Feedback from the Ministry of Health, Welfare and Sport of The Netherlands on the Inception impact assessment revision of the Blood Tissue and Cells (BTC) directives

Key points:

- A **centralized approach** tackling the identified shortcomings in the current legislation should be the main focus and need to be explored further
- Options need to be incorporated that aim for establishing and protecting **European sufficiency of substances of human origin (SoHO)**
- It should be explored how the interaction between SoHO directives and the pharmaceutical and medical devices directives concerning **borderline substances** can be improved.
- Attention needs to be given to the **fine balance between EU and national legislation**
- Specification required on **protective measures for donor health and prevention of unnecessary donations**
- Besides health also the **privacy** of children born from donated sperm, eggs or embryos should be taken into consideration when considering monitoring options

A. General feedback

The Ministry of Health, Welfare and Sport of the Netherlands welcomes the opportunity to respond to the inception impact assessment from the European Commission regarding the Union BTC legislation and supports a revision of the current legislation as we recognize the shortcomings identified in the Commission's evaluation report as published on 10 October 2019. In particular, in the Netherlands we recognize the problems with insufficient flexibility of the directives to amend to innovations and new scientific insights, the categorization of borderline substances, and European substances of human origin (SoHO) supply vulnerability.

B. Comments on the proposed policy options

The Netherlands is especially interested in policy option number 2. This option has, in our opinion, the most potential to solve shortcomings and should be included and further explored in the future Impact Assessment of the European Commission. This option entails a centralized approach addressing flexibility in amending legislation to new scientific insights, innovations, and adequate responsiveness in crisis-situations in a harmonized manner. Furthermore, the framework for joint compliance inspections might fulfill the need for improvement on oversight abilities on cross-border operating actors.

In our opinion exploration of policy option 1 seems least promising, since this option could result in diversification of technical rules and specifications between Member States and establishments. This could affect the safety of the patients and limit cross-border exchange. In our view, this option is therefore a setback to the harmonisation reached in Europe in the field of SoHO.

C. Additional feedback

Preserving European SoHO supply

Several solutions are suggested addressing the important issue of preserving European SoHO supply that is also considered of high national priority, including mandatory monitoring of supplies and setting up a rapid alert system. We however question if these are sufficient to improve SoHO sufficiency in Europe as they do not target the root of the problem. Solutions need to be sought that have the potential to strengthen the European health system by incorporating provisions in order to protect patients for sudden disturbances that endangers sufficient supply of SoHO.

Balance between national and EU legislation

EU legislation enables market dynamics and leaves room for commercial interests in cross-border exchange of SoHO. At the same time this could impact the principle of subsidiarity and national competences, specifically concerning national legislation on ethical aspects. For example, if

anonymous donation is not allowed in a particular Member State, a company based elsewhere should not be allowed to advertise anonymous donation at their facilities in that particular Member State. On the other hand, more stringent national rules and regulations regarding safety, quality and financing approaches could cause cross-border exchange difficulties. Solutions properly balancing these issues should be investigated as part of the impact assessment.

How revisions in the legislation affect import from and export to third countries

Third countries should be considered as relevant stakeholders when assessing the impact of policy options in the revision of the BTC directives, as exchange of substances between the EU and third countries influences the European SoHO field.

Protective measures for donors to prevent unnecessary donations

We support the need for a strengthened position of the donor in the current legislation including addressing donor health. Moreover, when incorporating measures to protect patients for unnecessary therapies, it should also be assessed how donors or relatives of the donors can be protected against unnecessary donations. Donations of SoHO should be prevented or at least the donors or relatives of the donors should be well informed if at the moment of donation it is already known that there is only a slight chance for ever using the material for therapies.

Clarity on borderline substances is needed

As identified in the evaluation, the Ministry recognizes the unclear situations that arise when substances fall between SoHO and pharmaceutical or medical devices legislation. More clarity is needed to improve oversight capabilities by MS, and introduction of innovations by healthcare professionals and pharmaceutical companies. As part of the impact assessment it should be explored how the interaction between the SoHO and pharmaceutical and medical devices directives can be fine-tuned to better cover these grey zones, improve oversight and facilitate innovative therapies like ATMPs. The Netherlands, together with 16 fellow member states also addressed the incapability of the current EU ATMP framework to meet all scientific and technological developments in a non-paper advocating its revision[1].

Consider right to privacy of children born from donated sperm, eggs or embryos

The inception impact assessment mentions that the current legislation lack the obligation to monitor the health of children born from donated sperm, eggs or embryos. We agree that it is important to pay attention to monitor also this application of SoHO for possible negative effects. A mandatory follow-up, however, would intrude on the privacy of a child that was not involved in giving consent to the treatment. This aspect should be considered as part of the impact assessment.

[1] **#Prescription4EU – Five remedies for a Pharmaceutical Strategy for Europe catering for national health systems and patients' needs** *by Austria, Belgium, Croatia, Estonia, Finland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovenia, Sweden and the Netherlands.*