European Commission

Study supporting the Impact Assessment of the Revision of Directive 2002/98/EC on safety and quality of human blood and blood components and of Directive 2004/23/EC on safety and quality of human tissues and cells and of their implementing acts

Workshops - Summary notes

Written by ICF International

August 2021

1 Authorising Novel BTC – 27 April 2021

The BTC evaluation identified a high level of innovation in the BTC sector and concluded that current requirements for the authorisation of new BTC processes and clinical uses are not adequate. A particular concern was the lack of clear rules for the demonstration of efficacy.The workshop aimed to explore different dimensions of authorisation procedures for novel BTC including the application and authorisation process, the role of stakeholders, the proportionality of clinical data collection requirements and the possible role of clinical outcome registries.

The event was attended by 80 participants from invited organisations, including national competent authorities (CAs), professional societies representing BTC establishments and clinical users, patient representative organisations and representatives from EU institutions (DG SANTE, HaDEA, EDQM). The scene was set in plenary by a presentation by the GAPP Joint Action (an EU-funded action with the full title *Facilitating the Authorisation of Preparation Process for blood, tissues and cells*). The 3-year action, involving a large number of Member State BTC CAs, was coming to the completion of its work. The co-ordinators provided an update on the work carried out to support CAs in improving the assessment and evaluation of novel BTC preparation processes and reflected in Commission policy options for revision of the legislation. Following the presentation, participants were split into 2 breakout groups, one focused on questions related to the authorisation process and the role of stakeholders and the other focused on questions related to the proportionality of clinical data collection requirements and the role of Clinical Outcome.

The key messages arising from the workshop discussions were the following. There was strong support for (i) referring to the EQQM BTC monographs as an indication that a specific preparation for a specific clinical application is not novel; (ii) requiring the use of a risk assessment tool such as that developed by the EU-funded Euro-GTP II project and (iii) applying the authorisation process and clinical study proposals of the GAPP Joint Action when a preparation process is not covered by an EDQM monograph. Specifically, the GAPP concepts of Minimum Information Preparation Process Dossier, Clinical Follow-up Plan (CFUpP) and Clinical Investigation Plan (CIP) should be reflected in legislation. . Clinical outcome registries were seen as useful resources to gather evidence of efficacy, although they can be costly to run. Mixed views were expressed on whether the Clinical Trial Framework (Regulation 536/2014) should be applied for the most novel and highest risk BTC. There was also strong support for having a central IT platform at EU level where information on the authorisation of BTC preparation processes could be shared with, and used by, other Member States.

Participants agreed that strengthening the authorisation of novel BTC processes would bring standardisation, more possibilities for inter-Member State mutual recognition, greater trust and confidence and increased availability for patients to novel preparations with demonstrated efficacy. This outcome would also stimulate further innovation in the BTC field. Concerns were expressed on the level of technical expertise needed for assessment at the CA level, the length of the process and its resource-intensive nature.

2 Regulating Point-of-Care BTC Processing (bed-side and same surgical procedure) – 12 May 2021

Many new ways of processing autologous blood, tissues and cells have been developed for use in hospital, both at the bedside and during surgery, often using medical devices. These procedures are generally not subject to the current BTC legislation and the approaches to ensuring their safety and efficacy vary across the EU. This workshop explored whether existing oversight (medical device certification, hospital governance) is adequate to ensure the safety and efficacy of these treatments. During this workshop, the potential impact of the removal of the tissue and cell 'same surgical procedure' exclusion from the EU legislation was considered, along with the potential impact of inclusion of autologous blood components collected and administered at the 'point of care'.

The event was attended by 58 representatives from invited organisations including national competent authorities, professional associations, the medical devices industry, hospitals and patient organisations the European Commission and the Council of Europe (EDQM). The plenary scene was set by three presentations of point of care BTC treatments that are increasingly applied: autologous platelet rich plasma used in a wide range of procedures including cosmetic applications, extracorporeal photopheresis carried out with 'open' and 'closed' devices and autologous fat prepared and used in a variety of ways. Consequently, the participants were split into breakout groups for discussion based on a series of questions.

There was a clear view among participants that BTC used in surgery, or next to the patient, should be regulated by the BTC legislation for both therapeutic and non-therapeutic preparations, if the BTC are processed in any way. The provisions should not, however, be equivalent to full blood or tissue establishment authorisation requirements but, rather, be limited to an authorisation of the preparation process, with a focus on efficacy. The authorisation requirements should be proportionate to the risks associated with the therapy, in line with the proposals of the GAPP Joint Action, although the action had not specifically considered point of care BTC. A suggestion of introducing mandatory registration of such point of care processes was also discussed. It might include activity data and vigilance reporting obligations, along with desk-based preparation process authorisation. It was noted that some of these processes also move the BTC under the Advanced Therapy Medicinal Product legislation and that close regulatory collaboration would be important.

3 Strengthening Blood and Plasma Donor Protection – 17 May 2021

An important shortcoming of the existing legislation is the limited degree of protection afforded to donors, defining only limited donor protection provisions. In both BTC basic acts, reporting of donor reactions is mandated, as part of vigilance, but only when the safety or quality of the donated substance itself has been compromised. This workshop explored the measures that could be introduced to protect blood and plasma donors more effectively. During this workshop, potential measures for eligibility for donation, donor health monitoring and long term follow up were considered, along with the principles that should be defined in legislation and the mechanism for keeping donor protection rules up to date.

The event was attended by 49 representatives from invited organisations including representatives from national competent authorities for blood and blood components, professional societies representing blood services and clinical users, public and private plasma fractionators and their representative organisations, donor associations, EDQM (Council of Europe) and DG SANTE. The scene was set in plenary by two presentations on how vigilance can help to strengthen blood and plasma donor protection, as well as on donor adverse events and how those should be identified and reported. Following this introduction, participants were split into two breakout groups for discussion based on a series of questions. The groups were divided according to participant interest in either the field of blood for transfusion or plasma for medicinal product manufacture.

There was an overall agreement that measures to strengthen blood and plasma donor protection should be introduced in revised legislation. Monitoring and reporting of donor reactions should be mandated, irrespective of the impact of the reaction on the quality of the donated substance. Policy Option 2 was considered the most appropriate approach to ensuring comprehensive, up-to-date provisions for donor care, while it was felt that high level principles needed to be defined in the legislation (i.e. combination of Policy Options 2 and 3).

There was also a strong support to adopt internationally harmonised definitions for donation eligibility and reactions. Participants considered that donor eligibility criteria should be evidence-based and should be defined to optimise donor care. For plasma in particular (which crosses EU borders at high frequency) harmonisation of donor eligibility ability criteria is desirable, although it was highlighted that local epidemiological differences should be taken into account. Participants felt there should be some form of long-term follow-up undertaken for donors, and that follow-up measures should be evidence based, while respecting the principle of proportionality.

4 Better Protection of Donors for Non-Reproductive Tissues and Cells – 17 May 2021

An important shortcoming of the existing legislation is the limited degree of protection afforded to donors. This workshop aimed to explore the measures that could be introduced to better protect donors of bone marrow, peripheral blood stem cells, cord blood and any relevant replacement tissues donated during life. During this workshop, potential measures for eligibility for donation, donor health monitoring and long term follow up were considered (taking into account special donation circumstances such as related or paediatric donation). The workshop also explored the principles that should be defined in legislation and the mechanism that should be adopted for keeping technical level donor protection rules up-to-date.

The event was attended by 60 representatives from invited organisations including representatives from national competent authorities for tissues and cells, professional societies representing tissue establishments and clinical users, donor associations, EDQM (Council of Europe) and DG SANTE. The scene was set in plenary by two presentations on the reporting of serious adverse reactions and events and its consequences on donors, as well as on how to safeguard cell donors (examining differences between family and unrelated donors). Subsequently, the participants were split into breakout groups for discussion based on a series of questions, depending on whether they were more interested in the tissues sector or the cells sector.

There was an overall agreement among participants that measures that can help strengthen donor protection should be included in revised EU legislation. Reporting of donor reactions should be mandated, irrespective of whether the quality or safety of the donated substance was impacted. Participants considered that there should be a risk-based assessment approach for donors in terms of eligibility. Harmonised eligibility criteria were considered as desirable although participants added that local epidemiological differences need to be taken into consideration.

Participants agreed that it would be more practical to have the high-level donor protection principles in the legislation (Policy Option 3). However, Policy Option 2 was seen as the preferable approach to setting donor care technical standards, allowing for agility and responsiveness and for inclusion of the professional bodies in setting standards. There was considerable discussion on long-term follow-up and health monitoring. It was considered that this should include all types of bone marrow and peripheral blood stem cell donors, and take into consideration the psychological impact on donors as well as the number of donations (to the extent possible – for some types of donations, long-term follow-up might be difficult). Participants also agreed that common approaches for donor care should be evidence-based and specified in the legislation.

5 Better Protection of MAR Donors and Children Born from MAR – 18 May 2021

The current BTC legislation contains important shortcomings affecting the protection afforded to gamete donors as well as children born from medically assisted reproduction (MAR). This workshop aimed to explore the possible measures that could be introduced to improve donor protection, especially for oocyte donors. These measures related to rules on eligibility for donation, donor health monitoring and long term follow up, particularly for oocyte donors and children born from donated gametes or embryos. In addition, the workshop aimed to explore the feasibility and effectiveness of the establishment of donor registries and/or registries to monitor the health of children born from MAR. The principles that should be defined in the legislation and the mechanism through which technical donor and child protection rules should be kept up to date were identified as topics for the discussion.

The event was attended by 51 representatives from stakeholder organisations including tissue and cell competent authorities, the European Society for Human Reproduction and Embryology (ESHRE), the Commission's Vigilance Expert Subgroup r, gamete banks, MAR patient associations including Fertility Europe and paediatric society representatives. DG SANTE was also represented. The workshop was opened with a summary of the proposed policy options and a presentation by DG SANTE of a selection of preliminary results from the online consultations for the Impact Assessment of the BTC legislation. This was followed by three stakeholder presentations to set the scene. The first two, from ESHRE and Fertility Europe, presented recommendations to improve protections for donors and for children born from donated gametes or embryos from the perspectives of professional and patient associations, respectively. These were followed by a presentation from the Vigilance Expert Subgroup (VES), detailing the most recent vigilance data before presenting steps the VES is recommending to improve the vigilance reporting on serious adverse reactions and events and recommendations regarding reporting future reporting requirements.

The key messages emerging from the discussions were the following. There was strong support for a range of measures to improve the protection afforded to oocyte donors (it was clarified that the use of term 'donor' in the context of these discussions applied , including limits on the frequency and number of donations, donor age, and donor compensation. The participants highlighted the need for improved traceability of donations to allow monitoring the number and frequency of donations. A proposal for an EU-level gamete donor registry was supported as a measure to improve protection of both donors and of children born from donated gametes and embryos. There was less support for a registry of children born from donated gametes and embryos, with concerns raised regarding whether this would provide benefits for individual children and might drive misleading associations between children born from MAR and certain conditions. There was a preference for integrating information on the health of these children into broader paediatric registries as an alternative. It was noted that high quality genetic testing of donors is the measure that gives the most effective protection to children born from donated gametes or embryos. There was support for defining a minimum list of genetic tests for donor screening at EU level, although ethical concerns regarding donors' right not to know were also raised. The group offered a range of suggestions to ensure genetic screening did not reduce the donor pool more than necessary, such as testing for conditions based on a threshold of prevalence in a given population and using genetic matching to allow donors with recessive conditions to remain eligible.

6 Strengthening Oversight (Inspection, Authorization, and Vigilance) – Authorities – 25 May 2021

The evaluation of the BTC legislation identified a need to strengthen the oversight of the BTC sector so that rules are implemented more uniformly, in order that inter-Member State confidence is improved and the cross-border exchange of BTC can take place more smoothly. This workshop aimed to explore the oversight principles which might be defined in EU legislation to ensure that oversight is independent, free of conflicts of interest, effective and transparent. Other measures, that might be taken to improve and standardise the approach to oversight in Member States, and described in the policy options, were also to be explored, including the proposed measure of an EU-level auditing system of BTC competent authorities and a possible move to risk-based inspection scheduling. This workshop aimed to explore these topics from the perspective of the competent authorities. A separate workshop explored the same topics from the perspective of the establishments regulated by this legislation.

The event was attended by 58 representatives from BTC competent authorities and representatives from EU institutions. The workshop was opened with a summary of the proposed policy options and a presentation by DG SANTE of a selection of preliminary results from the online consultations for the Impact Assessment of the BTC legislation. The scene was set by presentations from members of the Vigilance Expert Subgroup and the Inspections Expert Sub-group (both sub-groups of the Commission's SoHO Competent Authorities Expert Group), highlighting where they saw improvements needed. Participants were divided in two break-out groups, one on blood and one on tissues and cells, to discuss the topics in more detail.

The key messages that emerged from the discussions were the following. Policy Option 2 was seen as the approach that would be most effective for achieving strengthened oversight. There was strong support among the participants for referencing Commission guidance for the conduct of oversight activities in the revised legislation. The guidance would be developed by the competent authority expert sub-groups. Common training activities were also seen as being of key importance. In an online poll of participants, most indicated that the proposed oversight principles should be set out in the revised BTC legislation and would contribute to the aim of strengthening oversight, although a significant number were not sure if this measure would be effective. Participants indicated strong support for the EU to conduct audits of national control systems, and for joint compliance inspections between two or more Member States (as proposed in Policy options 2 and 3). Making inspection reports publicly available was not strongly supported, due to concerns regarding risks of misinterpretation by the public although it was suggested to publish summaries. . The most important concern expressed by the participants was the risk that resources might not be made available to allow them to effectively implement the strengthened oversight provisions likely to be included in revised legislation.

7 Strengthening Oversight (Inspection, Authorization, and Vigilance) – Operators – 26 May 2021

The evaluation of the BTC legislation identified a need to strengthen the oversight of the BTC sector so that rules are implemented more uniformly, in order that inter-Member State confidence is improved and the cross-border exchange of BTC can take place more smoothly. This workshop aimed to explore the oversight principles which might be defined in EU legislation to ensure that oversight is independent, free of conflicts of interest, effective and transparent. Other measures, that might be taken to improve and standardise the approach to oversight in Member States, and described in the policy options, were also to be explored, including the proposed measure of an EU-level auditing system of BTC competent authorities and a possible move to risk-based inspection scheduling. This workshop aimed to explore these topics from the perspective of the establishments regulated by this legislation. A separate workshop explored the same topics from the perspective of the competent authorities.

The event was attended by 37 representatives from organisations including BTC professional associations, the medicinal product manufacturing industry, patient organisations and the European Commission. The workshop was opened with a summary of the proposed policy options and a presentation by DG SANTE of a selection of preliminary results from the online consultations for the Impact Assessment of the BTC legislation. The scene was set by presentations from representatives of the European Association of Tissue and Cell Banks and the Plasma Protein Therapeutics Association, highlighting where they saw improvements needed. The need for common oversight definitions and for streamlining inspection/audit activities for greater efficiency were raised. Participants were divided in two break-out groups, one on blood and one on tissues and cells, to discuss the topics in more detail.

There was a strong indication from participants that policy option 2 would best achieve the goal of improving cross-border exchange of BTC. Participants felt that the measures in this policy option would help to improve harmonisation and trust between Member States, although there were some caveats to this. While there was widespread support both for joint inspections by Member States and for a system of EU audits of national oversight systems,, concerns were raised about how inspectors from different Member States might expect to see the more stringent requirements applied in their Member State, when inspecting in another Member State. There was broad support for including the proposed principles on independence, transparency in revised legislation, although some doubts were expressed concerning how the implementation of these principles would be ensured. There was generally little support for publishing inspection reports in full due to concerns this would be misinterpreted by the public; however, there was some support for publishing aggregated inspection data.

8 Key Definitions - Improvements and Additions – 1 June 2021

Various developments since the adoption of the BTC legislation have rendered certain definitions (Article 3 of both 2002/98 and 2004/23, as well as definitions in the implementing legislation) unclear, or out-of-date. Other necessary definitions are missing. In other cases, definitions differ between the blood and the tissue & cell Directives without a clear justification. The workshop aimed to review the existing definition lists in the basic acts and the implementing Directives, and to consider any gaps or improvements needed.

The event was attended by 69 participants including the study team, representatives from EU institutions (DG SANTE, EDQM) pharmaceutical industry representatives, medical devices representatives' organisations, national competent authorities (NCAs for BTC, pharmaceutical products, ATMP, medical devices), BTC establishment representatives (banking and collection of BTC), and representatives of patients/donors' organisations. The scene was set in plenary by a series of short presentations made by a number of stakeholders on key definitions needing improvement or additions: the European Society of Human Reproduction and Embryology (ESHRE), the European Plasma Alliance (EPA), the International Plasma and Fractionation Association (IPFA), the European Eye Bank Association (EEBA) and the European Blood Alliance (EBA). Following the presentations, participants were split into two breakout groups, one with a focus on the tissues and cells sector, and the other on the blood sector.

In both breakout groups, participants raised concerns concerning a number of current definitions, noting for instance that these definitions are either too broad and do not reflect the current reality, or that they need to be either expanded or further clarified. Definitions that were discussed in the group focusing on the tissues and cells sector included: 'tissue establishment', 'tissues for human application', 'processing', 'quality assurance', 'altruistic donation', 'partner donation', 'non-partner donor of gametes' and 'responsible person'. Definitions that were discussed in the group focusing on the blood sector included: 'distribution and transport', 'plasma fractionation', 'manufacturing', 'therapeutic', 'transfusion', 'blood component', 'blood product', 'recovered plasma', 'serious event' , haemovigilance', 'inspections', 'establishment' and 'hospital blood banks'.

Participants noted that definitions should be expanded to ensure that they capture all substances of human origin intended for human application.

Participants agreed that there is a need for greater harmonisation. Different Member States use different definitions in their transposed legislation. Participants explained that there are already definitions from the Council of Europe, WHO, etc. that could be used as guidance.

9 Refining the Scope of the BTC Legislation – 2 June 2021

There are several substances of human origin that are not included in the scope of the BTC legislation because of the wording of the definitions included there, even though the EU Treaty provides a mandate to regulate their safety and quality. Examples include human breast milk and intestinal microbiota. There are other substances for which it is unclear which regulations apply (blood or tissues & cells), such as serum eye drops. This workshop aimed to explore Article 2, and any definitions in Article 3, in Directives 2002/98 and Directive 2004/23 that contribute to defining the legislation's scope. It aimed to explore the impact of expanding the scope of the legislation to include substances of human origin for different intended purposes (including transfusion only, nutritional purposes, cosmetic purposes, etc., with the aim of improving protection for donors and citizens to whom these substances are applied.

The event was attended by 86 representatives from organisations including professional and patient associations, BTC and pharmaceutical competent authorities, the medical devices industry, as well as DG SANTE and EDQM (Council of Europe). The scene was set in plenary by two presentations in which the case was made for expanding the scope of the legislation to include new substances, namely faecal microbiota transplantation (FMT) and donor human milk. In both cases, speakers pointed to the need for an EU-wide framework for safety and quality for these substances and to the appropriateness of the BTC framework where donor and recipient safety are the focus. The noted, however, the need to take into account the specificities of these fields and to ensure proportionate regulatory measures. Following this, the participants were split into breakout groups for discussion based on a series of questions.

The key messages emerging from the discussions were the following. There was strong support among participants for expanding the scope of the legislation to include new substances and therapies. FMT, donor human milk and serum eye drops were all seen as substances to be included in the revised legislation, along with several other substances such as platelet rich plasma prepared and used in hospitals. While there was support for expanding the legislation's scope, several participants noted that any new measures for such substances should be proportional to the risks associated with their use and some suggested graded approaches to oversight activities. Participants also supported extending to scope of the legislation to the authorisation of further key players such as donor registries. To better address borderline substances going forward, suggestions were made by participants for the legislation to explicitly reference other frameworks so that ambiguity over which framework covers novel treatments can be avoided. It was clearly shown that for the fields of FMT and breast milk, for instance, there would be new borderlines with the pharmaceutical framework and the food supplements framework when certain processes are applied. In this context, there were calls for refining the definition of "industrially manufactured" to make this term clearer, and to ensure that it is understood in the same way across EU legislation.

10 Ethical Principles (Voluntary Unpaid Donation, Prohibition of Profit from the Human Body and BTC Allocation) – 8 June 2021

Given that all BTC start as a donation from an individual, there are inevitable ethical issues to consider. While these issues fall largely under Member State competence, some impact on safety, quality and sufficiency of supply and are relevant to the EU Charter of Fundamental rights. As such, some ethical principles are mentioned in existing EU legislation. The workshop aimed to discuss the EU level approach to voluntary unpaid donation, prohibition of profit from the human body, appropriate use of BTC and other issues impacting on fundamental rights in the BTC legislation. The focus was put on what could be in EU level legislative principles and whether current definitions should be improved.

The event was attended by 98 participants including the study team, representatives from EU institutions (e.g., DG SANTE, DG JUST,), EDQM (Council of Europe) and other organisations active in standards setting, pharmaceutical industry representatives, advanced therapy medicinal products representatives and medical devices representatives organisations, national competent authorities (NCAs for BTC, Pharmaceutical products, ATMP, Medical devices), BTC establishments representatives (banking and collection of SOHO) and representatives of patients/donors organisations. The scene was set in plenary by a presentation by DG Justice on the EU Charter of Fundamental rights and the need for all new EU legislation to be assessed against the principles in that Charter. This was followed by a DG SANTE presentation on how fundamental rights may be affected by the future update of the BTC legislation. The Council of Europe delivered a presentation on the "Guide on prohibition on financial gain" developed by their DH-BIO Committee. This was followed by a series of short presentations by stakeholders on their priorities and views on ethical issues related to BTC donation. The European Foundation for the Care of Newborn Infants (EFCNI), WMDA, European Blood Alliance (EBA), European Plasma Alliance (EPA), European Patient Organisation for patients with Inflammatory Neuropathies (EPODIN), Fertility Europe and CORESoHO presented positions during this session.

The key messages arising from the workshop discussions were the following. Most participants were in favour of introducing provisions for donor protection, and of ensuring up-to-date and evidence-based BTC technical rules safety and quality; aspects they saw as impacting on fundamental rights. They agreed that introducing measures that support a sustainable supply of critical BTC, as well as increasing harmonisation of BTC safety and quality rules would also increase protection of fundamental human rights of EU citizens. Most participants agreed that the prohibition of making the human body and its parts a source of financial gain as described in the Council of Europe (DH-BIO) recommendation should be specifically referenced in EU BTC legislation. Participants also agreed that the revision of the legislation should include the principle of informed consent and that donors should be aware of the potential uses of their donations.

11 Borderlines with Other Regulated Frameworks: Classification Advice and Interplay – 9 June 2021

The workshop explored the borderlines between the BTC framework and other EU regulatory frameworks; specifically, the borderline with medicinal products (non-ATMP), the borderline with ATMPs (Advanced Therapy Medicinal Products) and the borderline with medical devices. Online stakeholder consultation had confirmed a finding of the BTC Evaluation that a lack of clarity at the borderlines with other regulated substances represents a hurdle to innovation in the BTC sector. Stakeholders had indicated that this was one of the 3 highest priority issues to be addressed in the revision of the legislation. All three policy options for the revision include a mechanism for improving classification advice.

The event was attended by 105 representatives from: EU institutions, organisations in charge of standards setting, pharmaceutical industry, advanced therapy medicinal products and medical devices organisations, national competent authorities (NCAs), BTC establishments representatives (banking and collection of SOHO), patient/donor organisations, with a predominance of stakeholders and authorities from the pharmaceutical sector. The scene was set in plenary by two presentations. One on the new EU regulatory framework for medical devices and provisions it includes to promote interaction between authorities in different frameworks for combination products/substances. The second on the European Medicines Agency experience with borderline products, including their collaboration with Heads of Medicines Agencies in the EU-Innovation Network Borderline Classification Group (BLCG). This new informal initiative discusses borderline cases, some of which involve substances of human origin. The participants were then split into 3 breakout groups for discussion on the borderlines between BTC and pharmaceuticals (non-ATMP), between BTC and ATMPs and between BTC and medical devices.

Key messages emerging from these discussions were:

(i) Establishing a BTC advisory mechanism will promote a common approach between BTC authorities. It should work according to clear and agreed inclusion criteria, defined in the revised BTC legislation. While some dissenting views were expressed during the break-out discussion on classification criteria, the majority of participants considered ensuring safety and quality and patient access as the most important considerations when setting these criteria. The BTC advisory mechanism should be multi-disciplinary, with access to a pool of experts across different BTC sub-sectors.

(ii) Clear definitions and good collaboration across regulatory frameworks will be the most effective measures to improve classification mechanisms, particularly given that the number of novel therapies at the borderlines are likely to increase. The new BTC mechanism could interact with established EU advisory mechanisms in other frameworks. It was suggested that the parallel revision of the BTC and the pharmaceutical legislation offered a rare opportunity to put in place a cross-sectoral EU level mechanism for discussion on the regulatory status of novel substances at the borderlines between regulatory frameworks. Although deciding regulatory status is ultimately a Member State competence, all stakeholders shared the wish to see common guidance made across the EU.

(iii) When substances fall under more than one regulatory framework (e.g. BTC are the starting material for the manufacture of a medicine or a medical device), effective communication on donor requirements for starting materials, traceability, vigilance, etc. between the relevant authorities was seen as essential.