Member States.

Furthermore, aspects related to the European directive have been studied at several occasions. At the occasion of a review of the Belgian legislation on human body material, a number of aspects related to the European directive and its application in Belgium and the other European Union countries, were studied (advice of the Superior Health Council 9335).

(D4) Consultation

Key stakeholder groups

Ethics bodies

Why are ethic bodies mentioned? According to the current European directive, Ethical issues are not considered. In the past (e.g. at the moment of the elaboration process of the human cell and tissue Directives and the ATMP Regulation), comments of ethics bodies have never been taken into account.