Regulatory Survey ION-5391

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General

The information has been reviewed in year :	
Organisation name:	Poltransplant
Organisation ION:	ION-5391
Country:	Poland
Year the registry started operations:	

Products

		comment
Do you provide HPC, Marrow?	yes	
Do you provide HPC, Apheresis?	yes	
Do you provide HPC, Cord Blood?	yes	
Do you provide MNC, Apheresis?	no	
Do you provide NC, Whole Blood?	no	

Product quantity

Data valid for year	2018	
Number of products	**National**	**International**
HPC, Marrow products:	4	5
HPC, Apheresis:	48	34
HPC, Cord:	0	1

License

Organisation is licensed/accredited by the Competent Authority:	yes
Comment:	
Name of Competent Authority:	Ministry of Health
Date of last inspection:	2014
Link to website of Competent Authority:	www.mz.gov.pl
Can you provide the Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry ?	yes
Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited?	Not WMDA Qualified /Accredited
The registry is accredited by any other organisation:	
If yes, by which organisation?	

Affiliation

The registry works with the following number of affiliated donor centres:	
The registry audits its donor centres:	
The registry works with the following numer of affiliated collection centres:	
Ther registry audits its collection centres:	

The registry works with the following number of affiliated Cord Blood Banks:	
The registry audits its Cord Blood Banks:	
The registry works with the following number of affiliated transplant centres:	
The registry audits its transplant centres:	
The registry works with the following number of affiliated IDM Testing Laboratories:	
The registry audits its IDM Testing Laboratories:	
The registry works with the following number of affiliated HLA/other DNA markers testing laboratories:	
The registry audits 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:	
The Cord Blood Banks are FACT-NetCord accredited:	
If yes, the following Cord Blood Bank(s) are accredited:	
The registry is able to provide a copy of all the certificates:	
Affiliated centres comply with WMDA Standards and applicable national regulations:	yes
The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:	yes
If yes, what are these requirements?	

Donor policy

All donors are unpaid volunteers:	yes
All donors are informed about donation process and associated risks:	yes
Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff:	yes
The registry has systems in place to protect and control access to donor/patient records:	yes
The registry maintains donor anonymity:	yes
The registry has detailed donor evaluation and exclusion criteria in place:	yes
The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:	yes

IDM

IDM	Tested	Method	Days between test and sampling/workup
ALT/ASTALT/AST ratio, De-Ritis-Quotient	-		
ChagasChagas, T. cruzi	-		
CMV IgGCytomegalovirus (CMV) Antibody testing IgG	Yes		
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	Yes		
CMV TotalCytomegalovirus Total	On request		
EBV IgGEpstein-Barr Virus Antibody testing IgG	Yes		
EBV IgMEpstein-Barr Virus Antibody testing IgM	Yes		
HAV (NAT)Anti-hepatitis A virus nucleic acid testing	-		
HBV (NAT)Hepatitis B nucleic acid testing	On request		
HBc AbHepatitis B core antibody testing	Yes		
HBs AgHepatitis B Surface antigen testing	Yes		
HCV (NAT)Hepatitis C nucleic acid testing	On request		
HCV AbHepatitis C antibody testing	Yes		
HEV (NAT)Hepatitis E Virus nucleic acid testing	-		

HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	On request		
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	Yes		
HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	Yes		
HIV p24Human Immunodeficiency Virus p24 antigen testing	Yes		
HTLV-IHuman T-Lymphotropic Virus type I testing	No		
HTLV-IIHuman T-Lymphotropic Virus type II testing	No		
MalariaMalaria	-		
HSVHerpes Simplex Virus	-		
STSSerological tests for syphilis	Yes		
STS FTA-ABSSerological test for syphilis	On request		
ToxoplasmosisToxoplasmosis	-		
VZVVaricella Zoster Virus	-		
WNV-NATWest Nile Virus nucleic acid testing	No		
Other tests performed	-		

Testing

The physical and medical exam at donor workup is performed by a medical doctor:	
All donor testing (at workup) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority:	yes
HLA typing for patient specific request is performed in an appropriately accredited laboratory:	yes
Sterility testing is performed on the adult donor product:	yes
Sterility testing is performed on the cord blood product:	
Screening questionnaire to exclude communicable disease:	
Screening questionnaire to exclude donors with 'high risk' lifestyles:	
Donor reliability identified by a medical doctor:	
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.	

Customs regulations

Are there any customs regulations to follow, or customs paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	
Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify:	

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:	
- Mandatory National Reporting Scheme	
- Voluntary National Reporting Scheme	
- WMDA SEAR/SPEAR Reporting Scheme	
The registry will 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:	

Quality management

The registry does maintain Standard Operating Procedures for your work:	
The registry would be willing to provide these to WMDA or another registry upon request:	
The registry would be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in:	
Donor records relating to the medical exam and HPC collection process are the following number(s) of year(s) retained:	>20