RESPONSES TO OPEN CONSULTATION
on Draft Technical Requirements for blood and blood components

ANNEX I
Information requirements

	Section	Original text	Proposed modification	Justification
Spain	General		It should be made a clear differentiation between donors who come for the first time and usual donors on both the information to be provided and the information that should be required from the donors.	Foster the maintenance of donors
Czech Republic	General	A. Information To Be Provided To Donors	No comments / questions	
Denmark	Heading	A. Information to be provided to donors	Insert the text "*at every donation*"	For the avoidance of doubt
Finland	Heading	"	Information to be provided to donors at every donation	Avoidance of doubt
France EFS	Heading	"	Change to *information to be provided to donors <u>at every donation</u>*	For the avoidance of doubt
France Afssaps	**Heading**	Information to be provided to donors	Information to be provided to donors **<u>at every donation</u>**	For the avoidance of doubt
Portugal	Heading	"	A Information to be provided to donors at every donation	To avoid doubt
United Kingdom *UK Joint Professional Advisory Committee*	Heading	"	Insert **the text** "*at every donation*"	For the avoidance of doubt
Ireland, Luxembourg, Netherlands, EBA	Heading	"	Information to be provided to donors <u>at every donation</u>	For the avoidance of doubt

	Section	Original text	Proposed modification	Justification
WHO Regional Office for Europe	Item 1	Accurate but generally understandable educational materials about the essential nature of blood, the products derived from it and the important benefits to patients of blood and plasma donations	Add: information about blood donation procedures	The potential donors should be informed since the beginning on the specific process to undergo and the existing options
France EFS	Item 2	The reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of AIDS, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;	*Replace with* *The reasons for requiring an examination, medical history and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the significance of informed consent, self deferral and temporary and permanent deferral***.**	No need to provide information on the signs and symptoms of AIDS; the term "physical examination" implies more than is required.
France **Afssap2**	Item 2	The reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of AIDS, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;	**Replace** with The reasons for requiring **an examination,** medical history and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood **components;** the significance of informed consent, self deferral and temporary and permanent deferral.	No need to provide information on the signs and symptoms of AIDS; the term "physical examination" implies more than is required.

	Section	Original text	Proposed modification	Justification
United Kingdom *Uk Joint Professional Advisory Committee*	Item 2	“	*Replace **with** “ The reasons for requiring a medical history, health check and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the significance of ‘informed consent’, self-deferral, and temporary and permanent deferral.*	A physical examination is not the correct terminology for the type of health check that is required before every donation. It is not necessary to specify the signs and symptoms of A|IDS as this forms part of the information on the risks of infectious diseases that may be transmitted by blood and blood products.
United Kingdom *UK Forum*	Item 2	“	Remove: “physical examination”, “signs and symptoms of AIDS	”
EMEA	Item 2	“	The reasons for requiring a medical history, physical examination, and the testing of donations; the reasons for temporary and permanent deferral;	The information on the risk of infectious diseases that may be transmitted by blood and blood products is covered in point 5. Informed consent would fit well with point 6. Self-deferral is already mentioned under point 7. The early symptoms of AIDS and hepatitis cannot be distinguished from flu or a simple cold. Therefore, such information may cause harm without a benefit of increasing blood safety. The important issue is information on how to avoid transmission.
Ireland, Luxembourg, Netherlands, EBA	Item 2	“	*Replace with* *The reasons for requiring an examination, medical history and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the significance of informed consent, self deferral and temporary and permanent deferral.*	No need to provide information on the signs and symptoms of AIDS; the term “physical examination” implies more than is required.
Poland	Item 2	“	The reasons for requiring - add: an examination, cancel: physical examination	

	Section	Original text	Proposed modification	Justification
EMEA	Item 5	The reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV /AIDS, hepatitis, drug addiction and the use and abuse of drugs;	Information on the risk of infectious diseases that may be transmitted by blood and blood products; the reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV /AIDS, hepatitis, drug addiction and the use and abuse of drugs; information on the different forms of hepatitis;	See comment above on point 2. In addition, as the deferral criteria are different for different forms of hepatitis, it would be useful to provide information on the different forms.
France Afssaps	Item 5	The reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV /AIDS, hepatitis, drug addiction and the use and abuse of drugs;	**Change** to The reasons why they should not donate which put recipients at risk **to contracte infectious deseases that may be transmitted by blood and blood components, such** HIV /AIDS, hepatitis, drug addiction, and the use and abuse of drugs	The term " unsafe sexual behaviour " in the original text is more restrictive.
EMEA	Item 6	The option of changing their mind about donating prior to proceeding further without any undue embarrassment or discomfort;	The significance of 'informed consent' and the option of changing their mind about donating prior to proceeding further without any undue embarrassment or discomfort;	See comment above on point 2.
EMEA	Item 8	The opportunity to ask questions at any time;	10. The opportunity to ask questions at any time;	It is clearer to have this as the last point.
Denmark	Item 9	The undertaking that if test results show evidence of any pathology, they will be contacted by the blood collection centre;	***Replace*** *with* ***"The undertaking that if test results show evidence of any abnormality of significance to the donor's health, the donor will be contacted through an appropriate mechanism."***	***Rationale:*** The proposed term "pathology" is imprecise; the blood collection centre may choose to have an independent practitioner contact the donor.
Spain	Item 9	The undertaking that if test results show evidence of any pathology,…	'… The existence of any alteration'	More appropriate term
France EFS	Item 9	"	Change to The undertaking that if test results show evidence of any abnormality of significance to the donor's health, the donor will be contacted through an appropriate mechanism.	The term "pathology" in the original text is imprecise; the blood collection centre may choose to have an independent practitioner contact the donor.

	Section	Original text	Proposed modification	Justification
France Afssaps	Item 9**.**	The undertaking that if test results show evidence of any pathology, they will be contacted by the blood collection center;	**Change** to The undertaking that if test results show evidence of any **abnormality of significance to the donor's health, the donor** will be contacted by the blood collection center;	The term "pathology" in the original text is imprecise
Portugal	Item 9.	"	9. The undertaking that if relevant abnormal finding during the donor evaluation or if test results show evidence of any abnormality	Clinical and laboratory abnormalities is enough to contact donor; it is not necessary that findings will be pathological
Finland	Item 9.	"	The undertaking that if test results show evidence of any abnormality of significance to the donor's health, the donor will be contacted through an appropriate mechanism	The proposed term "pathology" is imprecise; the blood collection centre may choose to have an independent practitioner contact the donor.
United Kingdom *UK Joint Professional Advisory Committee*	Item 9.	"	***Replace** with* ***"The undertaking that if test results show evidence of any abnormality of significance to the donor's health, the donor will be contacted through an appropriate mechanism."***	The proposed term "pathology" is imprecise; the blood collection centre may choose to have an independent practitioner contact the donor.
United Kingdom *UK Forum*	Item 9.	"	Add "relevant" before pathology	
Ireland, Luxembourg, Netherlands, EBA	Item 9.	"	Change to The undertaking that if test results show evidence of any abnormality of significance to the donor's health, the donor will be contacted through an appropriate mechanism.	The term "pathology" in the original text is imprecise; the blood collection centre may choose to have an independent practitioner contact the donor.

	Section	Original text	Proposed modification	Justification
EMEA	Item 9	“	The undertaking that if test results show evidence of any pathology, they will be informed and deferred from donation, as recommended in Annex II.2, for their own safety as well as that of potential recipients; prospective donors who object to being so informed should be excluded from the donation process;	Extend the text as in Council Recommendation 98/463/EC to include the important information that this will result in a deferral, and if don’t agree – exclude from donation. The text of the Council Recommendation leaves it more open as to who will contact the donor. (This should be a physician, who could also give some counselling.) Is the protection of donors within the scope of the Blood Directive or does Article 152.5 of the EU Treaty mean that this is the responsibility of the Member States? If it is the latter, “for their own safety as well as that of potential recipients” should be deleted from the text.
Greece	Item 10		**Delete: ….f**or those willing to participate in apheresis programmes, whether for plasma or cellular components.	
United Kingdom *UK Forum*	Item 10		Stop after … “associated risks”	
Poland	Item 10		…and associated risk – add: in particular	
IFBDO	Item 10	Specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in apheresis programmes, whether for plasma or cellular components	Specific information on the nature of the procedures involved in the donation process and associated risks , **the insurance of donors against these risks, and of the possibility** to participate in apheresis programmes, whether for plasma or cellular components	Insurance of donors should be specifically mentioned, and the risks involved with any donation should be carefully explained. The possibility of taking part in apheresis programme should be mentioned when relevant.

	Section	Original text	Proposed modification	Justification
France Afssaps	**New item after Irem 10**		Ajouter un point 11 : **la mention de la nécessité d'informer le centre de collecte de tout événement survenant en post-don susceptible de mettre en cause la sécurité du donneur, du receveur ou du composant sanguin.**	Sensibilisation du donneur à informer l'établissement de transfusion sanguine de tout événement post-don remettant en cause la sécurité transfusionnelle.

Denmark	B. Heading	Information To Be Obtained From Donors	Insert **the text** " *at every donation*"	***Rationale:*** for the avoidance of doubt**.**
France EFS	B. Heading	"	Change to I*nformation to be obtained from donors at every donation*	For the avoidance of doubt
France Afssaps	B. Heading	Information to be obtained from donors	Information to be obtained from donors *at every donation*	For the avoidance of doubt
Portugal	B. Heading	"	Information to be obtained from donors at every donation	To avoid doubt
Finland	B. Heading	"	Information to be obtained from donors at every donation	Avoidance of doubt
United Kingdom *UK Joint Professional Advisory Committee*	B. Heading	"	Insert the text " *at every donation*"	for the avoidance of doubt**.**
Ireland, Luxembourg, Netherlands, EBA	B. Heading	"	Change to *information to be obtained from donors at every donation*	For the avoidance of doubt

	Section	Original text	Proposed modification	Justification
Denmark	Item 1.	**Identification** Appropriate means of identification, providing - name (first and surname) - address - date of birth or alternative means allowing the donor to be uniquely identified.	*Delete:*"Appropriate means…uniquely identified" *Replace* with text: *"Personal data uniquely and unmistakably identifying the donor and provide a means to contact the donor."*	*Rationale:* Proposed text indicates the requirements for donor identification more accurately.
France EFS	Item. 1.	"	Replace with *Personal data uniquely and unmistakably identifying the donor and provide a means to contact the donor.*	Proposed modification indicates the requirements for donor identification more accurately.
France **Afssaps**	Item. 1.	Appropriate means of identification, providing - name (first and surname), - address, - date of birth, or alternative means allowing the donor to be uniquely identified	Moyens d'identification appropriés, comprenant : - nom (nom de **naissance** et prénom), - adresse, - date **et lieu** de naissance, ou d'autres moyens permettant une identification univoque du donneur	Précisions sur le nom et le lieu de naissance du donneur notamment pour la recherche de facteur de risque spécifique (ex paludisme)
Italy	Item. 1	Appropriate means of identification [….] or alternative means allowing the donor to be uniquely identified	Personal donor data uniquely and unmistakably identifying the donor and providing a means to contact him/her	The wording "*alternative means* [to *appropriate means*]" is misleading
Portugal	Item.1.	"	Uniquely and unmistakably identifying data of donor and a way to contact him (identity card and phone n.º)	This is na unmistakably identification
Finland	Item 1.	"	Personal data uniquely and unmistakably identifying the donor and provide a means to contact the donor.	Proposed text indicates the requirements for donor identification more accurately.
United Kingdom *UK Joint Professional Advisory Committee*	Item 1.	"	*Delete:* "Appropriate means…uniquely identified" *Replace* with text: *"Personal data uniquely and unmistakably identifying the donor and provide a means to contact the donor."*	Proposed text indicates the requirements for donor identification more accurately.

	Section	Original text	Proposed modification	Justification
United Kingdom *UK Forum*	Item. 1.	"	Change to: *Personal donor data which uniquely (including the country where the donation is made) identifies to donor and provides a means to contact the donor.*	
Poland	Item. 1	"	Change: *Personal donor data uniquely and unmistakably identifying the donor and provide a means to contact the donor*	
Ireland, Luxembourg, Netherlands, EBA	Item. 1.	"	Replace with *Personal data uniquely and unmistakably identifying the donor and provide a means to contact the donor.*	Proposed modification indicates the requirements for donor identification more accurately.
Denmark	Item. 2.	**Health and medical history** - any relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to themselves or a risk of transmitting diseases to others, by way of a written questionnaire addressing the criteria listed in Annex II and a personal interview with a trained health care staff member. Abnormal conditions should be referred to the physician-in-charge who should have the final say on whether blood should be collected from a donor. If the physician is in doubt, the donor should be deferred.	*Replace* proposed text with: *"Health and medical history, given on a questionnaire, and in personal interview performed by a a trained health care staff member, including relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as a risk of transmitting diseases, or health risks to themselves."*	*Rationale:* Proposed text is too prescriptive. Donors may be a risk to others for reasons other than the transmission of disease – because of medication, or antibodies to leucocytes for example; there is no reason for the physician-in-charge (a role not specified in the Directive) to be consulted on whether or not a donor is bled. The clinic staff should be trained and procedures defined for appropriate action where doubt exists as to donor eligibility.

	Section	Original text	Proposed modification	Justification
Greece	Item 2	"	Health and medical history, *given on a written questionnaire addressing the criteria listed in Annex II and in personal interview performed by a trained health care staff member including* relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to themselves or *to others, such as* a risk of transmitting diseases. ….	
Spain	Item 2	"	… Any doubt should be communicated to the doctor	In order to not make necessary the constant presence of the doctor
Italy	Item 2	….. Abnormal conditions should be referred [….] If the physician is in doubt, the donor should be deferred	*Cancelled*	Not appropriate under the heading "Information to be obtained from donors"
Finland	Item 2.	"	Health and medical history, given on a questionnaire, and in personal interview performed by a trained health care staff member, including relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as a risk of transmitting diseases, or health risks to themselves	Proposed text is too prescriptive. Donors may be a risk to others for reasons other than the transmission of disease – because of medication, or antibodies to leucocytes for example; there is no reason for the physician-in-charge (a role not specified in the Directive) to be consulted on whether or not a donor is bled. The clinic staff should be trained and procedures defined for appropriate action where doubt exists as to donor eligibility.
France EFS	Item. 2.	"	**Replace** with *Health and medical history, given on a questionnaire, and in personal interview performed by a trained health care staff member, including relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as a risk of transmitting diseases, or health risks to themselves*.	Original text is too prescriptive. Donors may be a risk to others for reasons other than the transmission of disease – because of medication, or antibodies to leucocytes for example; there is no reason for the physician-in-charge (a role not specified in the Directive) to be consulted on whether or not a donor is bled. The blood centre staff should be trained and procedures defined for appropriate action where doubt exists as to donor eligibility.

	Section	Original text	Proposed modification	Justification
United Kingdom *UK Joint Professional Advisory Committee*	Item 2	"	***Replace*** proposed text with: "***Health and medical history, given on a questionnaire, and in personal interview performed by a a trained health care staff member, including relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as a risk of transmitting diseases, or health risks to themselves."***	Proposed text is too prescriptive. Donors may be a risk to others for reasons other than the transmission of disease – because of medication, or antibodies to leucocytes for example; there is no reason for the physician-in-charge (a role not specified in the Directive) to be consulted on whether or not a donor is bled. The clinic staff should be trained and procedures defined for appropriate action where doubt exists as to donor eligibility.
United Kingdom *UK Forum*	Item 2	"	Change to: Health and medical history, given on a questionnaire and in personal interview by a trained health care staff member, including information which may assist in screening out persons whose donation could present a health risk to recipients, or where the act of donating could present a health risk to themselves.	
Poland	Item 2	"	Add: Deferred donors should be given a clear explanation of the reasons of deferral	
Ireland, Luxembourg, Netherlands, EBA	Item. 2	"	Replace with *Health and medical history, given on a questionnaire, and in personal interview performed by a trained health care staff member, including relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as a risk of transmitting diseases, or health risks to themselves.*	Original text is too prescriptive. Donors may be a risk to others for reasons other than the transmission of disease – because of medication, or antibodies to leucocytes for example; there is no reason for the physician-in-charge (a role not specified in the Directive) to be consulted on whether or not a donor is bled. The blood centre staff should be trained and procedures defined for appropriate action where doubt exists as to donor eligibility.
IG Plasma	Item 2.	" … a written questionnaire addressing the criteria listed in Annex II and a personal …	… a written questionnaire addressing the criteria listed in Annex II , respectively an abbreviated donor questionnaire for repeated plasma donors, and a personal …	Due to higher plasma donation frequency, a short donor questionnaire should be possible for repeated donors.

	Section	Original text	Proposed modification	Justification
PPTA	Item 2.	… a written questionnaire addressing the criteria listed in Annex II and a personal …	… a written questionnaire addressing the criteria listed in Annex II, respectively an abbreviated questionnaire for repeat plasma donors, and a personal …	Due to higher plasma donation frequency, an abbreviated donor questionnaire should be possible for repeat donors.
Spain	Item 3	"	To consider the signature in one single document	More operational
Denmark	Item. 3.	**Signature** - Signature, on the donor questionnaire, countersigned by the health care staff member conducting the interview under the responsibility of the responsible person, or subject to the approval of this responsible person; - Signature on a separate attestation, - to acknowledge - that educational materials provided have been read and understood, - that opportunity to ask questions has been presented, and - that satisfactory responses have been received. - to agree that his / her blood or plasma donation could be used for patients needing ---; and to indicate his/her informed consent of the wish to proceed with the donation process.	***Replace*** proposed text with: ***"Signature, on the donor questionnaire, countersigned by the health care staff member conducting the interview, to acknowledge*** – ***that educational materials provided have been read and understood,*** – ***that opportunity to ask questions has been presented'*** – ***that satisfactory responses have been received, and*** ***to indicate the donor's informed consent or the wish to proceed with the donation process,*** ***to affirm that all information provided by the donor is true to the best of his/her knowledge."***	***Rationale:*** The agreement that the blood donation could be used in another country is not required per se to ensure high quality in blood transfusion. If it is considered necessary by a Member State to include consent to this, then it can be made explicit in the information provided in that Member State. A final paragraph is required to indicate that the donor affirms that all information provided by him/her is true to the best of his/her knowledge. There is no reason for a separate attestation. Use of a single donor signature is widespread, and is not associated with any problems. Use of a separate attestation as suggested would necessitate addition requirements in document control and storage for many Member States, along with additional expense, for no reason whatsoever. Due to emerging new technologies it should be emphasised that electronic signatures (donor and personnel) should be accepted.

	Section	Original text	Proposed modification	Justification
Italy	Item 3	[….] Signature on a separate attestation …	*Cancelled*	Signed documents should be kept for years; two separate signed attestations entail a doubling of paper sheets and of space needed to keep them
Italy	Item 3	- [to agree that his/her blood or plasma donation could be used] …. in the country where the donation is made or in another country…	*Cancelled*	Information related to the use of donated blood should be provided to and not obtained from donors. If the paragraph dealing with the exportation of blood should be maintained, it would be appropriate in Section A.
France EFS	Item 3	“	**Replace** with Signature, on the donor questionnaire, countersigned by the health care staff member **conducting the interview,** - to acknowledge - that educational materials provided have been read and understood, - that opportunity to ask questions has been presented, and - that satisfactory responses have been received. - **to indicate the donor’s informed consent or the wish to proceed with the donation process**; - **to affirm that all information provided by the donor is true to the best of his/her knowledge.** **Appropriate electronic signatures may be accepted.**	The agreement that the blood donation could be used in another country is not required per se to ensure high quality in blood transfusion. If it is considered necessary by a Member State to include consent to this, then it can be made explicit in the information provided in that Member State. A final paragraph is required to indicate that the donor affirms that all information provided by him/her is true to the best of his/her knowledge. There is no reason for a separate attestation. Use of a single donor signature is widespread, and is not associated with any problems. Use of a separate attestation as suggested in the original text would necessitate addition requirements in document control and storage for many Member States, along with additional expense, for no reason whatsoever.
France Afssaps	Item. 3.	- **Signature**, on the donor questionnaire, countresigned by the health care staff member conducting the	Paragraphe nécessitant une clarification de rédaction. En tout cas, le questionnaire ne devrait pas être signé. - Supprimer la dernière partie de la 1ère phrase : « ou moyennant l’approbation de cette dernière ».	Est-ce volontaire d’indiquer « le personnel médical conduisant l’entretien » ? ; l’article 19 de la directive utilise le terme « professionnel de santé qualifié ».

	Section	Original text	Proposed modification	Justification
		interview under the responsability of the responsible person, or subject to the approval of this responsible		
Portugal	Item. 3.	"	Delete: "Signature on a separate attestation"	One signature is enough
Finland	Item 3	"	**Signature, on the donor questionnaire, countersigned by** *the health care staff member conducting the interview, to acknowledge* – *that educational materials provided have been read and understood,* – *that opportunity to ask questions has been presented'* – *that satisfactory responses have been received, and to indicate the donor's informed consent or the wish to proceed with the donation process,* *to affirm that all information provided by the donor is true to the best of his/her knowledge.*	The agreement that the blood donation could be used in another country is not required per se to ensure high quality in blood transfusion. If it is considered necessary by a Member State to include consent to this, then it can be made explicit in the information provided in that Member State. A final paragraph is required to indicate that the donor affirms that all information provided by him/her is true to the best of his/her knowledge. There is no reason for a separate attestation. Use of a single donor signature is widespread, and is not associated with any problems. Use of a separate attestation as suggested would necessitate addition requirements in document control and storage for many Member States, along with additional expense, for no reason whatsoever. **

	Section	Original text	Proposed modification	Justification
United Kingdom *UK Joint Professional Advisory Committee*	Item 3.	“	***Replace*** proposed text with: ***“Signature, on the donor questionnaire, countersigned by the health care staff member conducting the interview, to acknowledge*** – ***that educational materials provided have been read and understood,*** – ***that opportunity to ask questions has been presented’*** – ***that satisfactory responses have been received, and to indicate the donor’s informed consent or the wish to proceed with the donation process,*** ***to affirm that all information provided by the donor is true to the best of his/her knowledge.”***	The agreement that the blood donation could be used in another country is not required per se to ensure high quality in blood transfusion. If it is considered necessary by a Member State to include consent to this, then it can be made explicit in the information provided in that Member State. A final paragraph is required to indicate that the donor affirms that all information provided by him/her is true to the best of his/her knowledge. There is no reason for a separate attestation. Use of a single donor signature is widespread, and is not associated with any problems. Use of a separate attestation as suggested would necessitate addition requirements in document control and storage for many Member States, along with additional expense, for no reason whatsoever.
United Kingdom *UK Forum*	Item 3.	“	Change to: Donor signature on the questionnaire, countersigned by the health care staff member conducting the interview to acknowledge that a) the educational materials provided have been read and understood b) the opportunity to ask questions has been presented c) responses which enable a donation to be collected have been received) indicate that the donor has given informed consent to proceed with the donation.	

	Section	Original text	Proposed modification	Justification
Ireland, Luxembourg, Netherlands, EBA	Item. 3.	“	**Replace** with Signature, on the donor questionnaire, countersigned by the health care staff member **conducting the interview,** - to acknowledge - that educational materials provided have been read and understood, - that opportunity to ask questions has been presented, and - that satisfactory responses have been received. - **to indicate the donor’s informed consent or the wish to proceed with the donation process**; - **to affirm that all information provided by the donor is true to the best of his/her knowledge.** **Appropriate electronic signatures may be accepted.**	The agreement that the blood donation could be used in another country is not required per se to ensure high quality in blood transfusion. If it is considered necessary by a Member State to include consent to this, then it can be made explicit in the information provided in that Member State. A final paragraph is required to indicate that the donor affirms that all information provided by him/her is true to the best of his/her knowledge. There is no reason for a separate attestation. Use of a single donor signature is widespread, and is not associated with any problems. Use of a separate attestation as suggested in the original text would necessitate addition requirements in document control and storage for many Member States, along with additional expense, for no reason whatsoever.
SFVTT **(Société Française de vigilance et de thérapeutique transfusionnelle)**	Item. 3.	“		La signature obligatoire du donneur sur deux documents à chaque don. Cela n'apporte rien à la sécurité transfusionnelle et nous fera perdre sûrement quelques donneurs.
EMEA	Item. 3.	- to agree that his/her blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country,… and	to agree that his / her blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country, to which it would be transferred in accordance with the provisions of the legislation of the country where the donation is made and of the destination country; and	The transfer of the donation between countries will have to be in accordance with the legislation of the destination country as well as the country where the donation is made.

	Section	Original text	Proposed modification	Justification
IFBDO	Item 3.	- to agree that his/ her blood or plasma donation could be used for patients needing transfusion or blood products …, and - to indicate his/ her informed consent of the wish to proceed with the donation process.	Delete Delete	The donors have no right or obligations over the blood once donated. The donor shall answer the questionnaire to the best of his knowledge, but no sanctions shall be applied to the donor under criminal or civil law. The responsibility for the use of blood remains with the relevant blood centres only. If the donor wants to stop during the process, he/she shall not be bound by the "informed consent". And such an obligation could not be enforced either.