EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Brussels,

SANTE B4/ (2016)

Meeting between the Alliance for Regenerative Medicine (ARM)

and

DG SANTE B4

27 July 2017

Summary Minutes

The Alliance for Regenerative Medicine ("ARM") had requested a meeting with DG SANTE to discuss their proposed feedback to the public consultation on the application of the EU legislation on tissues and cells and in this context, inquire about possibilities to participate in current and future discussions regarding the application of the EU tissue and cells legislation and receive information on its envisaged evaluation.

ARM is a global advocacy group for cell and gene therapies, containing over 250 members, mainly US and EU based. Two thirds of the members companies are SME's, about 8% is big pharma. Besides these, ARM has also 3% members who are Tissue and Blood Establishments, including the Scottish National Blood Service. ARM also has members from research organisations, patient and investor group.

ARM is organised around Committees (e.g., on EU regulation, or on EU market access) and Sections which are technology focused. ARM has Memos of Understanding with scientific societies like with ISCT.

SANTE introduced the Commission activities in Substances of Human Origin and presented the ongoing evaluation process of the EU legislation on safety and quality of blood, tissues and cells. SANTE explained the scope is limited to these products, and therefore excludes advanced therapy medicinal products (ATMP). However, coherence elements between the blood, tissues and cells legislations on the one hand and the ATMP regulation on the other hand do fall within the scope of the evaluation. SANTE explained the mandate of the evaluation, clarifying that decisions on any possible changes in legislation can only be made after the evaluation.

ARM asked whether SANTE is reflecting on aspects of international convergence, like testing criteria (where FDA requires US-specific test kits) and (15-30y) time-windows to store key documents. SANTE explained they have regular contacts with US FDA/CBER, but these specific topics are currently not addressed at EU level and as such, are not addressed in these meetings. SANTE did however refer to a 2015 comparative effort undertaken in the UK by HTA and presented to the National Competent Authorities.

ARM brought forward the topic of BREXIT and its possible impact. SANTE explained that at this moment, until further notice, UK is considered to be a Member State like any other. In case changes are expected, this will be communicated on the SANTE website. SANTE also explained that HTA, HFEA and MHRA (respective UK authorities) are all well informed and engaged in the ongoing evaluation exercise.

In the context of the evaluation exercise, ARM presented its preliminary views on the EU blood, tissues and cells legislations:

- Overall ARM is very pleased with some recent initiatives from SANTE that allow for more convergence across the EU and for more transparency. ARM referred to the public compendium of tissue establishments as example. ARM would welcome more such streamlining efforts, within the EU and globally.
- ARM finds it important that there is legal stability for all actors in the sector, and would for example be concerned on changes like broadening the scope of the hospital exemption . SANTE explained that the hospital exemption falls outside the remit of the blood, tissues and cells legislations.
- ARM would welcome more common views amongst Member States on how substances are to be classified. A particular problem brought forward relates to the classification and regulation of leukopheresis which is regulated in some countries under the blood legislation and in others under the tissues and cells legislation. ARM welcomed the pragmatic approach taken in the UK where the MHRA and HTA said that the procurement of leucopheresis material could be under the remit of the MHRA (CA for Blood) or the HTA (CA for Tissues). Such pragmatic, risk-based solutions are always welcomed by ARM.
- ARM would welcome more streamlining in the authorisation and inspection activities between tissue and pharma authorities, for example so that there is only one common inspection. The common HTA-MHRA approach in UK was brought forward as a good example.
- Some ARM members expressed difficulties with accessing starting materials where public tissue banks are not incentivized to increased processing/testing of collected T&C. Also the differences in views on non-commercial/commercial nature seems sometimes to be experienced as a barrier.
- ARM thought it could be useful to increase awareness with citizens that they can become, besides organ donors, also donors of T&C, as it is anticipated that more allogeneic ATMPs will be developed in the future.

SANTE services clarified that the EU mandate is limited to safety and quality. While SANTE would welcome ARM to put forward these points in the consultation, it needs to be recalled that many of the underlying issues are rather of national mandate (classifications, organisation of authorities, allowed public/private activities, allocation, consent).

ARM explained to be preparing a submission to the consultation. Where topics do not fit straight into the questionnaire, they might also be submitted through an attached document. Some ARM members might submit additional inputs.

SANTE invited ARM to bring an impulse statement during the 20/9 stakeholder event in the context of the evaluation of the blood, tissues and cells legislations.