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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

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Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The legislation on blood, tissues and cells (BTC) is based on Article 168 of the TFEU. This Treaty Article gives the EU a mandate to set out measures establishing high standards of quality and safety for BTC while allowing Member States to maintain or introduce more stringent protective measures.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of common safety concerns in public health, the Union's competence is shared with Member States.
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
- To collect all relevant views and engage with stakeholders as much as possible, different consultation methods were combined. DG SANTE consulted with stakeholders via (i) the publication of the inception impact assessment for feedback, (ii) two online consultations (one for all interested stakeholders/citizen, the other one targeted at organisations directly impacted by the BTC legislation), (iii) hearings with Member States competent authorities and stakeholders and (iv) bilateral meetings with stakeholder organisations. Because of the COVID-19 pandemic, all meetings were held in virtual format. In addition, a series of 11 three-hour online participatory workshops was conducted, involving competent authorities and invited stakeholders with experience relevant to the topics to be discussed. Some stakeholders were also engaged via semi-structured interviews. Finally, online questionnaires addressed to competent authorities, and representatives of all impacted stakeholders categories were used to fill remaining gaps in the evidence base. A summary of all these activities and their outcomes is provided in the Annex 2 – Synopsis report, of the Impact Assessment SWD. - The explanatory memorandum and the impact assessment SWD (chapter 3) contain a section on the principle of subsidiarity (see also question 2.2 below).
2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?
Ever-evolving disease threats, such as Zika, Human Immunodeficiency Virus (HIV) or Viral Hepatitis B, C and D, which can be transmitted through BTC, or more recently COVID-19, constitute cross-border threats to public health. The exchange of BTC between Member States and with third countries is necessary for ensuring patient access and sufficiency of supply. The extent of exchange is

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

considerable, although it varies highly from substance to substance.

The BTC legislation has been in place for more than 15 years now. Its evaluation concluded that, in general, the Blood and Tissues and Cells Directives improved the quality and safety of BTC in a manner that would not have happened, or would have happened more slowly, without EU legislation; indeed, intensive activity to raise safety and quality to a common level were seen across the EU following the adoption of the legislation. The outdating of technical requirements over the years has led to a diversification of standards with more stringent national requirements compensating for shortcomings of the legislation. Although this is permitted by the Treaty, it limits exchanges between Member States. EU action is required to reinforce the framework, increase trust and facilitate that patients in all Member States can benefit equally from safe and effective BTC. Increasing cross-border exchanges of BTC necessitate ever-closer cooperation between a number of health professional groups and authorities to ensure that BTC remain traceable from the donor to the recipient and vice versa. The evaluation confirmed the benefits of setting quality and safety standards for BTC at EU level although pointed to a need for a more responsive approach to changing risks.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The evaluation of the BTC legislation has shown that there are barriers to the exchange of BTC among Member States, due to more stringent requirements currently in place in some of them, and lack of trust. The problem affects all Member States, and it is more prominent in those Member States having more stringent protective measures in place. In the absence of EU level action, the problems highlighted in the evaluation of the BTC legislation are expected to further deteriorate. While Member States can take actions at national level, only EU action will allow for more harmonised standards for safety and quality of BTC in the whole EU, and more trust among Member States thanks to strengthened oversight practices. This will facilitate the exchange of BTC, hence access to patients to safe and effective therapies across all EU.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

As stated above, the extent of exchange of BTC is significant, within the EU and with third countries. There is significant import of bone preparations, particularly from the United States, and corneas are regularly exchanged between Member States and imported to the EU. There is a continuous and significant exchange and import of plasma for PDMP manufacture (25% of the plasma needed for manufacturing PDMP to treat EU patients is imported from the USA). Almost half of all haematopoietic stem cell transplants (around 17.500 units) involve a donation made in another country to improve the genetic match. There are substantial cross-border shipments from some EU hubs where gamete collection is organised (leading sperm banks in Denmark supply to many countries, Spanish IVF clinics collect and supply egg-cells to many patients from other countries).

However, the evaluation of the legislation has shown that there are barriers to the exchange of BTC so it is difficult to assess the full potential for exchange of those therapies among Member States, due to more stringent requirements currently in place in some of them, and lack of trust.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[2] or significantly damage the interests of other Member States?

[2] https://europa.eu/european-union/about-eu/eu-in-brief_en

To better protect the health of EU citizens, the Commission is building a strong European Health Union. In the absence of EU level action, the problems highlighted in the evaluation of the BTC legislation are expected to further deteriorate, as new epidemiological threats can emerge, scientific developments will continue, together with innovative practices in processing BTC. Such deterioration will have a negative impact on the timely access for patients to therapies that can save their life, and overall on the protection of patients, BTC donors and children born from medically assisted reproduction.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
Member States make national decisions on the organisation of healthcare, on ethical rules regarding permission for certain BTC practices such as third party egg donation or surrogacy, consent rules for donation after death or for the implementation of the voluntary unpaid donation (VUD) principle. In accordance with Article 168(4)(a) of the TFEU, they can also put more stringent protective measures in place for BTC. It should be noted that for the objective of "improving the resilience of the sector, mitigating risk of shortages", the Commission has no legal mandate to put in place direct measures affecting the demand for BTC. The organisation of collection and exchanges of BTC is a competence of Member States. However, from the evaluation, and even more with the pandemic, it became clear that not having monitoring measures and measures for crisis preparedness nor crisis management was an issue, and this is where the EU could act. Such tools would be crucial for Member States to take mitigation measures in case of drops in supply.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The problem varies according to Member States, being more prominent in those Member States having more stringent protective measures in place. Indeed, the outdating of technical rules for safety and quality, together with the incomplete scope, has caused some Member States to put increasing numbers of more stringent measures in place. However, in some other Member States or regions, where more stringent measures have not been put in place, the application of the outdated, or overly generic, requirements in the current legislation, mean that some patients treated with BTC therapies, BTC donors and offspring born from medically assisted reproduction are exposed to avoidable risks. Access to innovative therapies is also unequal for all EU citizens or innovative therapies are used with widely varying levels of supportive evidence of efficacy.
(e) Is the problem widespread across the EU or limited to a few Member States?
The problem is affecting all Member States, to diverse degrees.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
Some sector-specific expertise might not be easily available in all Member States, and it brings simplification and efficiency to provide for a framework allowing and supporting joint practices, such as joint inspections of establishments (those providing BTC to many Member States, or those having a specific technology/process in place), joint assessment of new processes etc.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
It should be noted that in the BTC sector, only three Member States (Germany, Italy and

Spain) have, in addition to the national authority, also regional authorities, which oversee the establishments. From the consultation activities carried out, a small number of specific comments were received from regional authorities (the Spanish ones, in the targeted consultation). Their views are in general similar to the consensus that emerged from all the consultation activities. They however prefer a stronger role of EU legislation for setting technical rules than the average of respondents, including the national authorities. They mention that also regional competent authorities should be able to access advice from the borderline classification mechanism, if it is set up, and they report complexities (it is also time-consuming) from their own experience on getting responses from national/EU level on borderline cases. They have more limited concerns than the national authorities on the cost and administrative burden of implementing requirements for reporting and monitoring of activity data (e.g. donations, supply, shortages) nationally and at an EU level.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

The key added value of the EU approach in this proposal is to ensure, where appropriate, that common standards and guidance make full use of the high level of latest scientific and technical expertise, as already available in expert bodies such as the ECDC and the EDQM, and therewith facilitate cross-border exchange of and access to safe BTC.
EU action will enable simplification and efficiency, by providing for a framework allowing and supporting joint practices, and building on and sharing Member States' expertise. In addition, the sharing of data through a common platform, and following common guidance, will enable policy making based on significantly more robust data.

(a) Are there clear benefits from EU level action?

The COVID-19 pandemic highlighted the risks for supply interruptions, the need for adequate donor and recipient protection, and the need for rapid and adequate authorisations of health innovations in the BTC sector. By providing a framework for cross-border cooperation, based on a common set of rules, EU-level measures are best placed to address such issues effectively. Establishing minimum standards of quality and safety for BTC at an EU level brings significant efficiencies for Member States, avoiding the need for multiple exercises in risk, benefit and cost analysis. Such minimum standards can also allow more stringent rules on national level if it is considered necessary by the Member State.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

More collaboration and support among the national competent authorities (NCAs) would help to address the issues highlighted in the evaluation, bringing simplification and improving the effectiveness of the legislation and the efficiency of its implementation. Sharing information across Member States at NCAs level, e.g. on the supply of critical BTC, authorisations of preparation processes, or results of the inspection of an establishment, will help other Member States. Surpluses for a certain BTC will be transparent and authorities may re-use an authorisation already given (by assessing that the procedure is equivalent, without re-assessing a complete risk assessment or clinical evidence provided). The burden associated with this data sharing will be significantly reduced by the provision of an EU digital platform where data can be entered directly by operators and accessed by authorities. Also, collaboration among Member States (e.g. joint inspections and joint preparation process assessments) will lead to building more trust among the NCAs, which ultimately should facilitate exchange of BTC, hence access for patients. All this will be more efficient at EU level, rather than compared to actions taken individual by all Member States. Commission audits of

national competent authorities will increase mutual trust and avoid the need for the administrative burden associated with treating inter-Member State distribution of BTC as import.

While substances of human origins are not considered tradeable commodities as such, there are significant cross-border exchanges taking place, in particular for substances where exact matching is required (e.g. bone marrow). Improving harmonisation of technical and safety rules, and increasing transparency where national differences in requirements remain in place, will reduce variations in national rules that create barriers to the exchange of BTC among Member States.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

There is already a BTC legislation in place at EU level. However, shortcomings were highlighted and this proposal aims at addressing them, to make the BTC legal framework more effective, future proof and crisis resistant.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed EU action will bring simplification and more harmonisation among Member States, to better protect all EU citizens and facilitate their access to safe, effective and innovative BTC therapies. Member States will not lose competences, and they will be able to maintain or introduce more stringent protective measures.

(e) Will there be improved legal clarity for those having to implement the legislation?

The evaluation of the BTC legislation showed that there are sometimes difficulties in defining the borderlines for novel BTC with other regulatory frameworks, in particular where medicinal products and medical devices are concerned. This creates administrative burdens and implicit disincentives for BTC establishments, healthcare professionals and academia to innovate. The proposal plans for an EU-level advisory mechanism to clarify the applicability of BTC requirements. A coherence mechanism with equivalent advisory mechanisms in other legal frameworks (pharma, devices) is planned to allow for common advice to public and commercial developers of borderline technologies.

The current co-existence of outdated technical rules in EU legislation with regularly updated guidance on the same topics from the European Centre for Disease Prevention and Control and the European Directorate for the Quality of Medicines will be replaced by a clear hierarchy of norms with cross-references to the source of technical standards to be followed. An EU digital platform funded and supported by the Commission will enable sharing openly information on the quality and safety requirements and will also allow timely updates in case of emergency (e.g new epidemiological threat that could be transmitted via BTC). This increased transparency, and the publication of national more stringent rules put in place in the same EU digital platform, will further bring clarity for all stakeholders implementing the legislation.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The measures proposed are limited to actions that need to be taken at an EU level in order to be effective and efficient.
For effectiveness, the newly defined scope, the new measures for donor protection and the clarification on the technical safety and quality rules to be applied, all ensure that citizens, whether donors, patients or children born from medically assisted reproduction, are guaranteed an equal level of protection across the EU, including when they are treated in Member States other than their own or when they donate BTC or are treated with BTC, including novel BTC, originating in another Member State.
For efficiency, the newly defined measures on joint inspections and joint preparation process authorisations, the provision of an EU digital platform with supply data from across the EU and the sharing of authorised process information will facilitate common use of single authorisations or inspections for multiple purposes in multiple Member States and will support the efficient sharing of BTC for patient benefit on a routine basis and in emergency situations.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposal takes the form of a new Regulation repealing two existing Directives. This type of instrument is considered most suitable, considering that a key element of the proposal is to establish more harmonised measures for Member States and organisations involved in collection, testing, processing, distribution, application of substances of human origin, from donors to patients. Insufficient harmonisation was identified as a key reason for reduced trust between Member States, resulting in reduced cross-border exchange and sub-optimal access for patients to BTC. The measures do not require the implementation of national measures and can be directly applicable.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Significant and wide-ranging expertise is needed to set technical standards for operators working with BTC and to keep them up to date with continuously evolving epidemiological risks and new technologies in this field. Very few Member States can harness this level of expertise for every technical aspect of ensuring the safety and quality of BTC for donors and patients in their own Member State. The added value of the EU approach in this proposal is to ensure full utilisation of the high level of scientific and technical expertise already concentrated in the European Centre for Disease Prevention and Control and the European Directorate for the Quality of Medicines.
The expertise and resources required by competent authorities to oversee these activities, particularly to authorise and monitor them, is available to varying degrees across Member States. The evaluation highlighted the need for strengthened oversight to improve inter-Member State trust and exchange of BTC but this strengthening brings increased workload and expertise requirements for authorities. In this context, the proposal includes measures to promote sharing of expertise at the authority level and provides for the use of EU level digital tools for monitoring and sharing, without the need for duplicating these at national level.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The current legislation for the BTC field includes two basic Acts, both Directives, and 7 implementing

Acts. The transposition of these Directives into national legislation in different ways has contributed to the variations in practice and oversight across the Union. This has been highlighted in the evaluation and stakeholders clearly support a more harmonised approach to ensuring safety and quality with clearer common rules. The main aim of this greater harmonisation is to increase the exchange of BTC and to ensure that all citizens have equal protection from the risks of donating or being treated with these substances, while ensuring that Member State competences for healthcare organisation are not compromised. To achieve this aim, the two basic Acts will be replaced by a Regulation and the existing implementing legislation will also be repealed. This instrument will provide a significantly higher level of clarity and conformity to common safety and quality principles.
In the legal proposal, an efficient implementation, adding flexibility and proportionality, will be followed. With regards to technical safety and quality rules, however, the proposed Regulation provides for a clear hierarchy of norms to be followed. As part of that hierarchy, co-regulation, based on legal references to the standards of expert bodies such as the ECDC and the EDQM, will become the most used approach for technical rules. The approach will facilitate an efficient and responsive updating of technical standards whenever risks and technologies change and is proportionate in that it ensures EU legislation would be adopted for technical rules only when necessary and when it adds value. At the lowest level of the hierarchy, when no technical standard is defined in the EU legislation or by referenced expert bodies, operators will apply a locally defined rule that is in line with internationally recognised standards, scientific evidence and/or a documented risk assessment. Finally, it needs to be recalled that Member States have the right in the TFEU to set more stringent standards. This proposal will respect this, but will bring more transparency on such more stringent national standards and facilitate cross-border exchange and optimal access to BTC for patients across the EU.
Some technical topics, such as coding and importing rules, will require implementing legislation but the number of implementing or delegated Acts will be significantly reduced, with this greater reliance on up-to-date expert standards. The harmonisation of oversight activities will be greatly increased by the adoption of guidance for authorities, in consultation with a representative ad-hoc co-ordination group of experts and Member State representatives.
Of the policy options considered in the Impact Assessment, this approach emerged as the most effective and simplest one to achieve the key objective of improved and common levels of donor and patient protection.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposal balances the need for clear and high standards to protect donors and patients equally while ensuring that Member State competences for health care organisation are not compromised. The legal basis allows Member States to adopt more stringent measures when they consider it necessary. The proposal does not interfere with that right but does increase the level of safety and quality to be achieved in all Member States, thus reducing the need for more stringent measures that can create hurdles to exchange and to patient access. In addition, the proposal will ensure the adoption of more stringent measures is made more visible so that exchanges can be more easily organised despite those measures.
The principle of proportionality is strongly reflected also in the new provisions for oversight of operators working on BTC. Although the scope of the proposal will affect operators and activities not previously within the scope of the BTC framework, a graded approach to oversight has been defined, with lighter requirements for registration only or for preparation process authorisation only for those entities carrying out BTC activities with lower risk levels. Some entities previously inspected and authorised as BTC establishments will change to a simpler registration with limited reporting

requirements. Furthermore, planning of inspections will be adapted to the inherent risk of the establishments, allowing for more frequent inspections for those with high volumes, complex activities or with a poor safety-record. Similarly, although the proposal includes new requirements for demonstrating efficacy for novel ways of processing or using BTC, these requirements are graded according to the degree of risk or novelty and the most demanding clinical studies will be required only for those novel processes that imply higher risk for patients.
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The administrative costs relative to the baseline have been estimated in the impact assessment as comprising a EUR 22 million one-off investment between 2023/4 and 2027, and EUR 12 million recurrent annual costs. Of these recurrent administrative costs for the public authorities, EUR 9 million are for the European Commission and EUR 3 million are for Member States public authorities). The largest part of the one-off investments would amount to EUR 12 million for the Commission and EUR 10 million for the Member States public authorities. These costs are relative to the baseline, expressed as present value over 2022-2031.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
Given that rules relating to ethical aspects of this field, or to healthcare organisation, are not included in this proposal, no special circumstances in individual Member States were identified that required a particular territorial variation in the measures to be applied.