

# (archived) 2019 Regulatory Survey ION-4398



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| General information                   |                                                                                 |
|---------------------------------------|---------------------------------------------------------------------------------|
| Organisation name:                    | Slovenský register placentárných krvotvorných buniek- Eurocord-Slovakia (SRPKB) |
| Organisation ION:                     | ION-4398                                                                        |
| Country:                              | Slovakia                                                                        |
| Year the registry started operations: |                                                                                 |

| Products                                                          |                                                                        | Comments                      |
|-------------------------------------------------------------------|------------------------------------------------------------------------|-------------------------------|
| This organisation provides HPC, Marrow:                           | <input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No |                               |
| This organisation provides HPC, Apheresis:                        | <input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No |                               |
| This organisation provides HPC, Cord Blood:                       | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |                               |
| This organisation provides MNC, Apheresis:                        | <input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No |                               |
| This organisation provides NC, Whole Blood:                       | <input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No |                               |
| This organisation provides other products, if yes please specify: | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Cord Tissue, Placental Tissue |
| Number of national HPC products provided in 2018:                 | HPC-Marrow:<br>HPC-Apheresis:<br>HPC-Cord:                             |                               |
| Number of HPC products exported internationally in 2018:          | HPC-Marrow:<br>HPC-Apheresis:<br>HPC-Cord:                             |                               |

| Licences and accreditations                                     |                                                                        | Comments |
|-----------------------------------------------------------------|------------------------------------------------------------------------|----------|
| Organisation is licensed/accredited by the Competent Authority: | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |          |

|                                                                                                                              |                                                                                                                                                          |  |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Name of Competent Authority:                                                                                                 | Ministry of Health of Slovak Republic, The State Institute for Drug Control of Slovak Republic                                                           |  |
| Date of last inspection:                                                                                                     | 2014/11                                                                                                                                                  |  |
| Link to website of Competent Authority:                                                                                      | <a href="http://www.health.gov.sk/Titulka">http://www.health.gov.sk/Titulka</a> , <a href="http://www.sukl.sk/">http://www.sukl.sk/</a>                  |  |
| Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry can be provided: | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No                                                                                   |  |
| The registry is WMDA Qualified or WMDA Accredited:<br><i>If yes, please specify:</i>                                         | <input type="checkbox"/> WMDA Qualified<br><input type="checkbox"/> WMDA Accredited<br><input checked="" type="checkbox"/> Not WMDA Qualified/Accredited |  |
| The registry is accredited by any other organisation:<br><i>If yes, please fill in the organisation:</i>                     | <input type="checkbox"/> Yes<br><input type="checkbox"/> No                                                                                              |  |

| Affiliated centre information                                                                                                                                                                                                             | Comments                                                               |  |
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| 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:<br><i>Tip: you can upload the full list here and make it available for the WMDA membership</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |  |
| The Cord Blood Banks are FACT-NetCord accredited:<br><i>If yes, which cord blood bank(s)?</i>                                                                                                                                             | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |  |
| The registry is able to provide a copy of all the certificates:                                                                                                                                                                           | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |  |
| Affiliated centres comply with WMDA Standards and applicable national regulations:                                                                                                                                                        | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |  |

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| The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:<br><i>If yes, please specify these requirements:</i> | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
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| Donor policy                                                                                                             |                                                                        |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| All donors are unpaid volunteers:                                                                                        | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| All donors are informed about donation process and associated risks:                                                     | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff: | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| The registry has systems in place to protect and control access to donor/patient records:                                | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| The registry maintains donor anonymity:                                                                                  | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| The registry has detailed donor evaluation and exclusion criteria in place:                                              | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |
| The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:                     | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> 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<br>Timeframe when the materials sample is taken for testing (for cords) (in number of days) |
|-------------------------------------------------------------------------------|-------------------------------------|--------------------------|-------------------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| ALT/AST:                                                                      | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/>            |             |                                                                                                                                                      |
| Chagas:                                                                       | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/>            |             |                                                                                                                                                      |
| CMV IgG:                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |             |                                                                                                                                                      |
| CMV IgM:                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            |             |                                                                                                                                                      |
| CMV Total:                                                                    | <input type="checkbox"/>            | <input type="checkbox"/> | <input checked="" type="checkbox"/> |             |                                                                                                                                                      |

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| EBV IgG:       | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |  |  |
| EBV IgM:       | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |  |  |
| HAV (NAT):     | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HBV (NAT):     | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HBc Ab:        | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |  |  |
| HBs Ag:        | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HCV (NAT):     | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HCV Ab:        | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |  |  |
| HEV (NAT):     | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HIV (NAT):     | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HIV-1 Ab:      | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HIV-2 Ab:      | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HIV p24:       | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HTLV-I:        | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |  |  |
| HTLV-II:       | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |  |  |
| Malaria:       | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| HSV:           | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| STS:           | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| STS FTA-ABS:   | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |
| Toxoplasmosis: | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |  |  |

|                        |                          |                                     |                          |  |  |
|------------------------|--------------------------|-------------------------------------|--------------------------|--|--|
| VZV:                   | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/> |  |  |
| WNV-NAT:               | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |  |  |
| Other tests performed: | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |  |  |

| Testing                                                                                                                         |                                                                        | Comments |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|----------|
| <i>Please indicate whether the following are completed on the donor during the medical examination:</i>                         |                                                                        |          |
| The physical and medical exam at donor work up is performed by a medical doctor:                                                | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |          |
| All donor testing (at work up) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority: | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| HLA typing for patient specific request is performed in an appropriately accredited laboratory:                                 | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Sterility testing is performed on the adult donor product:                                                                      | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Sterility testing is performed on the cord blood product:                                                                       | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |          |
| Screening questionnaire to exclude communicable disease:                                                                        | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |          |
| Screening questionnaire to exclude donors with 'high risk' lifestyles:                                                          | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |          |
| Donor reliability identified by a medical doctor:                                                                               | <input type="checkbox"/> Yes<br><input type="checkbox"/> No            |          |

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| <p>Donor clearance to donate is confirmed by a medical doctor, following as a minimum the donor exclusion criteria in Annex 1 of EU Directive <a href="#">2006/17/EC</a>:</p> <p>The party providing the Cell Product must exclude Donors when:</p> <ul style="list-style-type: none"> <li>• They are pregnant;</li> <li>• They are breastfeeding;</li> <li>• There is the potential for transmission of inherited conditions;</li> <li>• There is evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration <i>Donor travel and exposure history and local infectious disease prevalence</i>;</li> <li>• There is presence on the Donor's body of physical signs implying a risk of transmissible disease(s);</li> <li>• There is a history of a disease of unknown aetiology;</li> <li>• There is a risk of transmission of diseases caused by prions;</li> <li>• 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;</li> <li>• There is history of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the Cell Product;</li> <li>• There is recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist;</li> <li>• 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.</li> </ul> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |  |
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| Customs regulations                                                                                                                                   |                                                             | Comments |
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| Are there any customs regulations to follow, or customs paperwork required, to import cell products to your country? <i>If yes, please specify:</i>   | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Are there any customs regulations to follow, or customs paperwork required, to export cell products from your country? <i>If yes, please specify:</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Are there any import regulations to follow, or paperwork required, to import cell products to your country? <i>If yes, please specify:</i>            | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Are there any export regulations to follow, or paperwork required, to export cell products from your country? <i>If yes, please specify:</i>          | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |

| Reporting of Serious Adverse Events                                                                                                                                                                                     |                                                             | Comments |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|----------|
| <p><i>Please indicate which of the following schemes for reporting Serious Adverse Events relating to either the Donor or the product the Registry participates in:</i></p> <p>Mandatory National Reporting Scheme:</p> | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| <p>Voluntary National Reporting Scheme:</p>                                                                                                                                                                             | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| <p>WMDA SEAR/SPEAR Reporting Scheme:</p>                                                                                                                                                                                | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |

|                                                                                                                                                                                                             |                                                             |  |
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| Will the registry notify the receiving Registry within <b>24 hours</b> of receiving information relating to any serious adverse event that could be considered to affect the patient receiving the product? | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--|

| Quality management                                                                                                                          |                                                             | Comments |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|----------|
| Do the registry maintain Standard Operating Procedures (SOPs) for your work?                                                                | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| Would the registry be willing to provide these to WMDA or another registry upon request?                                                    | <input type="checkbox"/> Yes<br><input type="checkbox"/> 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? | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |          |
| How many years are donor records retained relating to the medical exam and HPC collection process?                                          | 30                                                          |          |