Regulatory Survey ION-9935

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General

Organisation name:	DKMS BMST Foundation India
Organisation ION:	ION-9935
Country:	India
Year the registry started operations:	November 2015

Products		comment
Do you provide HPC, Marrow?	no	
Do you provide HPC, Apheresis?	yes	
Do you provide HPC, Cord Blood?	no	
Do you provide MNC, Apheresis?	yes	Donors are not allowed to donate any type of donation within 6 months after a peripheral stem cell harvest due to Indian law.
Do you provide NC, Whole Blood?	no	

Product quantity

Data valid for year	2020	
Number of products	**National**	**International**
HPC, Marrow products:	0	0
HPC, Apheresis:	7	3
HPC, Cord:	0	0

License

Organisation is licensed/accredited by the Competent Authority:	no
Comment:	Not applicable in India
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 ?	
Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited?	WMDA Qualified
The registry is accredited by any other organisation:	yes
If yes, by which organisation?	WMDA Qualified through DKMS-Registry (ION-4596)

Affiliation

The registry works with the following number of affiliated donor centres:	Not applicable
The registry audits its donor centres:	Not applicable
The registry works with the following numer of affiliated collection centres:	3

Ther registry audits its collection centres:	Initial evaluation before starting operation. Regular evaluation is about to be implemented.
The registry works with the following number of affiliated Cord Blood Banks:	Not applicable
The registry audits its Cord Blood Banks:	Not applicable
The registry works with the following number of affiliated transplant centres:	via ION-4596
The registry audits its transplant centres:	via ION-4596
The registry works with the following number of affiliated IDM Testing Laboratories:	2
The registry audits its IDM Testing Laboratories:	No. IDM laboratory is accredited by NABL
The registry works with the following number of affiliated HLA /other DNA markers testing laboratories:	1
The registry audits its HLA/other DNA markers testing laboratories:	No. HLA laboratory is accredited by EFI and ASHI.
The registry would be able to provide a full list of name /addresses of each affiliated and their licence/accreditation status, on request:	yes
The Cord Blood Banks are FACT-NetCord accredited:	no
If yes, the following Cord Blood Bank(s) are accredited:	
The registry is able to provide a copy of all the certificates:	no
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?	Comply as per national regulations- Drugs and Cosmetics Rules, 1945

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	Yes	Biochemistry	<30 days
ChagasChagas, T. cruzi	-		
CMV IgGCytomegalovirus (CMV) Antibody testing IgG	Yes	ELISA	<30 days
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	Yes	ELISA	<30 days
CMV TotalCytomegalovirus Total	On request	ELISA	<30 days
EBV IgGEpstein-Barr Virus Antibody testing IgG	Yes	ELISA	<30 days
EBV IgMEpstein-Barr Virus Antibody testing IgM	Yes	ELISA	<30 days
HAV (NAT)Anti-hepatitis A virus nucleic acid testing	-		

HBV (NAT)Hepatitis B nucleic acid testing	Yes	PCR/TMA	<30 days
HBc AbHepatitis B core antibody testing	Yes	ELISA / CLIA	<30 days
HBs AgHepatitis B Surface antigen testing	Yes	ELISA / CLIA	<30days
HCV (NAT)Hepatitis C nucleic acid testing	Yes	PCR/TMA	<30 days
HCV AbHepatitis C antibody testing	Yes	ELISA /CLIA	<30 days
HEV (NAT)Hepatitis E Virus nucleic acid testing	-		
HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	Yes	PCR/TMA	<30 days
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	Yes	ELISA /CLIA	<30 days
HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	Yes	ELISA / CLIA	<30 days
HIV p24Human Immunodeficiency Virus p24 antigen testing	No		
HTLV-IHuman T-Lymphotropic Virus type I testing	Yes	ELISA	<30 days
HTLV-IIHuman T-Lymphotropic Virus type II testing	Yes	ELISA	<30 days
MalariaMalaria	Yes	Quantitative Buffy Coat (QBC)	<30 days
HSVHerpes Simplex Virus	-		
STSSerological tests for syphilis	Yes	TPHA	<30 days
STS FTA-ABSSerological test for syphilis	On request	FTA	<30 days
ToxoplasmosisToxoplasmosis	Yes	ELISA	<30 days
VZVVaricella Zoster Virus	-		
WNV-NATWest Nile Virus nucleic acid testing	No		
Other tests performed	Yes	irregular AB	<30 days

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:	no
Screening questionnaire to exclude communicable disease:	yes
Screening questionnaire to exclude donors with 'high risk' lifestyles:	yes
Donor reliability identified by a medical doctor:	yes

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:	Transplant centre has to provide 12-B form (Permit for the import of small quantities of drugs for personal use), entry letter for the courier, workup forms and information about person who will meet the courier at the airport.
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	Basic paperwork, Statement of Necessity, Authorization and Declaration Letter
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	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:	yes
The registry would be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in:	yes
Donor records relating to the medical exam and HPC collection process are the following number(s) of year(s) retained:	5 years