(national coat of arms of the Slovak Republic)
MINISTRY OF HEALTH
OF THE SLOVAK REPUBLIC

Done at Bratislava, 8 June 2023
Reference: S18387-2023-OP-6
Ad: S09541-2019-ONAPP

D E C I S I O N

The Ministry of Health of the Slovak Republic (the "Ministry") as the competent authority to issue a licence under the provision of Section 11(1)(c) in conjunction with the provision of Section 17e of Act No. 578/2004 Coll. on the Health Care Providers, Medical Professionals, Professional Associations in the Public Health, and on the alterations and amendments of other laws as amended (the "Providers Act"), and under Section 46 of Act No. 71/1967 Coll. on the Administrative Proceedings (the Code of Administrative Procedure) as amended (the "Act on Administrative Proceedings") after having established the matters of fact and matters of law rules

a s f o l l o w s:

the application filed by ***Sanatórium pre liečbu neplodnosti – SPLN, spol. s r.o.,*** *registered office:* ***Masarykova 17, 040 01 Košice, Company ID No.: 36 603 848****, represented by the governing body – executive directors: 1/ Ing. Jaroslav Jakubčin, resident of Adlerova 839/11, 040 22 Košice – Dargovských hrdinov, 2/ MVDr. Miroslav Martinček, resident of Gelnická 36, 040 11 Košice – Pereš (the "Applicant"), dated 13 February 2023 (amended on 21 April 2023, 19 May 2023, 6 June 2023 and 7 June 2023) for the alteration to the licence to operate a medical establishment (issued by the Ministry on 30 May 2019, ref. S09541-2019-ONAPP, final and conclusive as from 17 June 2019) under the provision of Section 17e(1) of the Providers Act is* ***granted*** *and the Applicant is in accordance with the provision of Section 7(3)(h) of the Providers Act* ***licensed*** *to operate*

MEDICAL ESTABLISHMENT PROVIDING OUTPATIENT HEALTHCARE SERVICES:

Tissue Establishment
within the scope of the following activities:
procurement, testing, processing, preservation, storage, distribution, import from the Member State, import from the third country, export

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within the scope of the following specialty:
gynaecology, obstetrics

Types of human tissues and cells of which the tissue establishment is to undertake the procurement, testing, processing, preservation, storage, distribution intended for human applications:

1. oocytes
2. sperms
3. embryos

Types of human tissues and cells of which the tissue establishment is to undertake the import from the Member State intended for human applications:

1. oocytes
2. sperms
3. embryos

Types of human tissues of which the tissue establishment is to undertake the import from the third country intended for human applications:

1. oocytes
2. sperms
3. embryos

Detailed description of a movement of the human tissues or human cells from the [place/time of] procurement thereof in the third country to the [place/time of] receipt thereof by the tissue establishment:

Transport of cells and/or tissues - oocytes, sperms, embryos shall be carried out after the procurement, testing, processing and cryopreservation thereof [completed] by ARK Cryo, Lviv city, Ye. Yaroshynska, Street, 5, ap. 1 (the "Sender") to Sanatórium pre liečbu neplodnosti SPLN spol. s r.o., Masarykova 17, 040 01 Košice (the "Recipient"). The Sender shall follow their standard operating procedures for the procurement, processing, preservation and storage of oocytes, sperms and embryos ("biological material") made in accordance with the law of the Sender´s country. The transported biological material shall be delivered (handed over) by the Sender´s staff mandated and authorised in accordance with the procedures set out in the Sender´s standard operating procedures. As per order [received] from the Recipient the Sender shall provide the shipping documents (protocol of delivery and acceptance) showing the accurate and detailed identification of the transported biological material (type, quantity, designation, date, and method of preservation, type and manufacturer of the freezing media and cryogenic carrier used), and data identifying the persons responsible for the issuing and transport of biological material. The shipping date shall be specified. On the shipping date, the Sender´s mandated staff shall transfer the biological material intended for transport from the storage container into the shipping container. The transport shall be carried out using a pre-ordered certified road transport

vehicle labelled as "transportation of human cells". The shipping container certified for the above purpose – a thermally insulated container – DEWAR container – is prior to the loading of the biological material filled with liquid nitrogen with a temperature of -196°C. The temperature inside the shipping container during transportation must not be less than -170°C. The temperature inside the shipping container is during the time of transportation monitored and recorded by an automatic device – data logger. The shipping container must have the following markings:

Do not x-ray
Human tissues and cells
Fragile
Keep up right

The total time of transportation of cells and/or tissues shall not exceed 6 days for a 1.5 litre container, and 10 days for a 3.5 litre container. The Recipient shall follow their standard operating procedures for the receipt of biological material made in accordance with the law of the Recipient´s country. The transported biological material shall be accepted (taken over) by the Recipient´s staff mandated and authorised in accordance with the procedures set out in the Recipient´s standard operating procedures. [The person] shall check the date of dispatch of biological material and then acknowledge the compliance with the specified time of transportation in the protocol of acceptance; turn off the data logger and then check the same and evaluate the shipping temperature conditions – downloading the data logger´s data and checking the liquid nitrogen level in the shipping container; check the biological material carrier(-s) and transfer the same into the Recipient´s storage container; enter the transportation data into the documents and acknowledge the receipt of the transported biological material; send the information on delivery by e-mail to the Sender´s responsible person (Uliana Dorofeyeva, e-mail: uliana.dorofeyeva@gmail.com)

In case of deficiencies and/or irregularities detected upon the acceptance (taking-over) of the transported biological material the taking over staff shall without delay contact the Sender´s responsible person and put the biological material concerned into quarantine. In the event of a breach of transportation conditions the same shall be consulted without delay with the Sender, the shipping container shall be subsequently analysed and the condition of the biological material delivered shall be upon agreement with the Sender evaluated. All the deficiencies and/or irregularities detected, including the subsequent solutions thereto, shall be recorded and filed by the responsible person within the Recipient´s internal documents.

Person responsible for receipt of biological material: embryologist, laboratory technician.

Legal name and registered office of the third country supplier of human tissues or human cells:

ARK Cryo Limited Liability Company, *registered office:* ***Yaroshynska ulica 5/1, 79071 Lviv, Identification Number: 44022699.***

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List of activities undertaken by the third country supplier of human tissues or human cells:

The third country supplier shall undertake the procurement, processing, testing, preservation, storage, distribution, export of oocytes, sperms, embryos.

List of activities which are guaranteed by contract [made by and between] the third country supplier of human tissues or human cells and another third country supplier of human tissues or human cells:

The "testing" of human tissues or humans cells by the third country supplier is guaranteed by contract, namely by cooperation agreements made and entered into with the following third country suppliers:
1. SYNLAB-UKRAINE Limited Liability Company
2. Eskulab, The First Social Medical Laboratory
3. L.E.S. Mikrogen Tani Merkez Ltd.Sti

Name of the third country in which the registered office of the third country supplier of human tissues or human cells is: ***Ukraine.***

Types of human tissues and cells of which the tissue establishment is to undertake the export intended for human applications:

1. oocytes
2. sperms
3. embryos

Place of the tissue establishment´s operations:
Masarykova 17, 040 01 Košice

Medical Establishment Identifier: 51-36603848-A0001

The EU tissue establishment code assigned by the National Transplantation Organisation: SK000479

Specialty Supervisor* *for the provision of healthcare in the tissue establishment is:* ***MUDr. Michal Poláček, MBA****, DOB: 24 April 1962, citizen of the Czech Republic, resident of Vinohrad 131/16, 724 00 Ostrava – Stará Bělá, Czech Republic, profession: doctor of medicine, field of study: general medicine, medical specialties: gynaecology and obstetrics, reproductive medicine, reg. number: 29368, licence issued by the Slovak Medical Chamber on 8 August 2016, referenced as L1C/KE/2396/16.*

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The Applicant has made and entered into the cooperation agreement on the tissue testing with the following healthcare provider: ***synlab slovakia s.r.o., RIA Laboratórium s.r.o., Košice.***

The Applicant shall also in accordance with the provision of Section 17(1) of the Providers Act be revoked the licence to operate a medical establishment issued by the Ministry on 30 May 2019, referenced as S09541-2019-ONAPP, final and conclusive as from 17 June 2019.

R e a s o n i n g

By letter dated 13 February 2023, received by the Ministry on 17 February 2023, the Applicant requested the Ministry to alter the licence to operate a tissue establishment issued by the Ministry on 30 May 2019, referenced as S09541-2019-ONAPP, final and conclusive as from 17 June 2019, namely to 1/ extend the licence to include the import of oocytes, sperms and embryos from the Member State – Italy, and the export of oocytes, sperms and embryos to the Member State – Italy, 2/ extend the licence to include the import of oocytes, sperms and embryos from the third country – Ukraine, and export of oocytes, sperms and embryos to the third country – Ukraine. By letter dated 20 April 2023, received by the Ministry on 21 April 2023, the Applicant amended their application dated 13 February 2023 requesting deletion of the tissue of which [the Applicant is to undertake] the procurement, testing, processing, preservation, storage, distribution intended for human applications "follicular liquid". By letter dated 18 May 2023, received by the Ministry on 19 May 2023, the Applicant amended their application dated 13 February 2023 submitting a detailed description of a movement of the human tissues or human cells from the [place/time of] procurement thereof in the third country to the [place/time of] receipt thereof at the tissue establishment. By letter received by the Ministry on 6 June 2023, the Applicant amended their application dated 13 February 2023 providing another supplier which conducts the testing for the third country supplier - L.E.S. Mikrogen Tani Merkez Ltd.Sti. By letter received by the Ministry on 7 June 2023, the Applicant amended their application dated 13 February 2023 providing the activities conducted by the third country supplier of human tissues or human cells: procurement, processing, testing, preservation, storage, distribution, export.

Under Section 47(1) of the Act on Administrative Proceedings "a decision must contain an operative part, reasoning, and guidance on the appeal (remonstrance). The reasoning is not required if all the parties to the proceedings are satisfied in full."

Given that the Applicant fulfils the conditions for issuing a licence under Section 13a and Section 17e of the Providers Act, the Ministry rules as given in the operative part of the decision.

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G u i d a n c e: *As provided by Section 61(1) of Act on the Administrative Proceedings as amended a remonstrance may be filed against the present decision within 15 days of the service thereof to Ministerstvo zdravotníctva Slovenskej republiky, Limbová 2, 837 52 Bratislava*
The present decision is not subject to the judicial review pursuant to Act No. 162/2015 Coll., the Code of Judicial Review Procedure, unless an ordinary remedy is exhausted.

Michal Palkovič
Minister

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Decision shall be served on:
Sanatórium pre liečbu neplodnosti – SPLN, spol. s r.o., Masarykova 17, 040 01 Košice

For the attention of:
- Košice Tax Office (Ďaňový úrad Košice)
- The Statistical Office of the Slovak Republic (Štatistický úrad Slovenskej republiky)
- The Healthcare Surveillance Authority (Úrad pre dohľad nad zdravotnou starostlivosťou)
- The City of Košice (Mesto Košice)
- health insurance companies
- The Košice Self-governing Region (Košický samosprávny kraj)
- The National Transplantation Organisation (Národná transplantačná organizácia)

(Translator´s Note:
**As provided by Act No. 578/2044 Coll. on the Health Care Providers, Medical Professionals, Professional Associations in the Public Health, a specialty supervisor is a natural person (an individual) who is personally responsible for the professional provision of healthcare in a healthcare establishment.)*