



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

## Meeting with the U.S. FDA Center for Biologics Evaluation and Research Thursday, March 8, 2018, Silver Spring, MD, U.S.A.

### Summary Minutes

#### Participants

A list of participants is provided in an annex. The meeting was co-chaired by Celia Witten, Deputy Director, CBER/FDA and Anna-Eva Ampelas, Head of Unit, Medical Products: quality, safety, innovation, SANTE-B4/EC.

#### Introduction

This meeting took place in the context of the ongoing Evaluation of the EU legislation on blood, tissues and cells (BTC)<sup>1</sup>. This legislation was first adopted in 2002 (blood) and 2004 (tissues and cells), with the aim of ensuring high standards of safety and quality when blood, tissues and cells are used for human application. The Evaluation aims to assess whether the Directives achieved this objective and whether they remain fit for purpose.

This meeting had been requested by the EC to present the preliminary findings of the Evaluation and to exchange views with the FDA on the issues raised through a stakeholder consultation organised as a key part of the process. The meeting was considered particularly valuable as the Evaluation exercise recognizes the exchange of blood (components), tissues and cells between US and EU as an area for which legislative coherence needs to be assessed. The meeting furthermore provided an opportunity to discuss common challenges as regulators of these sectors and to exchange experiences on how to address these challenges.

Following the introduction of the participants, discussion was structured according to the five criteria that the European Commission assesses for Evaluation exercises, in line with the EC Better Regulation Guidelines<sup>2</sup>:

1. **Effectiveness:** *"Has the legislation increased/ensured safety and quality? Are there unforeseen negative effects?"*
2. **Relevance:** *"Is the current framework up to date and aligned with sector developments?"*

<sup>1</sup> [https://ec.europa.eu/health/blood\\_tissues\\_organ/policy/evaluation\\_en](https://ec.europa.eu/health/blood_tissues_organ/policy/evaluation_en)

<sup>2</sup> [https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox\\_en](https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en)

3. **Efficiency:** *"Is there an acceptable cost-benefit ratio for professionals in the field and overseeing authorities?"*
4. **Coherence:** *"Is there consistency and effective interfaces with other EU regulatory frameworks, and with global regulatory frameworks?"*
5. **EU added-value:** *"Is the EU the correct level at which to regulate this field or could it be done as well or better at national or global levels?"*

SANTE presented preliminary findings for each of these criteria, which were discussed by the participants. CBER gave presentations on (a) FDA's Regenerative Medicine Policy Framework and 21<sup>st</sup> Century Cures (Dr Anatol, Office of Tissues and Advanced Therapies), on (b) Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (Dr Verdun, Office of Blood Research and Review) and (c) Pharmacovigilance - Blood, Tissues and Cells (Manette Niu, Office of Biostatistics and Epidemiology). While these minutes are structured according to the five Evaluation assessment criteria, key messages from these three presentations are integrated into the text.

### **Discussion on the Evaluation of the EU legal framework on blood, tissues and cells**

Dr Fehily (DG SANTE) presented the process and key messages brought forward during the open public consultation on the EU blood, tissue and cell legislation. Key messages also reflected views noted in the summary of the September 20<sup>th</sup> Stakeholder Event and in other summaries of meetings SANTE services had with stakeholders, and which can be found on the SANTE website<sup>3</sup>. [Since this meeting was held, a Summary of the Open Public Consultation has been published by the DG SANTE<sup>4</sup>]

#### 1) Relevance

Key messages from the EU consultation included that the legislation is not adaptable enough to address, in a timely manner, the many changes (technological, scientific, epidemiological, societal etc.), including new risks, experienced in the sectors. In addition, some provisions were highlighted as missing or inadequate. The discussion focused in particular on the following issues emerging in the EU evaluation:

- *Use of guidance Vs regulations:* DG SANTE noted that many stakeholders point to specific technical requirements in the legislation that are considered too difficult to update in line with changing technologies and risks. Apart from a small number of very particular exceptions, EU BTC legislation is not reinforced or enhanced by the issuing of official EU guidance or by regulatory cross-references to standards or guidance developed by others.

In contrast, FDA/CBER regularly publishes guidance for industry to clarify current thinking on recommended measures for achieving compliance with binding legislation and regulations; the guidance itself is not legally binding. One advantage of issuing guidance is that its development takes less time, on average 6-12 months compared to at least 12 months for a change to regulations. This period includes a public comment period of 3 to 6 months. When needed, FDA/CBER can also rapidly issue guidance for immediate implementation, with the submission of public comments permitted any time after issuance of the guidance. In 2016, for example, the risks posed by Zika virus (ZIKV) were addressed mostly through guidance for immediate

<sup>3</sup> [https://ec.europa.eu/health/blood\\_tissues\\_organ/events\\_en](https://ec.europa.eu/health/blood_tissues_organ/events_en)

<sup>4</sup> [https://ec.europa.eu/health/blood\\_tissues\\_organ/consultations/implementation\\_legislation\\_en](https://ec.europa.eu/health/blood_tissues_organ/consultations/implementation_legislation_en)

implementation. One of the objectives of the new blood donor eligibility rule, presented by Dr. Verdun and effective as of May 2016, is to provide more flexibility with regards to mitigating the risks posed by emerging and re-emerging infectious diseases. FDA/CBER also referred to instances where guidance developed by professional associations is officially 'recognised by FDA' as an acceptable means to comply with the regulations. Finally, FDA/CBER mentioned one case where guidance was converted into a legally binding regulation, for reasons of standardization and to avoid challenges to the FDA authority.

- *Clarity of Scope:* DG SANTE noted that many stakeholders consider the regulatory borderlines between tissues and cells and medicinal products or medical devices not to be adequately clear, particularly as new processes and products are developed.

FDA/CBER often uses guidance to clarify for industry what is the scope of the different legal requirements. Recent examples of guidance documents that were described during the meeting clarified:

- Scope of exception for the 'Same Surgical Procedure'
- Homologous use of Human cells, tissues, and cellular and tissue-based products (HCT/Ps)
- Minimal Manipulation of HCT/Ps
- Regulatory considerations HCT/Ps from adipose tissue.

While such guidance documents are usually developed by the CBER's Office of Tissues and Advanced Therapies (OTAT), other CBER offices are involved, as well as other Centers within FDA.

- *The involvement of experts (such as from EDQM, ECDC or professional societies):* EU stakeholders expressed the view that the expertise of professionals is often not adequately utilised in the development of legislation or guidance.

FDA/CBER noted that it engages with professionals by making draft guidance subject to consultation. In some cases, FDA/CBER directly recognises industry standards, developed by professional societies, as an appropriate way to comply with certain regulatory requirements. Examples provided were the circular for users of blood (components) and the donor history questionnaires developed by the American Association of Blood Banks (AABB) and the American Association of Tissue Banks, together with other professional groups. FDA/CBER is currently drafting guidance on the procedure to recognize such technical standards. FDA/CBER experts that have participated in EDQM expert and drafting groups expressed the view that, in Europe, the use and recognition of some EDQM technical standards and guidance would facilitate the maintenance of up-to-date rules in a more flexible way.

- *Provisions for emergency preparedness for emerging infectious agents:* EU stakeholders had noted that the current legislation does not include adequate provisions for reacting to emergencies that might impact the safety of BTC or the sufficiency of supply, in particular the emergence of infectious diseases.

Dr Verdun presented CBER's Donor Eligibility Rule, effective as of May 2016. The purpose of the rule is to ensure a safe blood supply and donor protection, align donor eligibility and testing with current practices, provide flexibility with regard to addressing infectious diseases and accommodate technological advances. She explained that a list of specific agents are identified as Relevant Transfusion Transmitted Infections (RTTI) in the regulation, and a set of testing and screening requirements have been defined through guidance for each RTTI. The RTTI list can be

easily adapted, as well as the applicable testing and screening approaches. Infections not defined in the regulation can be covered under the RTTI framework if appropriate screening or testing measures are available, the agent may be transmissible by blood and has sufficient incidence/prevalence to affect the donor population. For these newly defined RTTI, FDA would issue guidance addressing screening, testing and educational measures. FDA did this for example in 2016, requiring nationwide ID-NAT testing or pathogen reduction for ZIKV. It was noted that the testing requirements allow for flexibility, e.g., to address regional differences or to discontinue testing. Such flexibility is usually based on epidemiological factors (e.g. geography, seasonality) and technological possibilities (e.g. pathogen reduction technology).

- *Use of pathogen inactivation and automation:* EU stakeholders consider that the current legislation does not adequately reflect the potential benefits and risks brought by these technologies.

FDA explained that, while the use of pathogen reduction technology in the US is approved for platelets and plasma products, it is not mandated. The 2016 Rule allows for using FDA approved devices to control bacterial contamination of platelets including the use of bacterial testing or pathogen reduction devices, or other methods found acceptable by FDA.

## 2) Effectiveness

The large majority of stakeholders indicated that the legislation has helped increase safety and quality of BTC. However, several provisions were considered to be lacking. The discussion focused in particular on the following topics:

- *Requirements for Donor safety:* EU stakeholders consider that the legislation is not adequate to protect living donors. This view was expressed in relation to donor selection, donor registration and follow-up and the reporting requirements for adverse reactions in living donors. All key stakeholder groups across the BTC sectors consider this an important gap in the legislation. The discussion at this meeting focused mainly on blood, for which required reporting of donor-related adverse incidents in the US is currently limited to fatalities, although FDA has issued a proposed rule that would require reporting of serious adverse event in blood donors. In contrast, in the EU, donor reaction reporting is limited to situations where the quality or safety of the donated substance has been affected. FDA/CBER considered that such reactions for HCT/P donors are rather seen as a responsibility for the clinical professionals and might therefore be better addressed by professional societies. For HCT/P falling under 361 (see below regulatory classification under coherence), requirements focus on donor TTI and processing, not on the donors themselves. For HCT/P falling under 351, requirements can be somewhat broader, including reporting of recipient clinical outcome data and of data on (some) donor issues.
- *Voluntary Unpaid Donation:* Many EU stakeholders had commented on this topic, some considering that the requirements for VUD are not stringent enough while others consider that VUD is sometimes used to limit trade in substances or disadvantage those organisations that pay donors. There is consensus that the definitions of VUD, incentive, compensation etc. are not sufficiently precise and are interpreted differently in different EU Member States.

FDA/CBER recognizes this as an important debate, however believes there is no easy solution to reconcile different views. The participants considered that, from a safety and quality point of view, there could however be a focus on defining maximum donation frequency and enhancing donor protection in other ways. For oocyte donors, some concerns were expressed in relation to high sums that can be paid for donations in the US (up to 10,000 USD) and related to the fact that pick-ups from oocyte donors typically generate more eggs than in partner donation. These topics, however, do not fall under the FDA/CBER regulatory mandate.

- *Unclear vigilance definitions and requirements:* EU stakeholders appreciate the achievements of the legislation in establishing vigilance reporting systems for BTC at national and EU level but point to many specific definitions and requirements that are not considered clear enough or adequate. In particular, requirements for reporting of all serious donor reactions, for reporting of denominators and for reporting of genetic transmissions in children born from donated gametes are considered lacking.

Current U.S. regulations require reporting for blood donor or recipient fatalities. For human cells, tissues, and cellular and tissue-based products (HCT/Ps) (including gametes) the requirements are to report to FDA any serious adverse reactions involving a communicable disease if it is fatal, life-threatening, results in permanent impairment of a body function or permanent damage to body structure or necessitates medical or surgical intervention, including hospitalization. Other types of adverse reactions are not reportable. In addition, FDA/CBER collects partial data through four different voluntary systems, including one system relying on a database managed by insurers for claims handling. FDA/CBER can provide further information on these vigilance systems.

- *Authorisation of novel/experimental treatments including the use of clinical follow-up data:* Many EU stakeholders had commented that the legislation does not adequately address a need for collecting and reporting clinical outcome data in BTC recipients as part of the authorisation of processes applied to BTC. This was a particular concern for more novel processes.

- *Oversight of same surgical or same treatment autologous use of BTC and point of care devices:* Some key EU stakeholders argue that the legislative exemption of autologous tissues and cells used in the same surgical procedure is no longer appropriate in the context of the many bedside and operating theatre processes that are now carried out during surgery or treatment, sometimes in the context of stem cell tourism.

FDA/CBER has issued a guidance document on the interpretation of when the US exception for 'same surgical procedure' can apply. This guidance document clarifies that this exception can entail steps such as rinsing, cleansing, sizing, shaping, but also some (limited) storage before further use.

- *Emergency preparedness for supply in crisis situations in general:* EU stakeholders, particularly in the blood sector, consider that the legislative provisions to support continuity of supply in the case of natural disasters or other emergencies are inadequate.

For blood, in the US, the 2012 FDASIA-act allows for emergency preparedness plans to be operated through the American Association of Blood Banks (AABB) Inter-organizational Task Force of Domestic Disasters and Acts of Terrorism. From these new authorities, FDA established

regulations that require any operator supplying more than 10% of national needs to notify FDA of a drop of 20% or more in inventory. The act aims to guarantee a supply for 7 days, but in reality, inventories are usually adequate for approximately 3 days. For plasma derivatives, import requirements can be lightened in case of derivative shortages.

- *On direct distribution of sperm:* Many EU stakeholders call for a clear prohibition of distribution of sperm directly to patients.  
FDA/CBER policy is not to prevent imports of gametes/embryos into the U.S., and not to interfere in private family planning decisions. FDA/CBER has no position or view on any flows of gametes between U.S. and Europe. FDA/CBER also clarified that, in any case, a majority of the requirements in the US Current Good Tissue Practice regulations, such as vigilance (recipient adverse reaction) reporting, does not apply to gametes. The Donor Eligibility regulations do apply.
- *The absence of EU quality requirements:* The EU described comments from stakeholders that point to an emphasis on safety in the legislation, with a perceived gap in relation to legally defined quality (release) criteria for BTC.  
FDA/CBER explained that the US does not have specifications for specific quality characteristics as release criteria for HCT/Ps, except for a few products such as cord blood.

### 3) Efficiency

The main message of the stakeholder consultation was that the legislation did indeed lead to higher costs, but also brought benefits that justified these costs. Nevertheless, some specific cost issues were raised. Following points were further explored during the meeting:

- *The use of CE-marked vs in-house devices:* Some stakeholders consider that costs associated with the use of CE-marked devices, including blood grouping reagents or culture media in ART, are not always justified by higher quality.  
FDA/CBER mentioned that in the U.S. there are several advocates for more permissive use of in-house tests, with less oversight. The use of blood-grouping diagnostics was given as an example, where FDA limits its requirement to an in-house validation.
- *Inspection planning/intervals:* EU legislation prescribes a 2-year inspection cycle for all blood and tissue establishments; many stakeholders consider that a risk-based approach to inspection scheduling would be more cost-effective.  
The planning of inspections of U.S. blood establishments shifted in 2012 (with the FDASIA act) from a 2-year interval to risk-based intervals. HCT/P inspections have been risk based since the legislation was adopted. The inspections system also foresees inspections being organised in tiered levels/types of inspection depending on the risks identified. Inspectors are state-based FDA employees, usually specialised in biologics only. There are both investigators and supervisors in the inspection teams.

### 4) Coherence

The EU legislation is largely considered coherent within its own provisions, however inconsistencies between blood and tissues and cells were highlighted, as well as incoherencies with other sets of EU legislation. Views were exchanged on following points:

- *The absence of a common EU classification mechanism:* Many EU stakeholders, mainly from tissue and blood establishments and related authorities, consider the absence of an EU-level BTC classification mechanism in the BTC legislation to be a gap. They express the view that decisions on the classification of BTC Vs medicinal product Vs medical devices should be taken jointly by regulators from across the sectors.

Within FDA, a Tissue Reference Group (TRG) was created that includes representatives from CBER, CDRH, and OCC. This TRG has 10 members that provide recommendations as to whether HCT/Ps are regulated solely under section 361 of the Public Health Service (PHS) Act or under both sections 351 and 361.

- *Different national classifications in the EU:* EU stakeholders point to the same product being classified differently in different EU Member States.

FDA is the sole regulatory entity with the authority for HCT/Ps in the U.S. FDA does not classify HCT/Ps. Stakeholders make the determination and FDA provides recommendations or binding decisions if asked. The classification of some products was clarified in the course of the meeting:

- Faecal microbiota are considered biological products, subject to sections 351 of the PHS Act. FMT is not an HCT/P so section 361 of the PHS Act does not apply. However, FDA/CBER focuses oversight on faecal microbiota produced on industrial scale, not on production by SMEs.
- Serum eye drops are regulated as biological products subject to section 351 of the PHS Act. Serum eye drops are not HCT/Ps.
- Demineralised Bone Matrix may be regulated solely under section 361 when it meets the four criteria defined in 21 CFR 1271.10(a) (see below). If it is further manipulated, contains live cells, is combined with another article or is intended for a non-homologous use it would not be eligible for regulation solely under section 361 and may be regulated as a biologic or device depending upon what it is combined with and its intended use .

The US regulates HCT/Ps under section 361 PHS Act, or as drugs, devices, or biological products.

- **Human cells, tissues and cellular and tissue-based products (HCT/Ps)** that are regulated solely under 21 CFR part 1271 and section 361 of the PHS Act must Some examples may include the following when all of the criteria in 21 CFR 1271.10(a) are met:
  - bone (including demineralized bone)
  - ligaments
  - tendons
  - fascia
  - cartilage
  - ocular tissues (corneas & sclera)
  - skin
  - vascular grafts (veins & arteries), except preserved umbilical cord veins
  - pericardium
  - dura mater
  - heart valve allografts
  - autologous hematopoietic stem cells derived from

- peripheral or umbilical cord blood
  - oocytes
  - embryos
- semen
- **Human somatic cell therapy and gene therapy products** are regulated as drugs and/or biological products under section 351 of the PHS act and/or the Food Drugs and Cosmetics Act. This includes:
  - cultured cartilage cells
  - cultured nerve cells
  - lymphocyte immune therapy
  - gene therapy products
  - human cloning
  - human cells used in therapy involving the transfer of genetic material (cell nuclei, oocyte nuclei, mitochondrial genetic material in ooplasm, genetic material contained in a genetic vector)
  - unrelated allogeneic hematopoietic stem cells
  - unrelated donor lymphocytes for infusion
- **Devices composed of human tissues** regulated under the FD&C Act and device regulations including:
  - corneal lenticules
  - preserved umbilical cord vein grafts
  - human collagen
  - femoral veins intended as a-v shunts

For **combination products**, the regulatory framework depends on the products as in the following examples:

- **Demineralized bone combined with handling agents** (glycerol, sodium hyaluronate, calcium sulfate, gelatin, collagen) - are regulated as devices
- **Bone-suture-tendon** allografts - regulated as devices
- **Cultured cells** (fibroblasts/keratinocytes/nerve/ligament/bone marrow) **on synthetic membranes or combined with collagen** may be regulated as devices or biological products (these products are currently under review and may be regulated by CBER under either the device authorities or under section 351 of the PHS act)
- **Encapsulated pancreatic islet cells** are regulated as biological products

For '361 HCT/Ps', a premarket review and approval is not needed, while HCT/Ps that are regulated as drugs or biological products, are subject to requirements both in sections 361 and 351 and/or the Federal Food, Drug and Cosmetic Act, and pre-market review and approval is required.

FDA/CBER presented a decision algorithm, clarifying that for HCT/Ps to fall under 361 alone, they need to (1) be minimally manipulated, (2) be intended for homologous use only (based on the manufacturers objective intent), (3) not be combined with another article and (4) not have a systemic/ metabolic effect or be dependent on the activity of a living cell, unless for autologous or reproductive use. See 21 CFR 1271.10(a).



In terms of coherence between the US and EU legislative frameworks, it was noted that a number of these are regulated differently between the US and the EU. Particularly, unrelated haematopoietic stem cells and donor lymphocyte infusions, all of the US devices, apart from human collagen, and all of the US combination products are regulated differently in the EU.

- *The link to communicable diseases and ECDC*: EU Stakeholders point to a lack of direct reference to guidance from the European Centre for Disease Prevention and Control (ECDC) in the BTC legislation.

For guidance and recommendations related to Relevant Transfusion Transmitted Infections (RTTI), FDA/CBER gets significant inputs from the Centers for Disease Control and Prevention (CDC). CDC has a dedicated team of 7 staff members working on blood, tissues, and organs.

#### 5) EU added value

The legislation has helped increase safety and quality, harmonisation and confidence in the sector. However, differences in national interpretations, together with the application of more stringent requirements by some EU Member States, are considered as factors hampering realisation of this EU added value.

#### **Other points discussed**

- *FDA/CBER presented an introduction to the Regenerative Medicine Policy Framework and 21st Century Cures Act* (presented by Dr Rachael Anatol of OTAT). One of its key aims is to simplify for sponsors determinations on whether premarket authorizations are needed. This Framework also foresees an RMAT designation when a drug is a regenerative medicine therapy, intended to treat a serious life-threatening disease or condition, and preliminary clinical evidence indicates the potential to address an unmet clinical need. It can therefore be considered equivalent to the EU PRIME scheme. FDA's draft guidance on Expedited Programs for Regenerative Medicine Therapies clarifies the expedited development programs that are available to sponsors of regenerative medicine therapies.
- FDA also described an innovative clinical trial design whereby multiple clinical sites participate in a multi-center trial with the intent of sharing the combined clinical trial data to support BLAs from each of the individual centers/institutions.
- In the US, in order to allow manufacturers of HCT/Ps that require premarket review and approval time to comply with the requirements, for *36 months after November 2017*, FDA intends to exercise *enforcement discretion* for certain products that are subject to the FDA's premarket review under the existing regulations, but are not currently meeting these requirements. The FDA does not intend to exercise such enforcement discretion for those products that pose a potential significant safety concern. FDA explained that in such cases its strategy is to target the 'mother' team/unit that develops and promotes the novel therapy, and less for peripheral/satellite teams/units that follow this mother team/unit.

- *On BREXIT:* DG SANTE explained that there is a concern that many US tissue and plasma supplies to the EU are imported through UK-based establishments. It is likely that these flows will have to be reorganised once the UK has withdrawn from the EU. FDA/CBER has no comprehensive data on cross-Atlantic flows of HCT/P, blood or plasma. However, it was noted that surveys are conducted by the American Association of Tissue Banks, the National Tissue Recovery through Utilisation Survey (NTRUS) every few years and the results, including data on export by country of destination, are published. For HCT/P, it was expected that the main flows concern bone and demineralised bone matrix.
- *Blood donor deferral criteria for vCJD:* FDA/CBER explained that there is a proposal to narrow the geographic scope for donor deferral based on vCJD from all donors coming from all EU Member States to donors coming from the UK, Ireland and France. FDA/CBER confirmed, however, that this change would not be reflected by a change to policy that bans import of plasma collected in the EU and plasma derived medicinal products manufactured from EU plasma.

### **Meeting conclusion**

Participants expressed their appreciation for the informative and constructive discussions and agreed to maintain open channels of communication on the many common issues that had been presented and discussed.

*The meeting was followed by a CBER laboratory tour. Four teams and laboratories were presented: (1) vaccine/therapy targets for gastrointestinal pathogens, (2) cell therapy product characterisation, (3) methods to improve safety and availability of tissues and (4) safety and efficacy of platelets. The tours and discussions were very much appreciated by the DG SANTE delegation.*

## **Annex : Participant list**

### **European Commission (EC), DG SANTE**

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