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D6.1 Questionnaire to investigate the import practices in EU Member States

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Description:

Questionnaire to collect regulatory information from EU Member States, to be used in 2019.

Product:

https://share.wmda.info/x/uQXkEw

Regulatory Questionnaire import practices EU Member States

Introduction

The EU has a common set of standards to ensure the quality and safety of:

- Organs for transplantation, and
- tissues and cells for human use, including reproductive cells

For EU registries to import cells into a EU Member State, the EU Member States must be able to ensure that cells imported under their licenses meet the quality and safety requirements set out in the EU tissues and cells Directive 2004/23/EC and its implementing Directives, including 2006/17/EC and 2006/86/EC.

This questionnaire will be sent out in 2019.

General information	
Organisation name:	
Organisation ION:	
Country:	
Year the registry started operations:	

Products		**Comments**
This organisation provides HPC, Marrow:	☐ Yes ☐ No	
This organisation provides HPC, Apheresis:	☐ Yes ☐ No	
This organisation provides HPC, Cord Blood:	☐ Yes ☐ No	
This organisation provides MNC, Apheresis:	☐ Yes ☐ No	
This organisation provides NC, Whole Blood:	☐ Yes ☐ No	
This organisation provides other products, if yes please specify:	☐ Yes ☐ No	
Number of national HPC products provided in 2018:	HPC-Marrow: HPC-Apheresis: HPC-Cord:	
Number of HPC products exported internationally in 2018:	HPC-Marrow: HPC-Apheresis: HPC-Cord:	

Licences and accreditations		**Comments**
Organisation is licensed/accredited by the Competent Authority:	☐ Yes ☐ No	
Name of Competent Authority:		
Date of last inspection:	YYYY/MM/DD	
Link to website of Competent Authority:		
Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry can be provided:	☐ Yes ☐ No	
The registry is WMDA Qualified or WMDA Accredited: *If yes, please specify:*	☐ WMDA Qualified ☐ WMDA Accredited ☐ Not WMDA Qualified/Accredited	
The registry is accredited by any other organisation: *If yes, please fill in the organisation:*	☐ Yes ☐ No	

Affiliated centre information	Comments	
How many affiliated donor centres does the registry work with?		
How often does the registry audit its donor centres?		
How many affiliated collection centres does the registry work with?		
How often does the registry audit its collection centres?		
How many affiliated cord blood banks does the registry work with?		
How often does the registry audit its cord blood banks?		
How many affiliated transplant centres does the registry work with?		
How often does the registry audit its transplant centres?		
How many affiliated IDM Testing Laboratories does the registry work with?		
How often does the registry audit its IDM Testing Laboratories?		
How many affiliated HLA/other DNA markers testing laboratories does the registry work with?		
How often does the registry audit its HLA/other DNA markers testing laboratories?		
The registry would be able to provide a full list of name/addresses of each affiliated and their licence/accreditation status, on request: *Tip: you can upload the full list here and make it available for the WMDA membership*	☐ Yes ☐ No	
The Cord Blood Banks are FACT-NetCord accredited: *If yes, which cord blood bank(s)?*	☐ Yes ☐ No	
The registry is able to provide a copy of all the certificates:	☐ Yes ☐ No	
Affiliated centres comply with WMDA Standards and applicable national regulations:	☐ Yes ☐ No	
The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations: *If yes, please specify these requirements:*	☐ Yes ☐ No	

Donor policy	
All donors are unpaid volunteers:	☐ Yes ☐ No
All donors are informed about donation process and associated risks:	☐ Yes ☐ No
Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff:	☐ Yes ☐ No
The registry has systems in place to protect and control access to donor/patient records:	☐ Yes ☐ No
The registry maintains donor anonymity:	☐ Yes ☐ No
The registry has detailed donor evaluation and exclusion criteria in place:	☐ Yes ☐ No
The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:	☐ Yes ☐ No

IDM Testing at donor workup (please fill in Yes, On Request, No, Test method)	YES	On request	NO	Test method	Timeframe before stem cell donation date (for donors) or Timeframe when the materials sample is taken for testing (for cords) (in number of days)
ALT/AST:	☐	☐	☐		
Chagas:	☐	☐	☐		
CMV IgG:	☐	☐	☐		
CMV IgM:	☐	☐	☐		
CMV Total:	☐	☐	☐		
EBV IgG:	☐	☐	☐		
EBV IgM:	☐	☐	☐		
HAV (NAT):	☐	☐	☐		
HBV (NAT):	☐	☐	☐		
HBc Ab:	☐	☐	☐		
HBs Ag:	☐	☐	☐		
HCV (NAT):	☐	☐	☐		
HCV Ab:	☐	☐	☐		
HEV (NAT):	☐	☐	☐		
HIV (NAT):	☐	☐	☐		
HIV-1 Ab:	☐	☐	☐		
HIV-2 Ab:	☐	☐	☐		
HIV p24:	☐	☐	☐		
HTLV-I:	☐	☐	☐		
HTLV-II:	☐	☐	☐		
Malaria:	☐	☐	☐		
HSV:	☐	☐	☐		
STS:	☐	☐	☐		
STS FTA-ABS:	☐	☐	☐		
Toxoplasmosis:	☐	☐	☐		
VZV:	☐	☐	☐		
WNV-NAT:	☐	☐	☐		
Other tests performed:	☐	☐	☐		

Testing *Please indicate whether the following are completed on the donor during the medical examination:*		**Comments**
The physical and medical exam at donor work up is performed by a medical doctor:	☐ Yes ☐ No	
All donor testing (at work up) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority:	☐ Yes ☐ No	
HLA typing for patient specific request is performed in an appropriately accredited laboratory:	☐ Yes ☐ No	
Sterility testing is performed on the adult donor product:	☐ Yes ☐ No	
Sterility testing is performed on the cord blood product:	☐ Yes ☐ No	
Screening questionnaire to exclude communicable disease:	☐ Yes ☐ No	
Screening questionnaire to exclude donors with 'high risk' lifestyles:	☐ Yes ☐ No	
Donor reliability identified by a medical doctor:	☐ Yes ☐ No	
Donor clearance to donate is confirmed by a medical doctor, following as a minimum the donor exclusion criteria in Annex 1 of EU Directive 2006/17/EC: The party providing the Cell Product must exclude Donors when: • They are pregnant; • They are breastfeeding; • There is the potential for transmission of inherited conditions; • There is evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration *Donor travel and exposure history and local infectious disease prevalence*; • There is presence on the Donor's body of physical signs implying a risk of transmissible disease(s); • There is a history of a disease of unknown aetiology; • There is a risk of transmission of diseases caused by prions; • There is systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated; • There is history of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the Cell Product; • There is recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist; • There is ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.	☐ Yes ☐ No	

Customs regulations		**Comments**
Are there any customs regulations to follow, or customs paperwork required, to import cell products to your country? *If yes, please specify:*	☐ Yes ☐ No	
Are there any customs regulations to follow, or customs paperwork required, to export cell products from your country? *If yes, please specify:*	☐ Yes ☐ No	
Are there any import regulations to follow, or paperwork required, to import cell products to your country? *If yes, please specify:*	☐ Yes ☐ No	
Are there any export regulations to follow, or paperwork required, to export cell products from your country? *If yes, please specify:*	☐ Yes ☐ No	

Reporting of Serious Adverse Events *Please indicate which of the following schemes for reporting Serious Adverse Events relating to either the Donor or the product the Registry participates in:*		**Comments**
Mandatory National Reporting Scheme:	☐ Yes ☐ No	
Voluntary National Reporting Scheme:	☐ Yes ☐ No	
WMDA SEAR/SPEAR Reporting Scheme:	☐ Yes ☐ No	
Will the registry notify the receiving Registry within ***24 hours*** of receiving information relating to any serious adverse event that could be considered to affect the patient receiving the product?	☐ Yes ☐ No	

Quality management		**Comments**
Do the registry maintain Standard Operating Procedures (SOPs) for your work?	☐ Yes ☐ No	
Would the registry be willing to provide these to WMDA or another registry upon request?	☐ Yes ☐ No	
Would the registry be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in?	☐ Yes ☐ No	
How many years are donor records retained relating to the medical exam and HPC collection process?		