Regulatory Survey ION-6939

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General

The information has been reviewed in year :	2024
Organisation name:	ZKRD - Zentrales Knochenmarkspender-Register Deutschland (Germany)
Organisation ION:	ION-6939
Country:	Germany
Year the registry started operations:	1992

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?	yes	
Do you provide NC, Whole Blood?	yes	

Product quantity

Data valid for year	2022	
Number of products	**National**	**International**
HPC, Marrow products:	182	90
HPC, Apheresis:	1837	811
HPC, Cord:	0	14

License

Organisation is licensed/accredited by the Competent Authority:	no
Comment:	
Name of Competent Authority:	
Date of last inspection:	
Link to website of Competent Authority:	
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?	WMDA Accredited
The registry is accredited by any other organisation:	yes
If yes, by which organisation?	ISO 9001 certified

Affiliation

The registry works with the following number of affiliated donor centres:	26
The registry audits its donor centres:	yes
The registry works with the following numer of affiliated collection centres:	67
Ther registry audits its collection centres:	Yes, paper audit, centers are audited by regulatory agency

The registry works with the following number of affiliated Cord Blood Banks:	5
The registry audits its Cord Blood Banks:	Yes, and banks audited by regulatory agency
The registry works with the following number of affiliated transplant centres:	75
The registry audits its transplant centres:	Yes, paper audit
The registry works with the following number of affiliated IDM Testing Laboratories:	IDM laboratories affiliated with DCs and CCs
The registry audits its IDM Testing Laboratories:	Verification of appropriate certification
The registry works with the following number of affiliated HLA/other DNA markers testing laboratories:	Laboratories affiliated with search and donor centers
The registry audits its HLA/other DNA markers testing laboratories:	Verification of appropriate certification
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:	DKMS, University Hospital Erlangen CBB
The registry is able to provide a copy of all the certificates:	yes
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?	Adherence to German Standards for Unrelated Blood Stem Cell Donations

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		30
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	Yes		30
CMV TotalCytomegalovirus Total	No		30
EBV IgGEpstein-Barr Virus Antibody testing IgG	Yes		30
EBV IgMEpstein-Barr Virus Antibody testing IgM	Yes		30
HAV (NAT)Anti-hepatitis A virus nucleic acid testing	No		
HBV (NAT)Hepatitis B nucleic acid testing	Yes		30
HBc AbHepatitis B core antibody testing	Yes		30
HBs AgHepatitis B Surface antigen testing	Yes		30

HCV (NAT)Hepatitis C nucleic acid testing	Yes		30
HCV AbHepatitis C antibody testing	Yes		
HEV (NAT)Hepatitis E Virus nucleic acid testing	Yes		30
HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	Yes		30
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	Yes		30
HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	Yes		30
HIV p24Human Immunodeficiency Virus p24 antigen testing	No		
HTLV-IHuman T-Lymphotropic Virus type I testing	Yes		30
HTLV-IIHuman T-Lymphotropic Virus type II testing	Yes		30
MalariaMalaria	No		
HSVHerpes Simplex Virus	No		
STSSerological tests for syphilis	Yes		30
STS FTA-ABSSerological test for syphilis	-		
ToxoplasmosisToxoplasmosis	Yes		30
VZVVaricella Zoster Virus	No		
WNV-NATWest Nile Virus nucleic acid testing	Yes		dependent on season, donor history
Other tests performed	Yes	Various IDMs dependent on donor (travel) history; tests and timeframe vary for cords	

Testing

The physical and medical exam at donor workup is performed by a medical doctor:	yes
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:	yes
Screening questionnaire to exclude communicable disease:	yes
Screening questionnaire to exclude donors with 'high risk' lifestyles:	yes
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.	yes

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:	Yes, is communicated during workup, forms provided by our registry
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	Yes, documents provided by our registry
Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify:	Yes, is requested during workup as needed (e.g. proof of licensing)
Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify:	Paperwork provided by our registry

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	yes
- Voluntary National Reporting Scheme	
- WMDA SEAR/SPEAR Reporting Scheme	yes
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:	yes

Quality management

The registry does maintain Standard Operating Procedures for your work:	yes
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:	30