



**EUROPEAN COMMISSION**  
 DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 2017

SANTE B4

# Summary of the Blood, Tissues and Cells Stakeholder Event

## 20th September 2017

### Contents

<b>1</b>	<b>Background .....</b>	<b>3</b>
1.1	The Evaluation of the Blood, Tissues and Cells Legislation .....	3
1.2	The Stakeholder Event .....	3
1.3	The Stakeholder Event in numbers .....	4
<b>2</b>	<b>Opening of the event .....</b>	<b>4</b>
<b>3</b>	<b>Summary of the debate .....</b>	<b>5</b>
3.1	Session one: The key importance of donors – the gift of life .....	5
3.2	Session two: Regulatory oversight of the sectors – how to ensure safety and quality? .....	6
3.3	Session three: Availability and sufficiency – are patients getting the blood, tissues and cells that they need? .....	7
3.4	Session four: Legal consistency and coherence – regulatory pathways for Substances of Human Origin.....	8
3.5	Session five: A changing world – technological, societal, epidemiological and international developments.....	9
<b>4</b>	<b>Conclusions .....</b>	<b>11</b>
4.1	Closing remarks.....	11
4.2	Feedback from participants .....	11
4.3	Next steps.....	11
<b>Annex 1</b>	<b>: Event agenda .....</b>	<b>13</b>



*This report provides a summary of a Stakeholder Event organised by DG Health and Food Safety in the context of an ongoing Evaluation of the EU Legislation on Blood, Tissues and Cells. It provides background information about the event and summarises the key issues raised by stakeholders.*

*The report was drafted for the European Commission by ICF Consulting Services Ltd.*

# 1 Background

## 1.1 The Evaluation of the Blood, Tissues and Cells Legislation

This Evaluation aims to assess whether Directives 2002/98/EC (on blood and blood components) and 2004/23/EC (on tissues and cells) have effectively met their objective, i.e. ensuring safety and quality, and whether these Directives are still fit for purpose in the current environment<sup>1</sup>. It is examining the functioning of the legislation across the EU, assessing its relevance, effectiveness, efficiency, coherence and EU added value. The contribution of the Implementing Directives is included in this assessment.

The evaluation is expected to provide a sound evidence base which will be used to consider the need for any changes to the legislation. It has been designed to comply with the Commission's Better Regulation guidelines<sup>2</sup>. Its steps are stipulated in a published roadmap<sup>3</sup>, which foresees a public consultation and this stakeholder event.

## 1.2 The Stakeholder Event

This one day Stakeholder Event took place in Brussels on 20th September 2017 and was organised by the European Commission services (DG SANTE).

The main purpose of the event was to provide an opportunity to validate the main messages that emerging from open and targeted consultation activities, and to explore remaining evidence gaps.

The event brought together members of the public, national authorities, patient and donor groups, professionals working with blood, tissues, and cells, industry representatives and other relevant stakeholders, who had the opportunity to express their views on key topics regarding the EU Blood, Tissues and Cells legislation. The meeting was open to all interested stakeholders who had to register online before participating.

The meeting was structured around five main themes relating to the current legislation, which were discussed in five dedicated sessions:

- They key importance of donors: The gift of life
- Regulatory oversight of the sectors - How to ensure safety and quality?
- Availability and sufficiency - Are patients getting the blood, tissues and cells that they need?
- Legal consistency and coherence - Regulatory pathways for Substances of Human Origin
- A changing world – Technological, societal, epidemiological and international developments.

Each session opened with a number of short impact statements made by a panel of stakeholders with diverse experiences, views and perspectives, followed by an open discussion with participants.

---

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

<sup>2</sup> [https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox\\_en](https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en)

<sup>3</sup> [http://ec.europa.eu/smart-regulation/roadmaps/docs/plan\\_2016\\_154\\_evaluation\\_eu\\_legislation\\_on\\_blood\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_154_evaluation_eu_legislation_on_blood_en.pdf)

### 1.3 The Stakeholder Event in numbers

The event was attended by 205 participants. The majority of participants were from EU Member States (21 Member States were represented) and 10 were from non-EU countries (USA, Norway, Switzerland and the Russian Federation). The audience represented a variety of sectors and stakeholders, as shown in Figure 1.

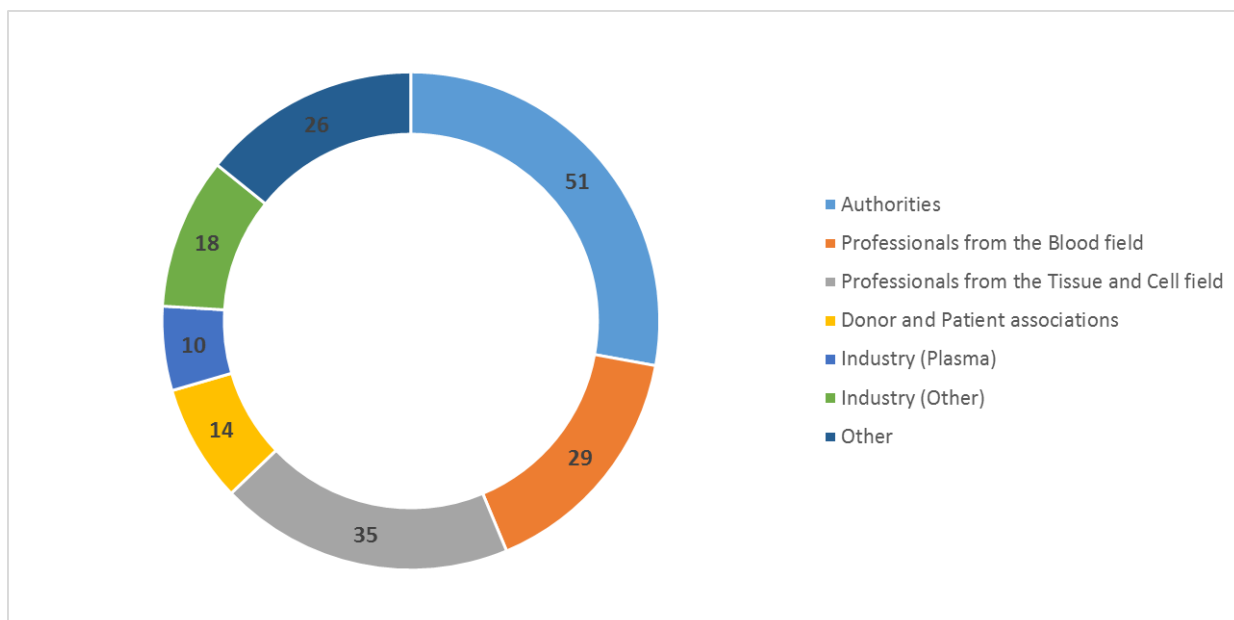


Figure 1: Participants by stakeholder group

## 2 Opening of the event

The stakeholder event was opened by Martin Seychell, deputy Director General for DG Health and Food Safety (SANTE), and Anna-Eva Ampélas, Head of Unit (SANTE/B4: Medical Products - Quality, Safety and Innovation). During the opening session, a short background on the sectors and context of the evaluation was presented, to frame discussions for the day.

The EU blood legislation and the EU tissue and cells legislation were established by the European Commission in 2002 and 2004, respectively (Directives 2002/98/EC and 2004/23/EC). Their aim was to harmonise heterogeneous Member State (MS) practices through common and binding standards for quality and safety, ensuring the availability and exchange of safe blood, tissues and cells and enhancing donor and recipient confidence in the processes of donation, transfusion, transplantation and assisted reproduction.

Since then, these Directives have both been complemented by several implementing Commission Directives specifying more technical requirements.

The Directives place obligations on several sub-groups of professionals working with blood, tissues and cells, in particular in the following areas:

- Blood and blood components for transfusion;
- Plasma for manufacturing of plasma derived pharmaceuticals;
- Gametes and reproductive tissues for assisted reproduction;
- Haematopoietic stem cells from bone marrow, peripheral blood or cord blood for transplantation;

- Replacement tissues such as skin, bone, cornea or heart valves for transplantation.

The legislation has a significant impact on donors, patients and professionals across the EU. 14 million citizens donate 20 million whole blood units per year allowing for 26 million transfusions of blood components that have been collected and processed in around 1350 authorized blood establishments. In addition, around 8 million litres of plasma collected in the EU is manufactured by public and private fractionators to provide plasma derived medicinal products.

There are 1,357 authorized tissue establishments in the EU that distribute more than 300,000 replacement tissues for transplantation each year. An additional 1,047 authorized tissue establishments supply 30,000 haematopoietic stem cell donations for transplantation each year and 1,723 IVF clinics, authorized as tissue establishments in the EU, carry out IVF using 500,000 units of collected gametes.

The EU legislation lays down safety and quality requirements for all professional players handling these substances during the entire flow from donor to recipient. In addition it specifies requirements for oversight by national competent authorities in each of the EU-28 MS, including provisions for inspection, authorisation, traceability and the notification of serious adverse reactions and events (vigilance). Finally, the legislation places obligations on the European Commission to coordinate and facilitate aspects of oversight between the EU-28 MS.

### 3 Summary of the debate

The event was structured around five sessions covering major topics that had come forward to date in the evaluation. Each session started with short (five minute) impact statements with high-level views presented by a panel of four different stakeholders, each with a different background. This was followed by an open, moderated discussion where event participants could ask for the floor and express views. The event agenda is shown at Annex 1.

#### 3.1 Session one: The key importance of donors – the gift of life

The first session focused on donors and their protection, addressing topics such as voluntary unpaid donation, compensation, donor safety and follow up, donor recruitment and donor registries.

The Panel stressed the importance of donors and the dependence of patients who are in need of transplantation, transfusion or donor-assisted conception on the willingness of citizens to donate. Voluntary unpaid donation (VUD) was brought forward as a main point of discussion as well as the need to ensure common standards for blood, tissue and cell collection, established on the basis of evidence based risk assessments, in order to ensure the safety of recipients.

Several panellists expressed concern that EU legislation lacks adequate provisions to ensure donor safety and that reporting of serious adverse reactions in donors is currently not required unless there is a quality or safety implication for the donated substance. Systematic analysis of donor vigilance reports was highlighted as a means to support preventive measures to reduce donor risks. Donor protection was stressed as a key element to ensure overall willingness to donate. The view was expressed that for certain kinds of potential living donors, e.g. family donors of bone marrow or peripheral blood stem cells, access to independent counselling should be mandated, with provision of information regarding risk, to help potential donors reach an informed decision. In the field of assisted reproduction, donor protection

issues were highlighted such as a need to limit the number of oocyte donations, to define strict rules on economic compensation and to improve cross-border. It was also noted that professionals and their associations can play an important role in developing guidance on the basis of international consensus, limiting the need for detailed administrative rules. Some proposed that donor safety could best be monitored by putting in place formal requirements for donor follow-up in defined circumstances.

The floor was then opened for discussion, with the following key issues raised:

- Many participants considered the concept of VUD not to be sufficiently clear in the legislation. The specificities within each sector were highlighted by speakers noting that blood donation, plasma donation, sperm donation, egg donation and tissue donation are different and involve different levels of effort and risk for the donor. While some called for VUD to be made mandatory, others argued that compensation should be aligned to the different efforts and risks, and that the impact of compensation on donors is not always well understood. Participants also argued that the discussion would benefit from a clear and broadly accepted definition of terms currently used when addressing the principle of voluntary unpaid donation e.g. reimbursement, compensation, inconvenience costs. It was noted that similar levels of compensation have different economic values for donors in EU MS with different levels of average income (GDP/capita).
- In relation to Donor Vigilance, there were calls to ensure that reporting of donor serious adverse reactions and events (SARE) be made mandatory even when the quality or safety of the donated substance is not affected. The need to align the type and frequency of donation to the risks to donors was stressed.
- The need for traceability and donor registries was also discussed at some length, particularly in relation to the haematopoietic stem cell (HSC) and assisted reproduction technology (ART) sectors, where many donors are subject to medicinal treatment (hormonal stimulation) prior to donation.
- Some participants, particularly those representing patients dependent on plasma derivatives, indicated the need to also consider insufficient supply as an important risk to the safety of recipients. They stressed that safety and quality requirements should be balanced so that they do not unnecessarily reduce availability.

### **3.2 Session two: Regulatory oversight of the sectors – how to ensure safety and quality?**

The second session focused on the impact and cost of organising regulatory oversight, addressing topics such as inspection, authorisation, vigilance and traceability.

The Panel introduced a number of general observations on areas where they consider there to be inadequate (or non-existing) regulatory oversight foreseen in the current directives. These include donor and recipient follow up, same surgical procedures (i.e. the use of autologous blood/tissues/cells within a single surgical procedure, excluded from the current legislation) and processes for authorising new processing methodologies/therapies. On the latter point, it was noted that the current directives, beyond the reporting of serious adverse reactions, do not address safety or efficacy after clinical application even when the preparation process or the therapy is novel. It was suggested that oversight requires a digitised approach with the sharing of clinical data demonstrating quality, safety and efficacy/functionality. Additionally, it was highlighted that many substances being applied to patients today

were not in clinical use when the directives were adopted and, consequently, are not being regulated in a consistent framework across the EU.

Panellists brought forward the need to reflect on the evidence base for existing technical requirements which they consider, in some cases, to be inadequate or missing and also called for harmonisation or mutual recognition of national requirements, practices and authorisations to promote inter-MS exchanges.

Emergency preparedness to ensure supply in crisis situations was identified as an area where co-ordination of regulatory oversight in the European setting should be considered. In particular, a need to co-ordinate regulatory oversight at the interface between medical devices, particularly in-vitro diagnostics, and blood and blood components was highlighted as being of key importance for ensuring continuity of supply.

Panel members furthermore highlighted a number of difficulties in reporting and analysis of serious adverse reactions and events (SARE) at EU level, related to legal definitions and the need to strengthen hospital vigilance. It was also suggested that more structured feedback is needed on root cause analysis and lessons learned to authorities and professionals so that practices can be continuously improved.

Some called for cross-references in the legislation to the guidance developed by expert bodies such as EDQM (Council of Europe) as a means to keep technical requirements up to date and a view that guidelines or provisions to regulate commercialisation are required was also expressed.

Many participants expressed views in line with the panellists. The main points brought forward during the open discussion were:

- A view that there is insufficient flexibility in the Directives to ensure they remain up-to-date with scientific and technological changes. The absence of a robust and risk-based approach to all aspects of the provisions was mentioned repeatedly.
- Concerns were expressed on divergence evident in national interpretations and implementation of inspection requirements by competent authorities (CAs), this was seen as posing barriers for cross-border exchange of substances.
- The strict requirement of a two-year inspection interval was considered inadequate and speakers favoured a risk-based planning of inspections. Mutual recognition programmes and enhanced collaboration between authorities were suggested as approaches to be explored.
- A need for more co-ordination of regulatory oversight with other sectors was expressed, in particular with authorities overseeing the many medical devices used in tissue and blood establishments, or the in-vitro diagnostic kits in use for the multiple donor tests used in the sector.
- A lack of emergency preparedness plans for EU crisis situations was seen as problematic, posing a risk to ensuring continued supply of blood, tissues and cells.

### **3.3 Session three: Availability and sufficiency – are patients getting the blood, tissues and cells that they need?**

The third session focused on the challenges in ensuring adequate availability and sufficiency of blood, tissues and cells for patients and on related topics such as access, matching supply and demand, cross-border exchanges.



In the context of increasing demand for plasma derived medicinal products (PDMPs), particularly immunoglobulins (reported as increasing by 6.5% per annum in Europe), several members of the Panel stressed the risks of supply interruption associated with the existing high dependency on the USA for plasma to manufacture adequate quantities of these products for EU patients. There was a call for EU legislation to advocate and enforce a degree of 'strategic plasma independence', focusing efforts on increasing EU plasma collection, together with a reduction of wastage of plasma separated from whole blood. It was stressed again that supply shortages are an important factor affecting safety for patients.

Further factors that were brought forward included a reduction in the availability of specific substances due to technical requirements that are considered unjustifiably strict; the re-classification of consolidated tissue and cells therapies as medicinal products impacting negatively on patient access and the extremely high cost of new cell-based therapies that could be provided by tissue establishments more cost-effectively. The coexistence of two "parallel tracks" using the same allogeneic cells or tissues as the starting material to manufacture medicinal products by industry or engineer cell transplant by tissue establishments may create different incentives or pressures for donation, and challenge the principle of VUD. The need for a transparent regulation of the VUD principle and a clear definition of terms currently used when addressing the principle of voluntary unpaid donation e.g. reimbursement, compensation, inconvenience costs, was reiterated. Several panellists pointed to the value of registries to monitor long-term follow-up of blood, tissue and cell therapies. While cross-border exchanges are generally considered positively, it was noted that in some cases these transfers can undermine national efforts to achieve self-sufficiency. Ensuring the supply of substances for research and training was also highlighted as an important issue for patients in the long term.

The main points brought forward during the open discussion related to:

- A view that the definition of 'self-sufficiency' in the legislation is unclear, particularly regarding whether it refers to the national or EU level. It was noted that the optimal level might be different for different types of substances.
- Many advocated for developing 'strategic independence' from the USA for the supply of plasma for manufacturing. This would include the promotion of collection of plasma within the EU as well as the need to support Blood Establishments (BEs) to utilise recovered plasma and avoid/minimize wastage.
- Donor management was also discussed and it was suggested that there is a need to re-examine the donor selection criteria in the legislation as many provisions are considered outdated, or not in line with scientific, technological or socio-demographic trends. Within the donor management context, the need to enhance donor vigilance was reiterated, in particular with a view to promoting regular blood donation.
- In addition, it was noted that it would be beneficial to establish a system for monitoring clinical outcome data and to make the information available in a transparent way to patients, public and potential donors.

### **3.4 Session four: Legal consistency and coherence – regulatory pathways for Substances of Human Origin**

The fourth session aimed at exploring the consistency and coherence of the blood, tissues and cells legislation with other relevant EU legislation and with equivalent legislation internationally.



Panel members considered that some key definitions in the current legislation lack clarity, resulting in ambiguous, and sometimes inadequate, national interpretations and legal uncertainty. It was considered that this has contributed to a lack of harmonisation across the EU in many areas of the directives, for example, testing and classification of blood, tissues and cells. A case study was presented that demonstrated how a lack of legal certainty and harmonisation resulted in an ATMP developer limiting its area of activity to the UK rather than across several MS. For PDMPs, it was suggested that there are excessive national deviations from the Internal Market principles.

Panellists also flagged the need for a clear and common classification and demarcation between different SoHO sub-sectors, including between blood for transfusion and plasma for manufacture of PDMPs, and for more clarity at the borderlines between SoHO legislation and the legislation on medicinal products and medical devices. Joint clarifications regarding the interface where human substances become starting materials for ATMP were considered necessary, including requirements for testing, storage, labelling, inspections and responsible persons. It was stressed that harmonization of rules and interpretations also brings more clarity for stakeholders in non-EU countries.

Noting that around 600,000 tissue grafts were sent from US tissue banks to the EU in 2016, there was a call for greater alignment and clarity across the EU directives and regulations, for greater clarity regarding coding requirements and for the exclusion for cells and tissues from VAT requirements in the EU.

In summary, legal uncertainty related to regulatory interfaces and definitions are considered to pose significant barriers to harmonisation. The lack of harmonisation is in turn seen as an obstacle to access, sustainability and self-sufficiency and to the investment in, and development of, new innovative therapies (particularly cell therapies).

The main points raised in the open discussion were the following:

- The need for EU legal clarification on the borderlines between blood, tissues, cells, medicinal products and medical devices was raised. In particular, concerns regarding an unclear borderline between tissues and cells and ATMPs were expressed, including the lack of a definition of 'industrial processes'. The scope of the new Medical Device Regulation was also raised, where derivatives of non-viable cells are included in a manner that was not considered adequately clear.
- The lack of provisions for mutual recognition and joint inspection programmes across EU MS were highlighted as barriers to harmonisation between national requirements.
- Further inconsistencies between MS were reported relating to the application of VAT on tissues and cells and the application or not (exemptions and exclusions) of the coding requirements for traceability of tissues and cells.
- There were calls to 'future proof' the legislation so as to ensure continuity of supply and patient access – balancing the need for very high technical standards with the capacity of all MS to maintain the supply at these standards.

### **3.5 Session five: A changing world – technological, societal, epidemiological and international developments**

The fifth session explored the main developments that might affect the current legislative climate. Topics such as changing risks, changes in society, bio-

technological innovation, globalisation and commercialisation were discussed in particular.

Panel members discussed the way in which epidemiological changes, in particular increasingly frequent outbreaks of communicable diseases such as Malaria, West Nile Virus and Zika, challenge the relevance of the current EU legislation on Blood, Tissues and Cells and raise the need for EU-wide approaches to preparedness. Other societal changes were also noted to have a significant impact on the sectors; examples referred to included ageing of the (donor and recipient) population, migration, the increased age of women giving birth, changes in lifestyle and behavioural attitudes in younger generations, and changes in family compositions. Technological progress has brought new possibilities in the sectors such as genetic screening or correction of genetic defects; developments that also require ethical reflections at national level.

The increasing commercialisation, or even commodification, of human substances was presented as a growing trend that raises questions of safety and quality as well as ethical challenges.

The question of how all 28 MS can ensure an equal level of compliance to the requirements of the legislation, while ensuring an adequate supply for patients, was raised particularly in the context differences in GDP per capita and differences in epidemiological threats. In this regard, strengthening cooperation between MS was considered a key need for newer MS and applicant/candidate countries. The challenge of continuously adapting the safety and quality framework to societal and technological changes and the possible risks they bring was also highlighted. It was suggested that adaptive and risk-based decision making, on the basis of scientific evidence, is preferable to the adoption of rigid and specific legal requirements that quickly become outdated. In this context reference to appropriate guidelines was suggested as the optimal way forward.

The main points raised in the open discussion were:

- Globalisation and cross border movements, both of substances and of donors and recipients, are becoming increasingly important and are now significantly more developed than when the legislation was adopted. Such changes are not considered to be sufficiently accounted for in the current legislation. Future legislation should consider activities that occur both within EU MS, and outside the EU, in an effort to prevent medical tourism and access to unproven therapies.
- The use of social media and the internet was also raised for consideration. As an example the widespread use of the internet to order and ship donor sperm for home insemination was noted. Many considered that this practice raises serious concerns in terms of safety and quality.
- It was proposed that the availability of new technologies requires critical assessment of cost-effectiveness before implementation. The promotion of commercial solutions and their adoption without assessment of the impact and value within the entire existing framework of safety and quality measures was raised as a concern – especially in view of fast or accelerated approval of innovative therapies by competent authorities - with experts considering that health technology assessment can be helpful here.
- Given the above points and in view of increasing standards across all EU MS, it was underlined that strengthening co-operation between MS becomes increasingly important to allow for benchmarking, developing and sharing of expertise and resources. An Action Plan such as the one implemented for

organs field might be helpful, aiming for common progress through collaboration between MS.

- It was noted that ECDC now plays a key role in assessing threats and conducting risk assessments and proposing measures to prevent transmissions by transfusion, transplantation and assisted reproduction. The development of appropriate and shared preparedness plans and associated activities was mentioned as extremely important. Moreover it was stressed that the assessment of epidemiological changes is challenging at national level due to limited resources and expertise and speakers considered it more appropriate for such assessments and guidelines to be developed at EU level.

## 4 Conclusions

### 4.1 Closing remarks

In the closing session of the event ICF Consulting Services Ltd., the external contractor conducting an independent study for the Evaluation of the EU legislation on Blood, Tissues and Cells, presented preliminary findings from the Open Public Consultation launched by the European Commission on 29<sup>th</sup> May 2017, which ran until 14<sup>th</sup> September 2017. In total there were 206 submissions: 43 from citizens and 163 from stakeholder organisations. The key findings<sup>4</sup> were presented by evaluation theme and were in line with many of the topics covered during the event.

An overview of the main topics that had emerged during the day was then provided by a Thematic Expert from the external evaluation team. The expert also highlighted synergies between topics discussed during this event, and those brought forward in the open public consultation.

The Director of Directorate B, DG SANTE, Andrzej Rys, concluded the event, stressing the importance and relevance of gathering such a wide audience of stakeholders to raise key topics for this evaluation of a key set of legislation. He thanked and praised the participants, speakers and organisers for the contributions and lively debate and noted how the success of this event could be used as a reference for future multi-stakeholder events.

### 4.2 Feedback from participants

Participants were provided with a feedback form together with other documents during the Stakeholder Event. A total of 38 feedback forms were submitted.

The event was very well received by the respondents, with the large majority declaring the event was extremely informative or that they learned a lot. The majority of respondents that wished to contribute to the discussion reported that they had the opportunity to do so during the event.

### 4.3 Next steps

A synopsis of the submissions to the online consultation will be published on the Commission website, addressing the topics covered in this event as well as additional themes such as cost-effectiveness and EU added value. The individual

---

<sup>4</sup> The findings presented were preliminary and based on submissions received by 1<sup>st</sup> September 2017 (127 organisations and 35 citizens).

submissions themselves will also be published, where permission has been granted by the stakeholder. Subsequently, an independent study by the Commission's contractor will be completed by mid-2018. The study will provide evidence drawn from desk-based review of hundreds of published reports and articles, together with evidence provided by experts during focus group meetings, interviews and in the form of a targeted questionnaire. The study will provide a major source of documented evidence for incorporation in the final evaluation report to be published by the end of 2018 by the European Commission.

# Annex 1 : Event agenda



## Evaluation of the Blood, Tissues and Cells Legislation

### Stakeholder Event

September 20<sup>th</sup> 2017, Centre Albert Borschette, Room CCAB – 0A, Brussels

### Agenda

09:00 to 10:00 Registration and coffee

#### **10:00 Welcome and introduction to the evaluation**

**Welcome:** Martin Seychell, Deputy Director General, DG-Santé, European Commission

**Introduction to the evaluation:** Anna-Eva Ampélas, Head of Unit, Medical Products: Quality, Safety and Innovation

#### **10:30 The key importance of donors – The gift of life**

**Moderator:** Arlette Delbosc, Ministry of Health, France

**Panel members:**

- Alice Simonetti, International Federation of Blood Donor Organizations (FIODS)
- Arlinke Bokhorst, International Haemovigilance Network (IHN)
- Carlos Calhaz Jorge, European Society for Human Reproduction and Embryology (ESHRE)
- Lydia Foeken, World Marrow Donor Association (WMDA)

*Open discussion focusing on **donors** and their protection, addressing topics such as voluntary unpaid donation and compensation, donor safety and follow up, donor recruitment and donor registries.*

#### **11:30 Regulatory oversight of the sectors - How to ensure safety and quality?**

**Moderator:** Ian Rees, Medicine and Healthcare Products Regulatory Agency (MHRA), UK

**Panel members:**

- Simone Hennerbichler-Lugscheider, European Association of Tissue Banks (EATB)
- Alessandro Nanni Costa, National Transplant Centre Italy (CNT)
- Dorothea Stahl, Paul Ehrlich Institute (PEI) Germany
- Jo Wiersum, Vigilance Expert Sub-group to the Commission's Expert Group on Substances of Human Origin

*Discussion on the impact and cost of organising **regulatory** oversight, addressing topics such as inspection, authorisation, vigilance and traceability. Factors to take into account when organising oversight.*

## 12:30 LUNCH

### 13:30 Availability and sufficiency - Are patients getting the blood, tissues and cells that they need?

**Moderator:** Beatriz Dominquez-Gil, National Transplant Organisation (ONT), Spain

**Panel members:**

- Johann Prevot, the Platform of Plasma Protein Users (PLUS)
- Paul Strengers, International Plasma Fractionation Association (IPFA)
- Christian Chabannon, European Society for Blood and Marrow Transplantation (EBMT)
- John Armitage, European Eye Banking Association (EEBA)

*Discussion focusing on the challenges to ensuring adequate **availability and sufficiency of blood, tissues and cells for patients**, addressing topics such as access, matching supply and demand, cross-border exchanges, impact of epidemiological changes, expected changes in future needs.*

### 14:30 Legal consistency and coherence - Regulatory pathways for Substances of Human Origin

**Moderator:** Michael Cox, Danish Patient Safety Authority

**Panel members:**

- Jan Bult, Plasma Protein Therapeutics Association (PPTA)
- Esteve Trias, Common Representation of SoHO Associations (CoRe SoHO)
- Jacqueline Barry, Cell and Gene Therapy Catapult and the Alliance for Regenerative Medicine (ARM)
- Frank Wilton, American Association of Tissue Banks (AATB)

*Discussion to address **consistency and coherence** with other relevant Union legislation and with equivalent legislation internationally.*

### 15:30 A changing world – Technological, societal, epidemiological and international developments

**Moderator:** Mona Hansson, Health and Social Care Inspectorate, Sweden

**Panel members:**

- Dragoslav Domanovic, European Centre for Disease Prevention and Control (ECDC)
- Alina Mirella Dobrota, Expert on Blood of the Ministry of Health, Romania
- Kersti Lundin, European Society for Human Reproduction and Embryology (ESHRE)
- Philippe Vandekerckhove, European Blood Alliance (EBA)

*Discussion to focus on topics such as **changing risks, changes in society, bio-technological innovation, globalisation and commercialisation**. Is the existing legislation still valid and meeting regulatory needs?*

## 16:30 Conclusions and closing remarks

**Rapporteur summary and highlights from the Online Consultation:** ICF Consulting Ltd.

**Closing Remarks:** Andrzej Rys, Director, DG-Santé, European Commission