Contribution ID: 988373eb-e7be-41d2-9a12-f066a878000c
Date: 14/04/2021 12:32:07

# Online Public Consultation on the Revision of the EU Legislation on Blood, Tissues and Cells

Fields marked with * are mandatory.

## Introduction

The European Commission has conducted a comprehensive evaluation of the blood, tissues and cells (BTC) legislation, examining its functioning across the EU and published its findings in October 2019. In particular the evaluation assessed the extent to which the Main Directives met their original objectives and whether they remain fit for purpose, given all that has changed in the intervening period.

The evaluation of the legislation, published in October 2019, confirmed that **the legislation had improved safety and quality of blood, tissues and cells used for transfusion, transplantation or medically assisted reproduction**. The evaluation also highlighted a number of gaps and short-comings which will be addressed by a revision of the legislation to ensure the framework is up-to-date, fit for purpose and future-proof.

The Commission has launched an initiative to revise the legislation, addressing the identified shortcomings. The initiative aims to:

- update the legislation to provide a more flexible alignment with scientific and technological developments
- tackle the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic
- focus on the increasing commercialisation and globalisation of the sector.

This public consultation will be an important source of information for the process that will lead to the revision. The consultation does not address changes to other EU legal frameworks but it does explore if there are specific products that do not fall clearly under the blood, tissues and cells framework or the medicines and/or medical device frameworks.
Please note that a more in-depth and technical consultation is open in parallel to this one, for organisations that are directly involved in or impacted by these activities and have a good knowledge of the current legislation. If you are such an organisation, you should complete **both this consultation and the targeted one**, available on the Santé web pages.
An external contracted study will also gather evidence and views to support the Impact Assessment.

## About you

* Language of my contribution

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish
- ○ Dutch
- ◉ English
- ○ Estonian
- ○ Finnish
- ○ French
- ○ German
- ○ Greek
- ○ Hungarian
- ○ Irish
- ○ Italian
- ○ Latvian
- ○ Lithuanian
- ○ Maltese
- ○ Polish
- ○ Portuguese
- ○ Romanian
- ○ Slovak
- ○ Slovenian
- ○ Spanish
- ○ Swedish

* I am giving my contribution as

- ○ Academic/research institution
- ○ Business association
- ○ Company/business organisation
- ○ Consumer organisation
- ○ EU citizen
- ○ Environmental organisation
- ○ Non-EU citizen
- ◉ Non-governmental organisation (NGO)
- ○ Public authority

- ( ) Trade union
- ( ) Other

* First name

Catherine

* Surname

Hartmann

* Email (this won't be published)

c.hartmann@europeanbloodalliance.eu

* Organisation name

*255 character(s) maximum*

European Blood Alliance (EBA)

* Organisation size

- (•) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

Transparency register number

*255 character(s) maximum*

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

14985501062

* Does your organisation work in any of the following fields?

*between 1 and 12 choices*

- [x] Blood collection and/or blood banking
- [x] Plasma collection for manufacture of medicinal products
- [x] Tissue or cell donation or banking for transplantation
- [ ] Tissue or cell donation or banking for assisted reproduction
- [ ] Transfusion of blood and blood components
- [ ] Clinical application of tissues or cells - transplantation

- [ ] Clinical application of tissues or cells - assisted reproduction
- [ ] Government oversight of blood or tissue establishments (inspection, authorisation, vigilance)
- [ ] Medical ethics
- [ ] Pharmaceutical industry – plasma derived medicinal products
- [ ] Pharmaceutical industry – other BTC derived medicinal products
- [ ] Non-industrial developers of blood, tissue or cell based medicinal products
- [ ] Representation of donors of blood, tissues or cells
- [ ] Representation of patients treated with blood tissues or cells or products manufactured from them
- [ ] Government oversight of medicinal products
- [ ] Government oversight of medical devices
- [x] Research using blood, tissues or cells
- [ ] Other field relevant to this consultation
- [ ] No direct activity in this field

* Country of origin

Please add your country of origin, or that of your organisation.

| | | | |
|---|---|---|---|
| ○ Afghanistan | ○ Djibouti | ○ Libya | ○ Saint Martin |
| ○ Åland Islands | ○ Dominica | ○ Liechtenstein | ○ Saint Pierre and Miquelon |
| ○ Albania | ○ Dominican Republic | ○ Lithuania | ○ Saint Vincent and the Grenadines |
| ○ Algeria | ○ Ecuador | ○ Luxembourg | ○ Samoa |
| ○ American Samoa | ○ Egypt | ○ Macau | ○ San Marino |
| ○ Andorra | ○ El Salvador | ○ Madagascar | ○ São Tomé and Príncipe |
| ○ Angola | ○ Equatorial Guinea | ○ Malawi | ○ Saudi Arabia |
| ○ Anguilla | ○ Eritrea | ○ Malaysia | ○ Senegal |
| ○ Antarctica | ○ Estonia | ○ Maldives | ○ Serbia |
| ○ Antigua and Barbuda | ○ Eswatini | ○ Mali | ○ Seychelles |
| ○ Argentina | ○ Ethiopia | ○ Malta | ○ Sierra Leone |

- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia

- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d’Ivoire
- Croatia
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
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- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam

| | | | |
|---|---|---|---|
| Cuba | Kyrgyzstan | Russia | Wallis and Futuna |
| Curaçao | Laos | Rwanda | Western Sahara |
| Cyprus | Latvia | Saint Barthélemy | Yemen |
| Czechia | Lebanon | Saint Helena Ascension and Tristan da Cunha | Zambia |
| Democratic Republic of the Congo | Lesotho | Saint Kitts and Nevis | Zimbabwe |
| Denmark | Liberia | Saint Lucia | |

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **Fo r the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

## * Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**
  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.
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## The BTC evaluation findings

An evaluation of the BTC legislation was published on 11 October 2019. Although the evaluation concluded that the legislation had increased safety and quality of blood, tissues and cells in the EU, a number of shortcomings and gaps were identified.

### Q1 To what extent are the findings of the evaluation still valid one year since the publication of the evaluation?

*at most 8 answered row(s)*

| | Valid | Partially valid | Partially invalid | Invalid | No answer |
|---|---|---|---|---|---|
| * Technical requirements for safety and quality are not up-to-date | ◉ | ○ | ○ | ○ | ○ |
| * There are substances of human origin that should be in the scope of the legislation but currently are not (breast milk, fecal microbiota, serum eye drops etc.) | ◉ | ○ | ○ | ○ | ○ |
| * Divergent national approaches to oversight by authorities leads to unequal protection and lack of inter-Member State trust and barriers to BTC exchange | ◉ | ○ | ○ | ○ | ○ |
| * Donors of blood, tissues and cells are not adequately protected by the legislation | ◉ | ○ | ○ | ○ | ○ |
| * Children born from medically assisted reproduction techniques are not adequately protected | ○ | ○ | ○ | ○ | ◉ |
| * The requirements for authorising new ways of preparing and using blood, tissues and cells are not adequate, particularly because demonstration of efficacy and safety in the recipient is not required. | ◉ | ○ | ○ | ○ | ○ |
| * There are sometimes difficulties in defining the borderlines for novel BTC (used in transfusion, transplantation or assisted reproduction) with other regulatory frameworks | ◉ | ○ | ○ | ○ | ○ |
| * Current legislation has not proven adequate to protect EU patients from the risk of shortages or sudden supply disruption | ◉ | ○ | ○ | ○ | ○ |

Q2 Select up to 4 problems to which you would give highest priority

*at most 4 choice(s)*

- [x] Technical requirements for safety and quality are not up-to-date
- [x] There are substances of human origin that should be in the scope of the legislation but currently are not (breast milk, fecal microbiota, serum eye drops etc.)
- [ ] Divergent national approaches to oversight by authorities leads to unequal protection and lack of inter-Member State trust
- [x] Donors of blood, tissues and cells are not adequately protected by the legislation
- [ ] Children born from medically assisted reproduction techniques are not adequately protected
- [ ] The requirements for authorising new ways of preparing and using blood, tissues and cells are not adequate, particularly because demonstration of efficacy and safety in the recipient is not required.
- [x] There are sometimes difficulties in defining the borderlines for novel BTC (used in transfusion, transplantation or assisted reproduction) with other regulatory frameworks
- [ ] Current legislation has not proven adequate to protect EU patients from the risk of shortages or sudden supply disruption

Q3 How did, in your view, the Covid-19 pandemic influence the evaluation conclusions?

*at most 8 answered row(s)*

| The pandemic made them: | Stronger | Unchanged | Weaker | No answer |
|---|---|---|---|---|
| * Technical requirements for safety and quality are not up-to-date | ◉ | ○ | ○ | ○ |
| * There are substances of human origin that should be in the scope of the legislation but currently are not (breast milk, fecal microbiota, serum eye drops etc.) | ○ | ◉ | ○ | ○ |
| * Divergent national approaches to oversight by authorities leads to unequal protection and lack of inter-Member State trust | ○ | ◉ | ○ | ○ |
| * Donors of blood, tissues and cells are not adequately protected by the legislation | ○ | ◉ | ○ | ○ |

| | | | | |
|---|---|---|---|---|
| * Children born from medically assisted reproduction techniques are not adequately protected | ○ | ○ | ○ | ◉ |
| * The requirements for authorising new ways of preparing and using blood, tissues and cells are not adequate, particularly because demonstration of efficacy and safety in the recipient is not required. | ○ | ◉ | ○ | ○ |
| * There are sometimes difficulties in defining the borderlines for novel BTC (used in transfusion, transplantation and assisted reproduction) with other regulatory frameworks | ○ | ◉ | ○ | ○ |
| * Current legislation has not proven adequate to protect EU patients from the risk of shortages or sudden supply disruption | ○ | ◉ | ○ | ○ |

### Q4 Are there other lessons learned from the Covid-19 pandemic that should be taken into account in the revision of the BTC legislation? If so, please describe.

*1500 character(s) maximum*

The pandemic highlighted problems that we see with the yearly influenza epidemics. It illustrated that the donor base must be larger than that needed in non-epidemic periods so that it will be adequate even with the loss of sick donors during epidemic/pandemic situations. The EU legislation must state the responsibility of Member States to effectively provide the recruitment and retention of a large donor population.

The COVID-19 crisis has demonstrated the importance of contingency planning to respond adequately and quickly to crisis as pandemic and other disasters

## Keeping EU technical requirements up to date with scientific and medical knowledge and practice

The EU legislation includes many rules regarding technical issues such as who can donate, what tests must be carried out on donors, what quality criteria should be met for the blood, tissues and cells that are supplied to hospitals and clinics, which types of adverse occurrences should be notified to authorities, etc. According to the evaluation, many of these rules are currently out of date. The evaluation also concluded that the rules should be extended to include donor protection and the protection of children born from medically assisted reproduction.
The Commission is considering three possible options for setting and updating these technical rules:
1. By **professionals**: the blood and tissue centres would conduct their own risk assessments and establish rules based on the conclusions, together with professional society guidance. This process would be reviewed for approval by inspectors from the national authority.
2. EU law would require that professionals follow the rules and guidance of named **expert bodies** such as ECDC and EDQM , in consultation with professional associations.

3. All detailed technical requirements would be described in **EU legislation** and kept up-to-date with regular amendments.

Q5 Who should set out these technical rules to effectively achieve up-to-date safety and quality rules, based on good science? (Consider the time required to update the rules, including during crises, their quality as well as whether EU harmonisation is essential or not)

| | Professionals | Expert bodies | EU law | No answer |
|---|---|---|---|---|
| * Rules on donor suitability and testing | ○ | ◉ | ○ | ○ |
| * Rules on donation frequency and donor monitoring. | ○ | ◉ | ○ | ○ |
| * Rules on quality management by providers of blood, tissues and cells (air quality requirements, documentation, quality control testing, training etc.) | ○ | ◉ | ○ | ○ |
| * Rules on the technical characteristics of blood, tissues and cells provided for patients (e.g. volume, cell numbers, labelling) | ○ | ◉ | ○ | ○ |
| * Criteria and templates for reporting and investigation of adverse reactions and events to authorities. | ○ | ◉ | ○ | ○ |
| * Rules for the development of new processing methods or new clinical uses of blood, tissues and cells | ○ | ◉ | ○ | ○ |

Q6 In general, which of these options, in your view, would overall be most **cost-effective**?

| | Very | Quite | Rather not | Not at all | No answer |
|---|---|---|---|---|---|
| * Professionals | ○ | ○ | ◉ | ○ | ○ |
| * Expert bodies | ◉ | ○ | ○ | ○ | ○ |
| * EU law | ○ | ○ | ◉ | ○ | ○ |

The BTC evaluation showed that, over time, many new substances of human origin being used in patients do not fall within the scope of the BTC legislation. Some fall wholly or partially under other frameworks nationally and some are unregulated at the EU level.

Q7 In which of the following cases do you think that technical rules for safety and quality should be **included in the scope** of the BTC legislation?

| | Only for donation and testing | For all aspects from donation to distribution | No answer |
|---|---|---|---|

| | | | |
|---|---|---|---|
| * Fecal microbiota transplants | ○ | ◉ | ○ |
| * Donated human breast milk | ○ | ○ | ◉ |
| * Serum eye drops | ○ | ◉ | ○ |
| * Blood, tissues or cells used for cosmetic/esthetic purposes | ○ | ◉ | ○ |
| * Blood, tissues or cells removed from a patient, processed and returned to the patient at the bedside or during their surgery, without falling under a different legislative framework | ○ | ◉ | ○ |
| Others | ○ | ◉ | ○ |

Please provide a description of the other substances you consider should be included in this legislation and explain why.

*Text of 1 to 2000 characters will be accepted*

Platelet rich plasma : for all aspects from donation to distribution
Fibrin glue/fibrogen glue : for all aspects from donation to distribution

Q8 If you have further comments on the technical rules for safety and quality of blood, tissues and cells and other substances of human origin, please enter them here.

*Text of 1 to 2000 characters will be accepted*

The European Directives should concern solely the general principles and refer to the technical details of the EDQM guide (revised regularly) and ECDC recommendations taking into consideration epidemiological changes.

Epidemiological developments are transient by nature, so it is difficult to foresee every situation in the legislation. While the activities of ECDC in the field of SoHO safety has developed since 2010, there is still no formal mandate in the Blood Directives defining ECDC role in that regard, and ECDC recommendations are not mandatory for national competent authorities. This should be clarified in the next Directives. The Directives should include a coordination mechanism to deal with emergent threats in the field of blood safety (and other substances of human origin) in line with the mechanisms proposed in other proposals for a regulation (mandate of ECDC and cross-border threats) currently being discussed.

## Improving oversight of blood, tissue and cell activities

The evaluation indicated that variable national approaches to oversight of blood, tissue and cell activities in Member States results in a lack of trust and creates barriers to the exchange of blood, tissues and cells between Member States.

Q9 What would be the impact of introducing oversight principles for authorities in EU legislation. The principles might address independence of inspectors, conflicts of interest, and competency requirements for staff in authorities.

8

Q10 Would audits by the European Commission of Member State competent authority control systems (inspection, vigilance, reporting) improve trust and inter-Member State exchange of blood, tissues and cells?

8

Q11 Would greater collaboration between Member State competent authorities (e. g. joint inspections,  peer audits of inspections improve effectiveness of oversight and increase inter-Member state exchange of blood, tissues and cells?

6

Q12 Would an EU programme of training of staff in national/regional authorities to agreed guidelines improve effectiveness of oversight and increase inter-Member state exchange of blood, tissues and cells?

8

* Q13 For questions 9 to 12, do you see any risks or potential negative impacts?

- (●) Yes
- ( ) No
- ( ) No answer

Please describe the risk or negative impact, specifying which question you refer to.

*1500 character(s) maximum*

As a general comment, the proposition will bring an increase in costs and complexity to the implementation. The risk is that it will cost more that it is effective and only increase bureaucracy.
Additionally, the frequency of inspections should be unified in the EU as well as the extent of the inspection.

Q14 If you have further comments on oversight of the blood, tissues and cells sector, please enter them here.

*Text of 1 to 2000 characters will be accepted*

## Supporting innovation for patient benefit

The BTC evaluation found that innovation was not facilitated optimally. In particular, only laboratory validation of new processing methods is required (no animal or clinical studies to demonstrate safety and efficacy in the patient).

* Q15 Should legal requirements be introduced in EU legislation for demonstrating safety, quality and efficacy when blood, tissues or cells are prepared or used in new ways?

- (●) Yes
- ( ) No
- ( ) No answer

* Q16 Are you aware of cases where blood, tissues and cells are used to treat patients, without proven clinical benefit?

- (●) Yes
- ( ) No

Please describe the case(s) you are aware of briefly

*Text of 1 to 2000 characters will be accepted*

A good example is the COVID19 pandemic. At the start no-one knew if convalescent plasma would be effective. Now it seems that there is a need for certain criteria to be effective (high level of neutralizing antibodies and application in the first days with clinical signs). In such situation, it is important to be able to try a new treatment, even if it impossible in the early stages of an epidemic to measure certain qualities simply because the tests were not invented yet.
In the field of stem cells, claims for effectiveness are often unsubstantiated as well as for innovations in the collection, preparation, storage of BTC without stringent authorization measures.
Another example if the off-label use of intravenous immunoglobulins, albumin, and the surgical use of platelet rich-plasma. Regarding blood components, especially fresh frozen plasma, many hospitals do not always use them in the most appropriate way as their use is not always back up by scientific evidence of efficacy.

Member States are responsible for deciding the regulatory status of products/substances. They might classify as blood, tissues and cells (Substances of Human Origin) or under another legal framework such as the pharmaceutical or medical device frameworks. EU level regulatory advice can be sought on whether the legislation on Advanced Therapy Medicinal Products would apply (from the Committee for Advanced Therapies) and on whether the medical device legislation would apply (from an expert group of medical device authorities).

* Q17 Are you aware of cases where the regulatory classification of a substance of human origin is unclear?

- (●) Yes
- ( ) No

Please provide information on case(s) you are aware of

| | Description of the product/substance | The regulatory framework it borders | The impact of this for patients |
|---|---|---|---|
| 1 | Stem cell based suspension used for treating wounds, injuries and skin diseases | BTC vs. medicinal products vs ATMP | |
| 2 | Isolated hepatocytes (without expansion) | T&C vs. ATMP | |
| 3 | Serum eye drops | Blood vs. T&C vs. Medicinal products | |

* Q18 Do you consider that there are substances/products being regulated under one legal framework but would be better regulated under another?

- ○ Yes
- ◉ No
- ○ No answer

Q19 How would you assess the impact of a new EU level structure or committee to advise Member States on whether a substance falls under the BTC legislation or not, equivalent to those for ATMPs and medical devices?

9

If you have further comments on your answer please enter them here

*2000 character(s) maximum*

We are in favour of the creation of such a structure as long as its opinions remain non-binding and the final choice remains within the hand of the national competent authority. We believe such a structure will help competent authorities and expert bodies

* Q20 If an EU level structure or committee as described in Q19 were established, do you consider that it should co-ordinate decisions with the equivalent committees in the medicinal product and medical device frameworks?

- ◉ Yes
- ○ No
- ○ No answer

*

Q21 Are the donation, procurement and testing provisions for blood, tissues and cells that are used to manufacture medicinal products or medical devices adequate?

- ○ Very inadequate
- ◉ Somewhat inadequate
- ○ Adequate
- ○ Somewhat too stringent
- ○ Much too stringent
- ○ I don't know

Please describe the specific provisions you consider should be changed and why.

*2000 character(s) maximum*

Considering the manufacture process to obtain PDMP (inactivation steps), some donor eligibility rules aimed to the protection of the recipients are to stringent. As well, frequency of plasmapheresis should be reduced according to the protein concentration in the donor's plasma

There are rules for certain pathogens that the donor may have had, that can be accepted for plasma donation but not for blood donation. The requirements for testing are often higher for plasma collectors than for blood establishments. This should be regulated by EDQM and/or ECDC.

Q22 If you have further comments on the subject of innovation in blood, tissues and cells please enter them here.

*Text of 1 to 2000 characters will be accepted*

The BTC legislation should cover all BTC products irrespective of their medical application (transfusion) and irrespective of their production and distribution.

## Sufficiency of supply of blood, tissues and cells

Although an objective of the BTC legislation was to ensure a sustainable supply of critical blood, tissues and cells, the evaluation showed that there are dependencies on certain Member States and on third countries for certain substances, in particular plasma for the manufacture of medicinal products. In addition, it was highlighted that there is a lack of legal provisions to ensure appropriate emergency measures in the event of sudden supply interruptions.

Q23 What effect would mandatory EU monitoring and **routine** reporting of sufficiency data (mandatory reporting of donations, distribution, import, export and use by BTC establishments to national authorities and to the Commission) have?

### Additional costs and administrative burden for establishments and authorities

4

### Transparency for citizens

7

Q24 What effect would sharing of reported donation and supply monitoring data on an EU platform have?

### Additional costs and administrative burden for establishments and authorities

5

### Information for policy makers (for vigilance and sufficiency measures)

5

Q25 What would be the impact of mandatory rapid notification to the national authority, and by them to other Member State authorities, in the case of a sudden significant drop in supply due to an incident or other crisis?

8

* Q26 What other measures could be introduced in legislation to address a sudden drop in supply due to a crisis?

- [x] Co-operative actions between blood and tissue establishments
- [x] Notification to the national authority with a response at Member State level
- [x] Notification to the EU level with collective response co-ordination
- [x] Other
- [ ] No answer

Please describe

*1000 character(s) maximum*

A crisis must be met appropriately depending if local, national or several Member States are concerned. Notifications should be mandatory for different levels of regional national or international crisis and this must be detailed in the legislation.
To mitigate a sudden supply disruption, the European Commission should adopt common rules establishing favourable conditions for exchanges between Member States (simplification of procedures, paperwork and formalities, etc)

Some blood and tissue establishments and competent authorities have in place preparedness/contingency plans for emergencies such as infectious disease outbreaks, natural disasters or military conflicts.

* Q27 What would be the effect of making such **preparedness/contingency plans** mandatory?

- ( ) It would raise many concerns
- ( ) It would raise some concerns
- ( ) It would have no impact
- (•) It would bring some improvements
- ( ) It would bring many improvements
- ( ) No answer

Q28 If you have further comments on the topic of ensuring a sustainable supply of essential blood, tissues and cells. Please list any other measure you consider would support this objective.

*Text of 1 to 2000 characters will be accepted*

Although it may be difficult to imagine solutions for several situations beforehand, going through the plan will give preparedness and may shine lights on parts of the process that must be improved before the actual crisis is here.
However, it should be noted that BEs already have contingency plans.

It should be noted that preparedness involves not only BTC but also institutions for microbiology, for testing of blood, etc.  Such things can be coordinated in a contingency plan.

Regarding monitoring supply and data, it would be useful as it would force the policy makers to be proactive instead of reactive, as the problem can be identified beforehand.

We should however be careful regarding the rapid notification mechanism and its scope. If it is unbalanced, we have the risk of having a “crying wolf”.

## General comments and supporting documents

### Q29 If you have general comments on other topics related to the revision of the EU legislation on blood, tissues and cells, please enter them here.

*Text of 1 to 2000 characters will be accepted*

The exchange of BTC should be facilitated by including in the new Directives the text of the Treaty No 26 of the Council of Europe “European agreement on the Exchange  of Therapeutic Substances  of Human Origin”. In principal, only the exchange of rare blood types (frequency < 1/250) should be considered and the routine exchange of blood is not advised, self-sufficiency should be organized on regional or national basis

You may upload one supporting document to your submission here.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

**a8faa87d-d80f-48f4-87e8-3816f8c6bc03/EBA_Position_Statement_Revision_EU_BTC_Directives_140421.pdf**

THANK YOU FOR YOUR CONTRIBUTION!

## Contact

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