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

Paul

* Surname

Ormel

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* Scope

- ( ) International
- ( ) Local
- (•) National
- ( ) Regional

* Level of governance

- ( ) Parliament
- (•) Authority
- ( ) Agency

* Organisation name

255 character(s) maximum

Ministry of Health, Welfare, and Sports

* 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.

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

between 1 and 12 choices

- [ ] Blood collection and/or blood banking
- [ ] Plasma collection for manufacture of medicinal products
- [ ] 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
- [x] 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
- [ ] 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
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- 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

Bonaire Saint Eustatius and Saba	Guadeloupe	Nauru	Switzerland
Bosnia and Herzegovina	Guam	Nepal	Syria
Botswana	Guatemala	Netherlands	Taiwan
Bouvet Island	Guernsey	New Caledonia	Tajikistan
Brazil	Guinea	New Zealand	Tanzania
British Indian Ocean Territory	Guinea-Bissau	Nicaragua	Thailand
British Virgin Islands	Guyana	Niger	The Gambia
Brunei	Haiti	Nigeria	Timor-Leste
Bulgaria	Heard Island and McDonald Islands	Niue	Togo
Burkina Faso	Honduras	Norfolk Island	Tokelau
Burundi	Hong Kong	Northern Mariana Islands	Tonga
Cambodia	Hungary	North Korea	Trinidad and Tobago
Cameroon	Iceland	North Macedonia	Tunisia
Canada	India	Norway	Turkey
Cape Verde	Indonesia	Oman	Turkmenistan
Cayman Islands	Iran	Pakistan	Turks and Caicos Islands
Central African Republic	Iraq	Palau	Tuvalu
Chad	Ireland	Palestine	Uganda
Chile	Isle of Man	Panama	Ukraine
China	Israel	Papua New Guinea	United Arab Emirates
Christmas Island	Italy	Paraguay	United Kingdom

- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

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.

◉ **Public**

Organisation details and respondent 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. Your name will also be published.

☑ I agree with the personal data protection provisions

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)

- ☑ 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 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

Several lessons can be learned from the COVID-19 crisis.
1. Harmonised crisiscoordination should be explored (referring to the ECDC guidance papers including donor deferral criteria, safety testing strategies & paper published by the EC concerning continuation of transport of essential SoHO in case of closed borders).
2. The need for European selfsufficiency is highlighted by the COVID-19 crisis during which patients and healthcare workers are afraid that third countries stop/limit their export to provide for their own residents.
3. Contingency plans are essential for a continuation of supply of SoHO for the patient

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

In order to make the scope future-proof, the scope should be defined to include substances of Human origin in general that are donated with the goal to apply it to patients.

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

In our responses in Q5 we aimed to allocate the specific subjects of regulation based on the expected degree of flexibility required. If developments on the short term can be expected, it is preferred to allocate them to expert organs. If it concerns ground rules on a more abstract level that need safeguarding, e.g. the necessity for tracebility criteria, they should be allocated to EU-legislation.

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.

7

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?

10

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?

7

* 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

These additions to the workload of inspectors would require an increase in capacity. Attention need to be given that developments like joint inspections do not result in a delay of corrective measures due to prolonged administrative processes.

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

Shared responsibility and transparency is needed between, and preferably joint inspections and jointly written reports by, inspectorates of MS's in case an entity is operating in multiple countries.

Differences in legislation and specifically financial incentives (for profit/not for profit), are of influence in the activities and organization of these multi-country operating entities that should be taken into consideration.

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

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	Adipose tissue derived mesenchymal cells derived from belly fat and transplanted to the knee of the same individual to support regeneration of cartilage	ATMP	It delays and possibly prevents the possibility of performing this treatment (on the short term).
2	White blood cells (leukocytes/lymphocytes)	Tissues and cells / Blood	-
3			

* 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

Please provide information on substances/products that you consider are not regulated under the most suitable framework

	Description of the product/substance	Why you consider it is not regulated under the most suitable framework
1	Microbiotal feces transplantation	Should be included in the SoHO legislation as it is a substance of human origin that shares similar risks for the patient in application as SoHO that are already regulated. E.g. the risk of transmission of diseases
2	Mother milk donated for the treatment of an unrelated patient	Should be included in the SoHO legislation as it is a substance of human origin that shares similar risks for the patient in application as SoHO that are already regulated. E.g. the risk of transmission of diseases
3	Some substances are currently classified as ATMP, although the regulatory framework is not suitable for these products, due to the high variability of the starting product, rapid developments in processing methods and small patient groups that make it impossible to perform the necessary clinical trials	Some ATMP might fit better in the SoHO legislation if authorization procedures are introduced for novel processing methods

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?

8

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

2000 character(s) maximum

The advice of the new EU level structure should be published and freely available for transparency purposes and thereby simultaneously stimulate harmonization between member states. The advice on substances should be addressed in expert meetings to consider inclusion of the product classification in the Guide.

* 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

It should be investigated if different (less stringent) rules can apply concerning donation, procurement and testing for tissues and cells for which at the moment of donation is already clear that they will be used to manufacture medicincal products or medical devices to avoid an overly legislative burden.

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

Donors should be protected against unnecessary donations. Donations of SoHO should be prevented or at least the donors or relatives of the donors should be well informed if at the moment of donation it is already known that there is only a slight chance for ever using the material for therapies.

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

7

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)

7

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?

6

* 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

- [ ] Other
- [ ] No answer

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

See our input in the targeted consultation. More direct measures are needed to ensure European sufficiency in supply of SoHO. We support the other approaches as described in the targeted consultation, including:
- Investment in establishment equipment and staff
- Promotional donation compains
- Provisions to allow export bans
- More trust, collaboration and exchanges between Member States
etc.

We do also suggest to add the following points:
1. Financial support programs similar to the one currently held to stimulate and enable collection of COVID-19 convalescent plasma could help and stimulate the collection of plasma in Europe.
2. Measures to ensure the proper functioning of the internal market, also in times of public health crises.
3. If the BTC sector as a whole would be made not-for-profit, this could give better control over safeguarding European self-sufficiency.

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

You may upload one supporting document to your submission here.

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

THANK YOU FOR YOUR CONTRIBUTION!

Contact

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