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COMPETENT AUTHORITIES ON SUBSTANCES OF HUMAN ORIGIN EXPERT GROUP (CASOHO E01718) - REGULAR MEETING OF THE COMPETENT AUTHORITIES FOR TISSUES AND CELLS, 4 DECEMBER 2020 (BY TELECONFERENCE)

Summary Minutes

1. WELCOME AND INTRODUCTIONARY REMARKS

Competent authorities from 21 EU Member States (MS) participated in the meeting (all but BG, EL, LT, LX, SL and SK), as well as from NO, MK and TK. In addition, the representatives of the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation (WHO), the Council of Europe (EDQM) were present as observers. DG SANTE chaired the meeting

2. ADOPTION OF THE AGENDA

The Agenda was adopted without changes

3. LEGAL MATTERS

SANTE updated participants on the status of transposition checks and an infringement proceeding against one Member State.

Participants were informed that the GMP for ATMP regulation stipulates that blood-derived cells that serve as starting material for ATMP can be collected under either the Blood or TC legal framework. While this is in line with previous similar discussions amongst Blood and TC NCAs, it is important that these are informed of this guidance and their consequent responsibility under the ATMP framework.

ANSM/FR introduced a discussion on regulating extra corporal chemotherapy, which relates to a broader question on how to regulate bed-side preparations. This topic was

also flagged in the BTC evaluation, and highlights the need for regulatory actions with the authorities overseeing medical devices. The topic of bed-side preparations will therefore be addressed in the revision. ANSM and SANTE will therefore follow-up with a dedicated survey to understand current national views and practices.

Participants discussed possible regulation of breast milk and faecal microbiota transplants. SANTE reported on some exchanges with the sector, who in general would welcome these substances under the revised BTC legal framework.

SANTE reminded participants of the preparations for and expected impact of BREXIT, including upcoming changes in the coding and rapid alert platforms (RATC), and the need to organize import from UK through EU-27 importing tissue establishments.

4. OVERSIGHT FUNCTIONS

4.1 Inspection

A representative of the Inspection Expert Subgroup (IES) debriefed on progress made, including the development of guidelines for remote inspections. A draft document is to be commented by the NCA's. Such guidelines are much welcomed to allow continuation of oversight in the COVID setting.

The IES also mentioned plans for a first upcoming (remote) EU audit of national oversight systems in the BTC sector. NCA's will be debriefed of the outcomes, and the experience and learnings will feed into the revision of the BTC legislation.

The IES is also outreaching to inspectors in other legal frameworks (pharma).

Authorities recommended to include the work/good practices of the dedicated expert subgroups into the new legal framework.

4.2 Authorisation

A state of play was given on the GAPP joint action through which around 20 national authorities developed a proportionate authorisation model for (novel) BTC therapies. An initial risk assessment on a proposed change in process or use of BTC will allow blood/tissue establishments to discuss with the NCA to get a conditional authorisation with need for additional clinical data collection prior to a final authorisation. Different work-packages have developed the overall process (WP5), specificities for blood, IVF and other tissues/cell (WP6), microbiological factors (WP7), clinical data collection (WP8), a supporting IT-platform (WP9) and training (WP10).

Work Package 7 on microbiological safety has made particular progress covering guidance on requirements for laboratories, test kits, pathogen inactivation, sterilisation and microbiological quality of the end-product.

4.3 Traceability

No specific discussion took place

4.4 Surveillance and Vigilance

ECDC provided a short update on SoHO-relevant epidemiological diseases, beyond COVID. The participants expressed strong appreciation for this support by ECDC.

SANTE presented an overview of Rapid Alerts launched over the RATC system since the last meeting.

EDQM presented the final summary report of the 2018 serious adverse events and reactions (SARE) reported by the Member States. EDQM also presented a state of play of the 2019 data (2020 collection exercise). Member States were reminded of the legal obligation to report these data timely.

The TRIP organisation (NL) presented progress made the by Vigilance Expert Subgroup (VES), including voluntary reports on donor serious adverse reactions. Participants discussed the need to include reporting of donor reactions in the revised legislation. SANTE announced plans to have a small contract with TRIP to continue coordination of the VES work.

4.5 Clinical Outcome Data

The leaders of Work-Package 8 of the GAPP Joint Action (see above), presented the approach developed to organise a proportionate assessment and authorization of novel therapies/preparations, based on an upfront risk-assessment. This work will be taken up in the preparations to revise the legislation.

EDQM presented its work on data harmonization, in closed collaboration with professionals and authorities. Data harmonization is essential for reporting and for inputs to assess novel therapies (GAPP, point above). Good progress has been made with both professionals and authorities.

5. INTERNATIONAL DEVELOPMENTS

EDQM presented its activities to support the TC sector, which triggered an exchange amongst participants on the possible future role of EDQM in the revised BTC framework, in particular in order to develop guidance on tissue and cell quality.

6. SPECIFIC TOPICS RAISED BY MEMBER STATES

The Polish NCA briefed colleagues on the consequences of the bankruptcy of Cryosave, the largest collector of cord blood units. Units have been shipped from different EU Member States to a Polish tissue establishment, PBKM. The Polish national authority oversees verification of quality and of documentation. The NCA also explained that PBKM also has a multi-language website where concerned parents/families can retrieve further information on their cord blood units.

7. ANY OTHER BUSINESS

No topics were discussed