QUESTIONNAIRE FOR ADMINISTRATIONS, ASSOCIATIONS AND OTHER ORGANISATIONS

Fields marked with * are mandatory.

QUESTIONNAIRE FOR ADMINISTRATIONS[1], ASSOCIATIONS AND OTHER ORGANISATIONS[2]

GENERAL CONTEXT

The European Commission is conducting a comprehensive evaluation of the Union legislation on blood and on tissues and cells - Directives 2002/98/EC and 2004/23/EC, respectively ('the Main Directives') and their implementing (technical) Directives ('the Implementing Directives'), examining their functioning across the EU. In particular the evaluation is assessing the extent to which the Directives have met their original objectives and whether they remain fit for purpose, taking into account any relevant changes that have occurred since their adoption. The evaluation is expected to provide a sound evidence base which will be used to consider the need for any changes to the legislation.

The main objective of the Directives was to ensure a high level of human health protection through setting safety and quality standards for blood, tissues and cells for implementation by those providing these services and those overseeing them on behalf of citizens. Specifically, **the legislation aimed**:

- To ensure availability of safe blood, tissues and cells for EU citizens that need them;
- To provide citizens with transparent systems that would enhance public confidence, whether citizens are engaged as potential donors or recipients;
- Define clear lines of accountability for ensuring safety and quality both at service provider and health authority levels.

The specific objectives led to legislation with the following **operational objectives**:

1. To define technical safety and quality requirements for all stages of the chain from donor to recipient;

2. To ensure effective regulatory oversight of the blood, tissues and cells sectors;

3. To achieve a degree of harmonisation of safety and quality at Union level and facilitate EU-wide exchanges;

4. Establish a high level of legal certainty at Union level, i.e., to clarify how does the legislation on blood, tissues and cells relate to other Union legislation;

5. To achieve Union sufficiency through the encouragement of voluntary and unpaid donation and a strong public sector.

To achieve operational objective 1, the intention was to define legally binding minimum requirements for professionals that would address issues such as donor selection, testing, processing, storage and distribution and for blood establishments that would have to meet organisational provisions for personnel, quality management etc. These provisions would be adapted in line with scientific, technological and epidemiological changes, so that the public can support and trust in safety and quality in all steps from donation to application.

To achieve operational objectives 2 and 3, the legislation included provisions for the establishment of national competent authorities for each sector, working in an effective network across the Union. The authorities were tasked to establish programmes of inspection, authorisation and vigilance that would increase confidence and trust in safety and quality of blood, tissues and cells, including those circulating between Member States and those imported from outside the Union. The Commission would support the network through the organisation of meetings, the collection and publication of data and the provision of shared platforms for information exchanges (rapid alerts). This was to help ensure that risks are mitigated and unsafe activities are prevented.

Specific objective 4 was to be achieved through providing a clear legal scope and definitions of the blood, tissues and cells to be regulated by these sets of legislation.

To achieve operational objective 5, the legislation requires Member States to encourage voluntary and unpaid donation and the achievement of sufficiency through this type of donation. This aimed to increase public support and willingness to donate and reduce dependence on supply from 3rd countries.

The achievement of all 5 objectives would be supported via actions funded by the Public Health Programme.

OBJECTIVE OF THE CURRENT SURVEY

The aim of this targeted consultation is to gather detailed views and opinions to feed into the Evaluation of the blood, tissues and cells legislation. In particular, the survey seeks views and opinions on whether the legislation achieved its original objectives and to what extent it continues to be adequate today, taking into account any relevant technological, epidemiological, organisational or societal changes that have

occurred since its adoption. Views and opinions are also sought on the costs and burdens of implementing the legislation at an EU level and whether these have been justified by the results achieved and on the coherence of the Directives with other relevant EU legislation.

This questionnaire is addressed to administrations, associations, tissue and blood establishments, manufacturers of medicinal products using blood, cells or tissues as starting materials, and other organisations. Citizens are asked to fill in a separate non-specialised questionnaire, which can be found here: https://ec.europa.eu/eusurvey/runner/eulbtc

[1] For the purpose of this survey, administrations refer to both public administrations and private administrations with public service obligations

[2] For the purpose of this survey, associations and other organisations refer to professional associations, trade associations, professional,, academic and scientific societies and organisations representing the interests of specific stakeholders.

INFORMATION ABOUT THE RESPONDENT

Please provide the following information on your organisation/association/administration.

Select the country where your organisation/association/administration is based:

- ○ Austria
- ○ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czech Republic
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg
- ○ Malta
- ◉ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania

- Slovak Republic
- Slovenia
- Spain
- Sweden
- United Kingdom
- Other

Name of your organisation/association/administration:

Ministry of Health, Welfare and Sport

Please indicate whether your organisation/association/administration is listed in the Transparency Register?[3]
[3] In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

- Yes
- (•) No

The name of a contact person (please note that the name will not be made public and is meant for follow-up clarification only):

Mr. Frank J.M. van Linden

Please enter your e-mail address (this data will not be made public):

fj.v.linden@minvws.nl

Do you consent to the Commission publishing your replies

- (•) Yes (On behalf of my organisation/association/administration I consent to the publication of our replies and any other information provided, apart from my personal information, and declare that none of it is subject to copyright restrictions that prevent publication)
- No (The replies provided by my organisation/association/administration will not be published but may be used internally within the Commission. Note that even if this option is chosen, your contribution may still be subject to 'access to documents' requests.)(As set out in Regulation (EC) No 1049/2001, any EU citizen, natural, or legal person has a right of access to documents of the EU institutions, including those which they receive, subject to the principles, conditions and limits defined in this Regulation).

SECTION I: CHARACTERISATION OF THE RESPONDENT

*1.1. Main field of work of the responding organisation/association/administration

- (•) a) EU Public administration (Ministry of Health, competent authority etc.)
- b) Blood/Tissue Establishment and or/ Donor recruitment and procurement/collection
- c) Patients
- d) Donors

- ○ e) Healthcare provision (clinical use of blood, tissues, cells or medicinal products derived from these substances)
- ○ f) Manufacturers of downstream products using blood, tissues or cells as a starting material
- ○ g) Equipment or service provision
- ○ h) Academic or scientific research/development
- ○ i) Public administration outside the EU
- ○ j) Ethics
- ○ k) Other

*1.2. Please specify the geographic coverage of your organisation/association/administration

- ○ a) International/European
- ◉ b) National
- ○ c) Regional/local

*1.3. Are you an organisation/association/administration representing the interests of the stakeholders mentioned in question 1.1?

- ○ Yes
- ◉ No

*1.4. Please specify which sector is of interest for your organisation/association/administration *(one or more answers possible):*

- ☑ a) Blood and blood components
- ☑ b) Tissues for transplant
- ☑ c) Cells for transplant
- ☑ d) Tissues or cells for assisted reproduction
- ☑ e) Blood and/or blood components for the manufacture of medicinal products
- ☑ f) Tissues and/or cells for the manufacture of medicinal products
- ☑ g) Other

*1.4.a. For *Blood and blood components*, please specify which of the following is of most interest *(one or more answers possible):*

- ☑ i) Blood and blood components for transfusion
- ☑ ii) Other

*1.4.a.ii. If other, please specify:

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Plasma for fractionation
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*1.4.b. For *Tissues for transplant*, please specify which of the following is of most interest *(one or more answers possible):*

- ☑ i) Corneas and other tissues for eye surgery
- ☑ ii) Bone and/or soft tissues for reconstructive surgery
- ☑ iii) Skin
- ☑ iv) Heart valves and other cardiovascular tissues
- ☐ v) Other tissues

*1.4.c. For *Cells for transplant*, please specify which of the following is of most interest *(one or more answers possible):*

- [x] i) Bone marrow and/or peripheral blood stem cells
- [x] ii) Cord blood for allogeneic transplantation
- [x] iii) Cord blood for family or own use
- [ ] iv) Other cells

*1.4.d. For *Tissues or cells for assisted reproduction*, please specify which of the following is of most interest *(one or more answers possible):*

- [x] i) Sperm banking
- [x] ii) In vitro fertilisation
- [x] iii) Fertility preservation
- [ ] iv) Other

*1.4.g. If *other*, please specify:

No other

*1.5. Please specify the main activity in which you or your organisation is involved *(one or more answers possible):*

- [ ] i) Donor recruitment
- [ ] ii) Donor evaluation (medical history review)
- [ ] iii) Donation/procurement/collection
- [ ] iv) Donor testing
- [ ] v) Processing
- [ ] vi) Storage
- [ ] vii) Distribution
- [ ] viii) Import
- [x] ix) Other

*1.5.ix. If other, please specify:

Policy making, legal and regulatory framework

IMPORTANT INSTRUCTIONS:

> If you wish to provide answers to this questionnaire for **both** the blood and the tissues & cells sectors, please answer all questions.

> If you wish to provide answers **only for the blood and blood components** sector please reply only to Sections II to VI.

> If you wish to provide answers **only for the tissues and cells** sector, please go immediately to Section

VII and answer all questions from Sections VII to XI.

> If you wish to **upload documents** providing evidence that supports your responses, please do so in Section XII at the end of the questionnaire.

SECTION II: QUESTIONS ON EFFECTIVENESS – BLOOD AND BLOOD COMPONENTS

2.1. In your opinion to what extent has the legislation:

	A. To a great extent	B) To some extent	C) To a limited extent	D) No impact	D) I don't know
a) increased the quality and safety of blood and blood components?	○	◉	○	○	○
b) achieved a high level of human health protection for **recipients** of these substances	○	◉	○	○	○
c) achieved a high level of human health protection for **donors** of these substances?	○	○	○	◉	○

2.1.1. General comments on Safety and Quality of blood and blood components

The blood supply system in the Netherlands is regarded by all relevant parties as outstanding.

2.1.2.General comments on Human health protection for recipients or donors of these substances:

The blood supply system in the Netherlands is regarded by all relevant parties as outstanding.

2.2. To your knowledge has the legislation led to any unintended effects (positive or negative)?

- ◉ Yes
- ○ No

2.2.1. If yes, please describe:

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Positive:
- Many Dutch tissue establishments use the screening facilities of the Dutch
blood establishment Sanquin which enhances the efficiency of the SoHO
(substances of human origin) sector in general.

Negative:
- The testing requirements as laid down in the Blood Directives are not aligned
with the latest developments in science and technic. This leads to unnecessary
running of tests.
-  Inspection resources are necessary to fulfil the enforcement requirements.
The actual effort from the Inspectorate put in depends on internal
prioritisation.
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2.3. In your experience, have there been barriers preventing effective implementation of the legislation?

- ○ Yes
- ◉ No

2.4. In your opinion, do the rules on oversight (inspection, authorisation, vigilance) effectively ensure full application of the legislation?

- ○ Yes
- ◉ No

2.4.1. If no, please describe:

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- Inspection resources are necessary to fulfil the enforcement requirements.
The actual effort from the Inspectorate put in depends on internal
prioritisation.
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2.5. What, if any, are the challenges to maintaining compliance with the legislation? *(more than one can be selected)*

- ☑ a) Limited Competent Authority resources
- ☐ b) Limited resources at Blood Establishment level
- ☑ c) Requirements too stringent/detailed
- ☐ d) Requirements not specific enough
- ☑ e) Lack of clarity regarding scope
- ☑ f) Definitions inadequate
- ☐ g) Other

2.5.1. For any of the options selected in 2.5., please provide details

Ad a): Inspection resources are necessary to fulfil the enforcement requirements. The actual effort from the Inspectorate put in depends on internal prioritisation.
Ad c): The testing requirements as laid down in the Blood Directives are not aligned with the latest developments in science and technic. This leads to unnecessary running of tests, time and money.
Ad e): According to the scope (Article 2, section 1) of 2002/98 collection and testing requirements apply to blood(components), whatever their intended use. One might conclude that this even applies to blood drawn for diagnostics, which is highly unpractical.
Ad f): Mainly concerns definition of several blood products. Their seems to be overlap with legislation in the field of tissues and cells, medicinal products, medical devices. Definitions not aligned with developments in science and technics. It becomes apparent that it is difficult to determine the right legal framework for recently developed products like PRP.

2.6. To what extent, if any, has the legislation impacted on patient access to blood or blood components?

- ○ A) Increased patient access
- ◉ B) No impact on access
- ○ C) Reduced patient access
- ○ D) I don't know

2.6.1.General comments on patient access to these substances

SECTION III: QUESTIONS ON RELEVANCE – BLOOD AND BLOOD COMPONENTS

3.1. To what extent do you think the legislation is sufficiently adapted to:

	A) Fully adapted	B) Minor developments not addressed	C) Significant developments not addressed	D) Not suited to current situation	E) I don't know
a) developments related to donor eligibility (history screening)?	○	○	◉	○	○
b) scientific/technical developments related to donor testing for transmissible diseases?	○	○	◉	○	○
c) scientific developments related to blood and blood component processing (preparation and microbial inactivation), storage and distribution?	○	○	◉	○	○
d) epidemiological developments?	◉	○	○	○	○

3.1.a. If you answered B, C or D, please explain

Development in the selection criteria for donors, e.g. for risky behaviour, is giving rise to discussion about permanent or temperal deferral (Men having sex with other men (MSM)).

3.1.b. If you answered B, C or D, please explain

Testing requirements not aligned with latest developments, e.g. ID/MP-NAT

3.1.c. If you answered B, C or D, please explain

Scope of the Directive is not aligned with latest developments in processing, e. g. Platelet Rich Plasma/Fibrine, Serum Eye Drops.

3.2.Have there been developments to which the legislation is not adequately adapted other than those listed above?

- ○ Yes
- ◉ No

3.3. To what extent do you think the legislation is sufficiently adapted to societal changes in the sector such as commercialisation/internationalisation?

	A) Fully adapted	B) Minor changes not addressed	C) Significant changes not addressed	D) Current situation not reflected by the legislation	E) I don't know
a) Commercialisation	○	○	○	◉	○
b) Internationalisation	○	○	○	◉	○

3.3.a. If you answered B, C or D, please explain

Commercialisation of blood donation is addressed, mainly by encouraging voluntary and unpaid donations (Article 20 of 2002/98). Many plasma derived medicinal products from the USA though are prepared from paided donations. This triggers discussions within EU and Member States about paid donation.
The directive does not address commercial exploitation of the other activities in the blood sector like processing, testing, etc.

3.3.b. If you answered B, C or D, please explain

Internationalisation of blood sector:
- supply of blood for transplantation is national competence; health care sector though addresses the differences in prices between countries; this could effect donation willingness.
- plasma collection is still national competence while plasma derived medicinal products are marketed globally

Internationalisation in general (globalisation):
- People travelling more causes higher incidence and prevalence of infectious diseases in non-endemic countries; this leads to more deferrals and pressure on donor population.

3.4. Have there been societal changes in the sector **other** than commercialisation or internationalisation which are not adequately reflected or addressed in the legislation?

- (●) Yes
- ( ) No

3.4.1. If yes, please describe.

Some deferral criteria are based on social behaviour rather than facts, like MSM. This gives reason for dicsussion and puts pressure on donation willingness.

3.5. Are you aware of any gaps in terms of substances of human origin (substances not listed in Section 1 question 1.4) or activities (e.g. research, biobanking or other activities not listed in Section 1 question 1.5) that are not regulated by the Directives or other EU legislation?

- (●) Yes
- ( ) No

3.5.1. If yes, please describe.

Platelet Rich Plasma/Fibrine, Serum Eye Drops, haematopoetic stem cells, Donor Lymfocyten Infusion

3.6. Do you consider that there are substances or activities falling within the scope of the Directive 2002 /98/EC that should be removed?

- (●) Yes
- ( ) No

3.6.1. If yes, please describe.

The position of substances like Platelet Rich Plasma/Fibrine, Serum Eye Drops, haematopoetic stem cells, Donor Lymfocyten Infusion in relation to the scope of het directive should be discussed.

3.7. General comments on the relevance of the legislation today

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Reply 3.5.1 and 3.6.1 both are the same and refer back to the lack of clarity
regarding the scope of the legislation.
It could be discussed whether product which are not involved in transfusion
should be removed from the scope. This discussion should also be directed to
plasma for fractionation.
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SECTION IV: QUESTIONS ON EFFICIENCY – BLOOD AND BLOOD COMPONENTS

4.1. Did application of the legislation bring costs for you, your organisation or the stakeholders represented by your organisation that would not have been incurred without EU legislation?

- A) No additional costs
- B) Minor additional costs
- C) Significant additional costs
- D) I don't know

4.1.bc.If you answered B or C to the previous question, do you consider that the costs were justified by the benefits for patients?

- A) Costs fully justified by benefits
- B) Costs partially justified by benefits
- C) Costs not justified by benefits
- D) I don't know

4.1.bc.bc. If you answered B or C, please explain

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- The implementation of the directives in national legislation has lead to
costs.
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4.1.doc. If you have specific examples of data that support your response, please upload as a separate document in Section XII at the end of the questionnaire.

4.2. Are you aware of particular administrative or other burdens for **specific groups** of operators apart from your organisation or the organisations you represent?

- A) No additional costs
- B) Minor additional costs
- C) Significant additional costs
- D) I don't know

4.2.bc.If you answered B or C to the previous question, do you consider that the costs were justified by the benefits for patients?

- A) Costs fully justified by benefits
- B) Costs partially justified by benefits
- C) Costs not justified by benefits

- D) I don't know

4.2.bc.bc. If you answered B or C, please explain

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- Haemovigilance activities in health care institutions will lead to less
adverse reactions and events in patients, but a direct link with the costs for
haemavigilance activities (officers, organisation) might be difficult to prove.
- Because testing requirements are not aligned with latest developments
unnecessary tests are performed, which leads to unjustifiable costs.
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4.2.doc. If you have specific examples of data that support your response, please upload it as a separate document in Section XII at the end of the questionnaire.

4.3.General comments on the costs of implementing the legislation:

SECTION V: QUESTIONS ON COHERENCE – BLOOD AND BLOOD COMPONENTS

5.1. To what extent do you consider Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC to be consistent and coherent within their own provisions?

- (●) A. Full consistency across all blood and blood component Directives
- ( ) B. Minor inconsistencies between some of the Directives
- ( ) C. Significant inconsistencies between some of the Directives
- ( ) D. Major inconsistencies between many of the Directives
- ( ) E. I don't know

5.2. To what extent do you consider the legislation on blood and blood components to be consistent and coherent with other legislation on substances of human origin (i.e. on organs and on tissues and cells)?

- ( ) A. Full consistency across all blood and blood component Directives
- ( ) B. Minor inconsistencies between some of the Directives
- (●) C. Significant inconsistencies between some of the Directives
- ( ) D. Major inconsistencies between many of the Directives
- ( ) E. I don't know

5.2.bcd. If you answered B, C or D, please explain

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The minimum period of record keeping is different:
- blood: 15 years, article 13, 2002/98
- tissues and cells: 30 years, electronically storage allowed, article 8 2004/23
- medical devices: 15 years
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5.2.C. In which of the following provisions do you see inconsistencies?

- [ ] Scope
- [ ] Definitions
- [ ] Regulatory borderlines
- [ ] Oversight provisions – inspection and authorisation
- [ ] Oversight provisions - Vigilance
- [ ] Donor selection provisions
- [ ] Blood establishment or hospital blood bank provisions
- [x] Other

5.2.C. If Other, please specify

Record keeping

5.3. To what extent do you consider that the legislation to be coherent and consistent with other relevant Union legislation?

	A. Blood legislation is fully consistent and coherent	B. There are **some minor** inconsistencies or incoherencies in the blood legislation in relation to the other legislation	C. There are **some significant** inconsistencies or incoherencies in the blood legislation in relation to the other legislation	E. I don't know
a) Legislation on Communicable Diseases	◉	○	○	○
b) Legislation on Medical Devices	◉	○	○	○
c) Legislation on Medicinal Products	◉	○	○	○

5.4. To what extent do you consider that the legislation to be coherent and consistent with other relevant Union legislation regarding EU Charter of Fundamental Rights?

- (●) A. Blood legislation is fully consistent and coherent
- ( ) B. There are some minor inconsistencies or incoherencies in the blood legislation in relation to the Charter
- ( ) C. There are some significant inconsistencies or incoherencies in the blood legislation in relation to the Charter
- ( ) E. I don't know

5.5. To what extent do you consider that Directive 2002/98/EC, together with Directive 2001/83/EC, form an **effective** framework for ensuring the safety and quality of plasma derived medicinal products?

- (●) A. Adequately ensures the safety of the manufactured products
- ( ) B. The requirements in the blood legislation need minor modification to ensure safety and quality of manufactured products
- ( ) C. The requirements in the blood legislation need significant modification to ensure safety and quality of manufactured products
- ( ) D. The requirements in the blood legislation major modification to ensure safety and quality of manufactured products
- ( ) E. I don't know

5.6.To what extent do you consider that Directive 2002/98/EC, together with Directive 2001/83/EC, form an **efficient (cost effective)** framework for ensuring the safety and quality of plasma derived medicinal products?

- ( ) A. The framework is optimally efficient
- (●) B. The blood legislation introduces minor inefficiencies or unjustified burdens
- ( ) C. The blood legislation introduces significant inefficiencies or unjustified burdens
- ( ) D. The blood legislation introduces major inefficiencies or unjustified burdens
- ( ) E. I don't know

5.6.BCD. If you answered B C or D, please explain

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- Inspection resources are necessary to fulfil the enforcement requirements.
The actual effort from the Inspectorate put in depends on internal
prioritisation.
- Because testing requirements are not aligned with latest developments
unnecessary tests are performed, which leads to unjustifiable costs.
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5.6. To your knowledge, is the legislation coherent with other relevant international / third country approaches to the regulation of the quality and safety of blood and blood components?

- ( ) Yes
- (●) No

5.6.1. If no, please describe:

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Several plasma derived medicinal products from the USA are prepared from paided
blood donations which is not coherent with section 20 of Directive 2002/98
which asks EU member states to encourage voluntary and unpaid blood donations.
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5.7.General comments on Coherence:

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With all the evident and ongoing scientific and technical developments in the
field of substances of human origin it could be more coherent to regulate this
with a global legal framework rather then detailed technical requirements.
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SECTION VI: QUESTIONS ON EU ADDED VALUE – BLOOD AND BLOOD COMPONENTS

6.1. To what extent has the legislative framework at EU level added value to the regulation of blood and blood components across the EU-28 in a manner that could not have been achieved by measures taken at national or global level?

- A) Only EU legal provisions could have achieved the current safety and quality level
- B) EU legal provisions have greatly improved/accelerated what would have been achieved at national /global level
- C) EU legal provisions have somewhat improved/accelerated what would have been achieved at national /global level to a small extent
- (●) D) The same outcome would have been reached without EU legal provisions
- E) I don't know

6.2. To what extent do stricter national measures pose an obstacle to exchange of supplies between Member States?

- A) No impact on inter-MS supply
- B) Minor negative impact on inter-MS supply
- C) Significant negative impact on inter-MS supply
- (●) D) I don't know

6.3.General comments on EU Added Value:

SECTION VII: QUESTIONS ON EFFECTIVENESS – TISSUES AND CELLS

7.1. In your opinion...

	A. To a great extent	B. To some extent	C. To a limited extent	D. No impact	E. I don't know
To what extent has the legislation increased the quality and safety of tissues and cells?	○	(●)	○	○	○
To what extent has the legislation achieved a high level of human health protection for **recipients** of these substances	○	○	(●)	○	○
To what extent has the legislation achieved a high level of human health protection for **donors** of these substances?	○	○	○	(●)	○

7.2. General comments on Safety and Quality of tissues and cells

The legislation has irradicated tissue banks (mostly active with bone) that put financial gain over quality and safety.

7.3. General comments on human health protection for recipients or donors of these substances

The legislation has enhanced the already existing tracebility of tissues and cells in the donor - patient chain.

7.4. To your knowledge has the legislation led to any unintended effects (positive or negative)?

- (●) Yes
- ( ) No

7.4.1. If yes, please describe.

positive
- tissue banks are stimulated to use the high quality screeing laboratory of Sanquin, which is also positive for cost effectiveness.
negative:
- Inspection resources are necessary to fulfil the enforcement requirements. The actual effort from the Inspectorate put in depends on internal prioritisation.
- Tissue establishments are closed e.g. that could not fulfil the high standards of quality and safety which is regarded positive, but also leads to a decreased number of tissue suppliers.

7.5. In your experience, have there been barriers preventing effective implementation of the legislation?

- ( ) Yes
- (●) No

7.6. In your opinion, do the rules on oversight (inspection, authorisation, vigilance) effectively ensure full application of the legislation?

- (●) Yes
- ( ) No

7.7. What, if any, are the challenges to maintaining compliance with the legislation?

- [x] Competent Authority resources
- [ ] Limited resources at Tissue Establishment level
- [ ] Requirements too stringent/detailed
- [ ] Requirements not specific enough
- [x] Lack of clarity regarding scope

- [x] Definitions inadequate
- [ ] Other

7.7.2. For any of the options selected above, please provide details

```
- Resources: Inspection resources are necessary to fulfil the enforcement
requirements. The actual effort from the Inspectorate put in depends on
internal prioritisation.
- Scope: keeping up-to-date with scientific and technical developments (oocyt
/embryo storage and distribution, ATMP, personalised medicines, ....) is
challenging, as is the overlap with other legislation in the field of blood,
medicinal products (ATMP), medical devices.
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7.8. To what extent, if any, has the legislation impacted on patient access to tissues and cells?

- (●) A. Increased patient access
- ( ) B. No impact on access
- ( ) C. Reduced patient access
- ( ) D. I don't know

7.9. General comments on patient access to these substances

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T&C legislation has increased patient access to these products through a better
distribution.
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SECTION VIII: QUESTIONS ON RELEVANCE – TISSUES AND CELLS

8.1. To what extent do you think the legislation is sufficiently adapted to:

	A. Fully adapted	B. Minor developments not addressed	C. Significant developments not addressed	D. Not suited to current situation	E. I don't know
a) Developments related to donor eligibility (history screening)?	○	○	◉	○	○
b) Scientific/technical developments related to donor testing for transmissible diseases?	○	○	◉	○	○
c) Scientific developments related to tissue and cell processing (preparation and microbial inactivation), storage and distribution?	○	○	◉	○	○
d) Epidemiological developments?	◉	○	○	○	○

8.1.a. If you answered B, C or D to a), please explain

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Developments not addressed: donor screening in case of partner donation in the
field of ART (Artificial Reproductive Technics).
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8.1.b. If you answered B, C or D to b), please explain

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Developments not addressed: Testing requirements not aligned with latest
developments, e.g. ID/MP-NAT
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8.1.c. If you answered B, C or D to c), please explain

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Developments not addressed: ATMP development and production, storage and
distribution of oocytes and embryo's.
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8.2.Have there been developments to which the legislation is not adequately adapted other than those listed above?

- ○ Yes
- ◉ No

8.3. To what extent do you think the legislation is sufficiently adapted to societal changes in the sector such as commercialisation/internationalisation?

	A) Fully adapted	B) Minor changes not addressed	C) Significant changes not addressed	D) Current situation not reflected by the legislation	E) I don't know
a) Commercialisation	○	○	◉	○	○
b) Internationalisation	◉	○	○	○	○

8.3.a. If you answered B, C or D to a), please explain

```
Commercialisation:
- paid donation of oocytes,
- sperm and oocytes for surrogacy.
```

8.4. Have there been societal changes in the sector **other** than commercialisation or internationalisation which are not adequately reflected or addressed in the legislation?

- ○ Yes
- ◉ No

8.5. Do you consider that there are substances or activities falling within the scope of the Directive 2004 /23/EC that should be removed?

- (●) Yes
- ( ) No

8.5.1. If yes, please describe:

Preserving is not considered to be a seperately activity, but always part of either processing or storage.

8.6. General comments on the relevance of the legislation today

SECTION IX: QUESTIONS ON EFFICIENCY – TISSUES AND CELLS

9.1. Did application of the legislation bring costs for you, your organisation or the stakeholders represented by your organisation that would not have been incurred without EU legislation?

- ( ) A) No additional costs
- (●) B) Minor additional costs
- ( ) C) Significant additional costs
- ( ) D) I don't know

9.1.bc.If you answered B or C to the previous question, do you consider that the costs were justified by the benefits for patients?

- ( ) A) Costs fully justified by benefits
- (●) B) Costs partially justified by benefits
- ( ) C) Costs not justified by benefits
- ( ) D) I don't know

9.1.bc.bc. If you answered B or C, please explain

- In general, implementation of the directives in national legislation has lead to costs.
- More specific, the implementation of the Single European Code for tissues and cells (SEC; Directive (EU) 2015/565) is meant to lead to better access of patients to tissues and cells for human application, better tracebility, and higher quality and safety of these products. Tissue establishments and health care institutions might need to change relevant software/hardware systems to fulfil coding requirements.This probably will lead to certain expences.

9.1.doc. If you have specific examples of data that support your response, please upload it as a separate document in Section XII at the end of the questionnaire.

9.2. Are you aware of particular administrative or other burdens for **specific groups** of operators apart from your organisation or the organisations you represent?

- A) No additional costs
- (•) B) Minor additional costs
- C) Significant additional costs
- D) I don't know

9.2.bc.If you answered B or C to the previous question, do you consider that the costs were justified by the benefits for patients?

- A) Costs fully justified by benefits
- (•) B) Costs partially justified by benefits
- C) Costs not justified by benefits
- D) I don't know

9.2.bc.bc. If you answered B or C, please explain

Especially tissue establishments and health care institutions might need to change relevant software/hardware systems to fulfil coding requirements (SEC).

9.2.doc. If you have specific examples of data that support your response, please upload it as a separate document in Section XII at the end of the questionnaire.

9.3.General comments on the costs of implementing the legislation:

SECTION X: QUESTIONS ON COHERENCE – TISSUES AND CELLS

10.1. To what extent do you consider Directives 2004/23/EC, 2006/17/EC, 2006/86/EC and 2015/566/EC to be consistent and coherent within their own provisions?

- (•) A. Full consistency across all tissue and cell Directives
- B. Minor inconsistencies between some of the Directives
- C. Significant inconsistencies between some of the Directives
- D. Major inconsistencies between many of the Directives
- E. I don't know

10.2. To what extent do you consider the legislation on tissues and cells to be consistent and coherent with other legislation on substances of human origin (i.e. on organs and on blood)?

- ○ A. Full consistency across blood, tissues and cells and organs Directives
- ○ B. Minor inconsistencies between some of the Directives
- ◉ C. Significant inconsistencies between some of the Directives
- ○ D. Major inconsistencies between many of the Directives
- ○ E. I don't know

10.2.bcd. If you answered B, C or D, please explain

```
The minimum period of record keeping is different:
- blood: 15 years, article 13, 2002/98
- tissues and cells: 30 years, electronically storage allowed, article 8 2004/23
- medical devices: 15 years
```

10.2.C. In which of the following provisions do you see inconsistencies?

- ☐ Scope
- ☐ Definitions
- ☐ Regulatory borderlines
- ☐ Oversight provisions – inspection and authorisation
- ☐ Oversight provisions - Vigilance
- ☐ Donor selection provisions
- ☐ Blood establishment or hospital blood bank provisions
- ☑ Other

10.2.C. If Other, please specify

```
Record keeping:
```

10.2.D. In which of the following provisions do you see inconsistencies?

- ☐ Scope
- ☐ Definitions
- ☐ Regulatory borderlines
- ☐ Oversight provisions – inspection and authorisation
- ☐ Oversight provisions - Vigilance
- ☐ Donor selection provisions
- ☐ Blood establishment or hospital blood bank provisions
- ☐ Other

10.3. To what extent do you consider that the legislation to be coherent and consistent with other relevant Union legislation?

	A. Tissue and cell legislation is fully consistent	B. There are **some minor** inconsistencies or incoherencies in the tissue	C. There are **some significant** inconsistencies or incoherencies in the	

	and coherent	and cell legislation in relation to the other legislation	tissue and cell legislation in relation to the other legislation	E. I don't know
a) Legislation on Communicable Diseases	◉	○	○	○
b) Legislation on Medical Devices	○	◉	○	○
c) Legislation on Medicinal Products	◉	○	○	○

10.3.b.BC. If you answered B or C for *Legislation on Medical Devices*, please explain

Record keeping

10.3.b.B. For *Legislation on Medical Devices*, in which of the following provisions do you see inconsistencies?

- ☐ Testing or reporting requirements
- ☐ Vigilance and Surveillance communication requirements within or between Member States
- ☐ Role/mandate of EU agencies
- ☑ Other

10.3.b.B. If Other, please specify

Record keeping

10.4. To what extent do you consider that the legislation to be coherent and consistent with other relevant Union legislation regarding EU Charter of Fundamental Rights?

- ◉ A. Tissue and cell legislation is fully consistent and coherent
- ○ B. There are some minor inconsistencies or incoherencies in the tissue and cell legislation in relation to the Charter
- ○ C. There are some significant inconsistencies or incoherencies in the tissue and cell legislation in relation to the Charter
- ○ E. I don't know

10.5. To what extent do you consider that Directive 2004/23/EC, together with Directive 2001/83/EC, form an **effective** framework for ensuring the safety and quality of medicinal products manufactured from tissues and cells?

- ○ A. Adequately ensures the safety of the manufactured products

- B. The requirements in the tissue and cell legislation need minor modification to ensure safety and quality of manufactured products
- C. The requirements in the tissue and cell legislation need significant modification to ensure safety and quality of manufactured products
- D. The requirements in the tissue and cell legislation major modification to ensure safety and quality of manufactured products
- E. I don't know

10.5.BCD. If you answered B C or D, please explain

```
Legal coverage of tissues and cells that are used for production of ATMP is not
cleary elaborated in Directives 2004/23 and 2001/83.
```

10.6.To what extent do you consider that Directive 2004/23/EC, together with Directive 2001/83/EC, form an **efficient (cost effective)** framework for ensuring the safety and quality of medicinal products manufactured from tissues and cells?

- A. The framework is optimally efficient
- B. The tissue and cell legislation introduces minor inefficiencies or unjustified burdens
- C. The tissue and cell legislation introduces significant inefficiencies or unjustified burdens
- D. The tissue and cell legislation introduces major inefficiencies or unjustified burdens
- E. I don't know

10.6. To your knowledge, is the legislation coherent with other relevant international / third country approaches to the regulation of the quality and safety of tissues and cells?

- Yes
- No

10.6.1. If no, please describe:

```
Donor selection criteria for malignities applied in third countries (e.g. USA)
differ from the criteria used in EU.
```

10.7.General comments on Coherence:

```
With all the evident and ongoing scientific and technical developments in the
field of substances of human origin it could be more coherent to regulate this
with a global legal framework rather then detailed technical requirements.
```

SECTION XI: QUESTIONS ON EU ADDED VALUE – TISSUES AND CELLS

11.1. To what extent has the legislative framework at EU level added value to the regulation of tissues and cells across the EU-28 in a manner that could not have been achieved by measures taken at national or global level?

- A. Only EU legal provisions could have achieved the current safety and quality level
- (●) B. EU legal provisions have greatly improved/accelerated what would have been achieved at national /global level
- C. EU legal provisions have somewhat improved/accelerated what would have been achieved at national /global level to a small extent
- D. The same outcome would have been reached without EU legal provisions
- E. I don't know

11.2. To what extent do stricter national measures pose an obstacle to exchange of supplies between Member States?

- A. No impact on inter-MS supply
- (●) B. Minor negative impact on inter-MS supply
- C. Significant negative impact on inter-MS supply
- D. I don't know

11.3. General comments on EU Added Value:

```
Comments to 11.2
- In Germany all tissues and cells are considerd medicinal product, regulated
by 2001/83. Marketing of tissues and cells in Germany from other Member States
is restricted.
- Some Member States only allow distribution within EU (from to other Member
States) while distribution is mostly regarded as "delivery to end-user". This
leads to restricted distribution between different Member States.
```

SECTION XII: Uploading of Documents with Supporting Evidence

Upload documents as pdf files. Please include the Section and Question number in the name of the file along with an abbreviation of your organisation's name.

Please upload your file

Please upload your file

Please upload your file