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# D3.4 Webpages with information for organisations importing hematopoietic stem cells to EU Member States


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# Table of Contents

# 1. Preface

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.

In 2018, the following 19 Third Countries exported stem cell products to EU Member States

- Argentina
- Australia
- Brazil
- Canada
- China
- India
- Israel
- Japan
- Norway
- Russia
- Saudi Arabia
- Serbia
- Singapore
- South Africa
- Switzerland
- Taiwan - province of China
- Thailand
- Turkey
- United States

In 2018, WMDA established a Regulatory Survey to collect in order to collect regulatory information. In 2019, the aim was to build the infrastructure for collecting regulatory information by implementing the Regulatory Survey in an online format.

The information of the Regulatory Survey will be used to provide information to regulators and organisations that import/export stem cell products to/from EU member states.

To safe time for the persons, who fill in the survey, the WMDA office pre-filled the questionnaires for the different countries. Via email, the organisation profile administrators of the WMDA member organisations were requested to check the information and complement if necessary (*Figure 1)*.

*Figure 1. Email sent out to WMDA member organisations in 2019*

Update your organisation profile

Share | WMDA
To

Reply | Reply All | Forward | ...
Tue 24-09-2019 18:05

This message was sent with Low importance.

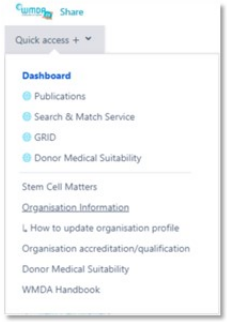
Dear organisation profile administrator,

**We would kindly like to ask you to update your organisation profile and complete the new and improved Regulatory Survey before November 1, 2019.** Each organisation has appointed an organisation profile administrator to ensure all information displayed is accurate at all times. You are one of those admins. By compiling, this resource will be a valuable tool for patients, donors, and organisations worldwide.

As you might have noticed, your profile (especially the Regulatory Survey) has changed. The WMDA has renewed and improved the Regulatory Survey and created a new page with this version. The old survey is archived and only visible for you as profile administrator. The data you provided previously has been converted to the new version. The new Regulatory survey includes new questions regarding Customs Regulations, Reporting of Serious Adverse Events and Quality Management.

**How to update your registry profile?**

1. Go to WMDA Share and login with your credentials.
2. Go to the organisation profile (underneath 'quick access' in the menu).




3. Search for your organisation in the organisation information space (https://share.wmda.info/x/4gdcAQ).
4. Update the data. *NOTE: Please have a look at the guidance page before updating the data. There are different instructions for different type of information (e.g. documents, regulatory/operational survey).*
   → **Find the guidance here: https://share.wmda.info/x/KYKbEw** OR **find the guidance underneath 'quick access' named 'How to update organisation profile'.**

Please send an email to share@wmda.info if you run into any problems.

Best regards,

This report describes the background information for Deliverable D3.4 *Webpages with information for organisations importing to EU Member States* as part of the 2019 work programme of the World Marrow Donor Association (WMDA) for the EU Third Health Programme (2014-2020).

The complete Organisations List – hosted by WMDA – is publicly accessible via:

**Organisation Information Public Access**

This includes online resources – on the website WMDA Share – setting out information and guidance for global registries that export stem cells to EU member states. Details of EU safety and quality regulations and the rationale underpinning them and are also covered. In additional, practical support tools to subsidy the efficient import of stem cells to EU member registries is included.

The Example Organisation Profile page is outlined in *Chapter 2*. This includes:

- Example profile: Documents ION-XXXX
- Example profile: Member documents ION-XXXX
- Example profile: Operational Information ION-XXXX
- Example profile: Regulatory Survey ION-XXXX

# 2. Example profile

## Example profile: ION-XXXX Donor Registry

Created by [redacted] (administrator), last modified by [redacted] about 2 hours ago

### Bone Marrow Donor Registry

| Australia | |
|---|---|
| **Contact details** | |
| Visit address | Street<br>Postal code<br>City |
| Invoice address | Street<br>Postal code<br>City |
| Primary phone | +xxx xxxxx |
| Secondary phone | +xxx xxxxx |
| Fax | +xxx xxxxx |
| Email | exampleprofile@wmda.info |
| Website | www.wmda.info |
| Location | |
| **Registry details** | |
| ION | XXXX |
| WO-id | WO-XXXX |
| Affiliation | |
| WMDA membership | |
| WSMS listed | |
| WSMS registration date | |
| WSMS shortcode | COUNTRY-ABB |
| EMDIS Code | DR |
| **Accreditation** | |
| Accreditation | |
| Year first status | |
| Current status from | |
| Current status to | |
| CBB Accreditation | |

**Additional pages**

Information about additional documents

Some, but not all organisations have additional pages.

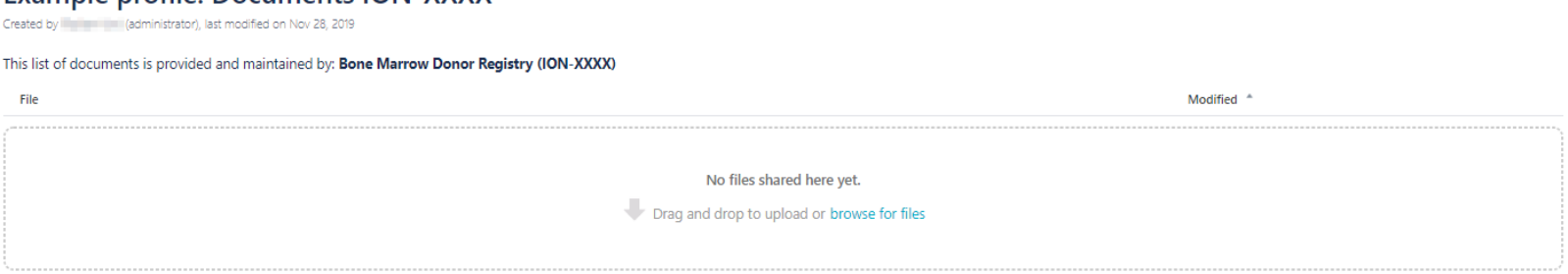
Although all resources are listed, member documents are only accessible to WMDA members.

- Example profile: Documents ION-XXXX
- Example profile: Member documents ION-XXXX
- Example profile: Operational Information ION-XXXX
- Example profile: Regulatory Survey ION-XXXX

**Additional data**

You are watching a public page.
WMDA Members may visit the Member version of this page: WO-XXXX
You may be asked to login.

Example profile: Documents ION-XXXX



## Example profile: Documents ION-XXXX

Created by [redacted] (administrator), last modified on Nov 28, 2019

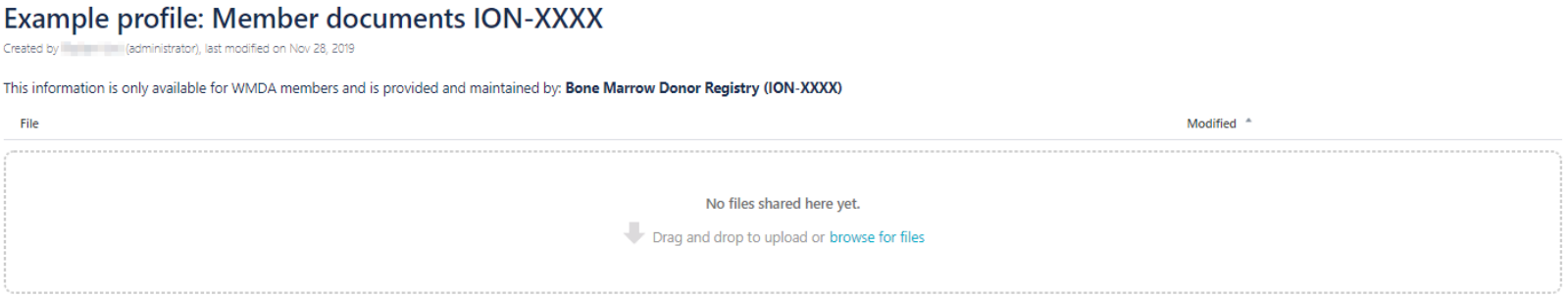
This list of documents is provided and maintained by: **Bone Marrow Donor Registry (ION-XXXX)**

File | Modified

No files shared here yet.

Drag and drop to upload or browse for files

## Example profile: Member documents ION-XXXX



# Example profile: Operational Information ION-XXXX

Created by [redacted] (administrator), last modified on Nov 28, 2019

This data is publicly available. Parent page : Example profile: ION-XXXX Donor Registry

| **Operational data for - ION-XXXX** | |
|---|---|
| **Organisation Overview** | |
| Issuing organisation Number (ION) | ION-XXXX<br>The Issuing Organisation Number of a organisation, this is globally unique number, as issued by the ICCBBA. |
| Time zone | The timezone in which this organisation operates. |
| Business hours | The daily hours in which this organisation operates. |
| Work schedule | The normal work week in which this organisation operates. |
| Organisation closures | For all organisation closures, please see the WMDA Calendar. |
| Donor ID example | ID to be expected on paperwork, samples, and products. |
| **Preliminary Search** | |
| Requires preliminary search request form | If yes, form required can be found on the Documents Page. |
| **Extended Typing** | |
| Typing options available for request | Please note special requirements listed |
| Requires organisation specific typing request form | If yes, form required can be found on the Documents Page. |
| Number of days donor is reserved for a patient after a request | |
| **Verification Typing** | |
| Maximum blood volume allowed | |
| Requires organisation specific typing request form | If yes, form required can be found on the Documents Page. |
| IDM testing performed at verification | |
| Number of days donor is reserved for a patient after a request | |
| **Workup Request** | |
| Product dosage limit | Number of donor cells allowed based on recipient weight. |
| Requires patient to meet certain standards in order to proceed with collection | Organisation may or may not allow donor collections for some patients. |
| Patient physician must report the following in order to proceed with collection | Must provide additional information to organisation. |
| Requires organisation specific work up forms | If yes, form(s) required can be found on the Documents Page. |
| Workup IDM completed 30 days prior to collection | Donor IDM results must be performed within 30 days of collection date to be valid and allow the collection to proceed. |
| Medical Health Questionnaire example available | If yes, the example can be found on the Documents Page. |
| **Post-Transplant** | |
| Subsequent donation policy | |
| Anonymous contact allowed | |
| Direct contact allowed | |
| Gift exchange allowed | |
| Cord blood contact allowed | |

**Calendar of registries**

Today ‹ › **December 2019**

| Mon | Tue | Wed | Thu | Fri | Sat | Sun |
|---|---|---|---|---|---|---|
| 25 | 26 | 27 | 28 | 29 | 30 | 1 |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 |
| 30 | 31 | 1 | 2 | 3 | 4 | 5 |

You haven't created or subscribed to any calendars

# Example profile: Regulatory Survey ION-XXXX

Created by [redacted], last modified on Nov 28, 2019

The data provided on this page is updated by the organisations.
The WMDA makes no representations or express or implied warranties regarding any information on this page.
Use of any information provided on this site does not and is not intended to create a contractual or other relationship.

| General | |
|---|---|
| Organisation name: | |
| Organisation ION: | |
| Country: | |
| Year the registry started operations: | |

| Products | | comment |
|---|---|---|
| Do you provide HPC, Marrow? | | |
| Do you provide HPC, Apheresis? | | |
| Do you provide HPC, Cord Blood? | | |
| Do you provide MNC, Apheresis? | | |
| Do you provide NC, Whole Blood? | | |

| Product quantity | | |
|---|---|---|
| Data valid for year | | |
| **Number of products** | **National** | **International** |
| HPC, Marrow products: | | |
| HPC, Apheresis: | | |
| HPC, Cord: | | |

| License | |
|---|---|
| Organisation is licensed/accredited by the Competent Authority: | |
| 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 ? | |
| Is your registry WMDA Certified, WMDA Qualified or WMDA 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: | |
| The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations: | |
| If yes, what are these requirements? | |

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

# IDM

| IDM | Tested | Method | Days between test and sampling/workup |
|---|---|---|---|
| ALT/AST<br>ALT/AST ratio, De-Ritis-Quotient | - | | |
| Chagas<br>Chagas, T. cruzi | - | | |
| CMV IgG<br>Cytomegalovirus (CMV) Antibody testing IgG | - | | |
| CMV IgM<br>Cytomegalovirus (CMV) Antibody testing IgM | - | | |
| CMV Total<br>Cytomegalovirus Total | - | | |
| EBV IgG<br>Epstein-Barr Virus Antibody testing IgG | - | | |
| EBV IgM<br>Epstein-Barr Virus Antibody testing IgM | - | | |
| HAV (NAT)<br>Anti-hepatitis A virus nucleic acid testing | - | | |
| HBV (NAT)<br>Hepatitis B nucleic acid testing | - | | |
| HBc Ab<br>Hepatitis B core antibody testing | - | | |
| HBs Ag<br>Hepatitis B Surface antigen testing | - | | |
| HCV (NAT)<br>Hepatitis C nucleic acid testing | - | | |
| HCV Ab<br>Hepatitis C antibody testing | - | | |
| HEV (NAT)<br>Hepatitis E Virus nucleic acid testing | - | | |
| HIV (NAT)<br>Human Immunodeficiency Virus nucleic acid testing | - | | |
| HIV-1 Ab<br>Human Immunodeficiency Virus HIV-1 antibody testing | - | | |
| HIV-2 Ab<br>Human Immunodeficiency Virus HIV-2 antibody testing | - | | |
| HIV p24<br>Human Immunodeficiency Virus p24 antigen testing | - | | |
| HTLV-I<br>Human T-Lymphotropic Virus type I testing | - | | |
| HTLV-II<br>Human T-Lymphotropic Virus type II testing | - | | |
| Malaria<br>Malaria | - | | |
| HSV<br>Herpes Simplex Virus | - | | |
| STS<br>Serological tests for syphilis | - | | |
| STS FTA-ABS<br>Serological test for syphilis | - | | |
| Toxoplasmosis<br>Toxoplasmosis | - | | |
| VZV<br>Varicella Zoster Virus | - | | |
| WNV-NAT<br>West Nile Virus nucleic acid testing | - | | |
| 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: | |
| HLA typing for patient specific request is performed in an appropriately accredited laboratory: | |
| Sterility testing is performed on the adult donor product: | |
| 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 : Click to show the exclusion criteria... 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: | |

## 3. Plan for 2020

At the end of September, a mail was sent out to all organisation profile administrators to update their organisation profile and complete the Operational information and Regulatory Survey. In October 2019, a reminder was sent out to remind the registries to check their profiles and add any possibly missing data.

As already mentioned in the preface, the following 19 Third Countries exported stem cell products to EU Member States in 2018:

- Argentina
- Australia
- Brazil
- Canada
- China
- India
- Israel
- Japan
- Norway
- Russia
- Saudi Arabia
- Serbia
- Singapore
- South Africa
- Switzerland
- Taiwan - province of China
- Thailand
- Turkey
- USA

Of these countries, 11 include registries that have completely or partly checked and filled in the Regulatory Survey.
Part of WMDA's accreditation program is to check and update the registry's profile and fill in the Regulatory Survey. Some registries with not-updated profiles are currently working on their qualification or accreditation application and WMDA is positive that those registries will update their profile soon.
The additional non-responding organisations are contacted personally and will be contacted again in 2020.