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Competent Authorities on Substances of Human Origin Expert Group
(CASoHO E01718)

Meeting of the Competent Authorities for for Tissues and Cells

22 June 2021

09:30 - 16:00 (CET)

BY TELECONFERENCE

MEETING SUMMARY

1. WELCOME, INTRODUCTORY REMARKS AND ADOPTION OF THE AGENDA

DG SANTE welcomed the participants (authorities and health attachés from the national Permanent Representations in Brussels). The context of the meeting was set by outlining the intense period of stakeholder consultations which had now closed, including in particular:

- Two online consultations: one on the [Have Your Say portal of the European Commission](#), open to any individual or organisation to complete, and one on the SANTE website, targeted to organisations that are impacted by the blood, tissues and cells (BTC) legislation and have knowledge/experience of it. Both consultations closed in mid-April.
- A series of 14 workshops on specific topics¹:
 - Three ‘hearings’ organised by DG SANTE, to which all NCAs were invited in addition to specific key stakeholder organisations. These organisations were invited to present their views to the authorities, who asked questions and indicated their general reaction to the stakeholder proposals via online polls.
 - In addition, 11 online workshops were organised by ICF, the contractor carrying out a study to support the impact assessment of the revision of

¹ More information is available at: https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/revision-eu-legislation-blood-tissues-and-cells_en

the BTC legislation. Those had a more interactive format with participants from authorities, expert bodies, stakeholder organisations etc., in line with the topic being discussed.

2. BTC IMPACT ASSESSMENT AND REVISION PROCESS – DEBRIEF FROM STAKEHOLDER HEARINGS AND WORKSHOPS

As an outlook for the rest of the meeting, DG SANTE explained that the outcomes of the stakeholder consultations would be outlined according to the 5 problems highlighted in the 2019 evaluation of the BTC legislation framework. Under these headings, DG SANTE would present the key results of the online consultations, the points emerging from relevant workshops, and the resulting planning for the drafting of the new legislation.

2.1 Keeping technical rules up-to-date

DG SANTE presented the key messages extracted from the online consultations and the outcomes of the hearing on technical rules, supplemented with relevant outcomes from the workshops on the scope, the definitions, and point-of-care use of BTC². The discussion centred on the strong support for policy option 2. It highlighted some concerns with its implementation as refers to the ongoing discussions with expert bodies (ECDC/EDQM) and the current state of the legal drafting.

2.2 Protecting donors

DG SANTE presented the outcomes of the online consultations as well as the dedicated workshops on donor protection, with relevant outcomes of the workshop on ethical issues³. In the following discussion, DG SANTE outlined their current thinking with regards to principles in legislation for donor protection, voluntary unpaid donations and potential monitoring for donors and for children born from MAR.

2.3 Strengthening oversight – increasing inter-Member States confidence and BTC exchange

DG SANTE summarised the outcomes of the dedicated questions in the online consultations and two workshops on oversight (one with competent authorities and one with operators)⁴, as well as the key messages from the NCA meeting in February 2021⁵. In particular, the presentation addressed principles for oversight to be included into the revised legislation as well as the possibility of extending oversight to other actors (such as end users, testing laboratories...) and implementing approaches and tools to support this (such as regulation of certain entities by registration, the separation of authorisation

² Keeping Technical Rules up to date (06 May 2021), Refining the Scope of the BTC Legislation (2 June 2021), Key Definitions: Improvements and Additions (1 June 2021), and Regulating Point-of-Care BTC Processing (bed-side and same surgical procedure) (12 May 2021).

³ Better Protection of Donors for Non-Reproductive Tissues and Cells (17 May 2021), Better Protection of MAR Donors and Children Born from MAR (18 May 2021), Ethical Principles (Voluntary Unpaid Donation, Prohibition of Profit from the Human Body and BTC Allocation) (8 June 2021).

⁴ Strengthening oversight (Inspection, authorisation, and vigilance) – authorities (25 May 2021) and Strengthening oversight (Inspection, authorisation, and vigilance – operators) (26 May 2021).

⁵ https://health.ec.europa.eu/events/covid-19-meeting-competent-authorities-tissues-and-cells-2021-02-12_en

procedures for BTC preparation processes and establishments, or the role of EU audits). The presentation also addressed concerns highlighted in the consultations about resources.

2.4 Facilitating access to innovative BTC that are safe and effective

The outcomes of two relevant workshops on authorising new BTC preparation processes and on borderlines were summarised⁶. The following discussion focussed on the possible inclusion of approaches developed in relevant joint action and project (GAPP and EUROGTPII), other aspects relevant to the oversight over innovative procedures, and possibilities for promoting cross-sector interactions with Medical Devices and Medicinal Products in the legislation.

2.5 Regulating for sufficiency

An overview of the outcomes from the online consultations and the dedicated SANTE hearings⁷, supplemented by relevant outcomes from the workshop on ethical principles, led to discussions on possible approaches to this issue, such as reporting and monitoring requirements, requirements for rapid notifications, or crisis contingency plans.

3. IMPACT OF COVID-19 ON THE BTC EVALUATION RESULTS

Results from the open and targeted consultations showed that the conclusions drawn from the evaluation of the BTC evaluation in 2019 were still valid and, as regards divergent oversight and inadequate protection from supply disruption, even exacerbated.

4. ONGOING EVIDENCE GATHERING FOR THE BTC IMPACT ASSESSMENT

DG SANTE outlined the ongoing work under the Feasibility Study on the implementation of the digital elements of the BTC revision.

ICF, the contractor carrying out a study to support the impact assessment of the revision of the BTC legislation, gave an outlook on the activities the study was working on, and stressed particularly the need for authorities' involvement in a survey on costs and burden of the assessed proposed measures.

5. UPDATE ON OTHER RELEVANT INITIATIVES

DG SANTE provided some information on other ongoing initiatives in the health field, including the evaluation of the EU's legal framework for pharmaceuticals and the EU4Health Programme.

⁶ Authorising novel BTC (27 April 2021) and Borderlines with other regulated frameworks: classification advice and interplay (9 June 2021).

⁷ Regulating for sufficiency: tissues and cells (5 May 2021).

6. ECDC UPDATE

This agenda point was not taken. The slides from the ECDC providing an update on the epidemiological situation in the EU in relation to blood and tissues and cells were circulated to the participants.

7. NEXT STEPS AND FINAL REMARKS

The chair thanked participants for their valuable contributions to the different consultation activities and underlined that the integration of inputs provided by stakeholders into the impact assessment was still ongoing.

The chair also gave participants an outlook on the next steps in DG SANTE:

- Publication of a short summary of contributions to the online consultations, together with the individual submissions;
- Use of the consultations feedback to feed into the impact assessment of the 3 proposed policy options, with the support of the study contractor, assessing each option (and each measure) against a set of criteria;
- Drafting of the Impact Assessment and the legislative proposal to revise the BTC legislation, and publication.

All attendants were thanked for their attention and participation.