Translation from the Czech Language

STATE INSTITUTE FOR DRUG CONTROL | Šrobárova 48 100 41 Prague 10 | Tel.: +420 272 185 111 Fax: +420 271 732 377 | e-mail: posta@sukl.cz Web: www.sukl.cz

ADDRESSEE
CZ Pharma s.r.o.

ADDRESS FOR SERVICE
náměstí Smiřických 42
Kostelec nad Černými Lesy
281 63

File No.: sukls244817/2022	Responsible Person/ Line	Date
Ref. No.sukl266621/2022	Mgr. Ivona Pěničková /403	05/12/2022

Dispatched on the date when handed over to the postal transportation service provider with the date being stated on the envelope by the postal service provider; or on the date of sending a data message from the data box of the State Institute for Drug Control, or in case of personal service, the date of dispatch is the date of the delivery to the addressee.

DECISION

In accordance with S. 67 of the Act No. 500/2004 Sb., the Rules of Administrative Procedure, as amended (hereinafter as the "Rules of Administrative Procedure"), the State Institute for Drug Control, based in Prague 10, Šrobárova 48 as the authority competent to make a decision pursuant to S.13, (2)(a)(2) of the Act No. 378/2007 Sb. on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals) as amended, has decided

as follows:

Based on the letter of application of CZ Pharma s.r.o. with its registered office at náměstí Smiřických 42, 281 63 Kostelec nad Černými Lesy, ID No. 281 77 738, the State Institute for Drug Control, pursuant to S.76 and S. 63 (1) of the Act No. 378/2007 Sb. on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals) as amended (hereinafter as the "Act on Pharmaceuticals"),

has changed the authorization to distribute medicinal products issued under file No. sukls52146/2013 as of 10th May 2013, as follows:

1. As at 01/01/2023, the original name of the company, i.e. CZ Pharma s.r.o., will have been exchanged for the new one, i.e. Olikla s.r.o.

2. The individual distribution points (approved storage sites) including the scope of distribution activities are listed in Annex No. 1 hereto.

The information stated in this Decision and annexes thereto are in compliance with the Compilation of Community Procedures on Inspection and Exchange of Information as amended on 2nd January 2013.

Reasoning

On 7th November 2022, CZ Pharma s.r.o. company with its registered office at náměstí Smiřických 42, 281 63 Kostelec nad Černými Lesy, ID No. 281 77 738, filed an application for a change of the authorization to distribute medicinal products. Upon filing the application, administrative proceedings have been commenced under the file No. sukls244817/2022. Within the scope of the proceedings the State Institute for Drug Control (hereinafter as the "Institute") assessed whether the requirements stipulated by the Act on Pharmaceuticals, its implementing regulations and special regulations have been met in this case. After the completed proceedings, the Institute states that the application can be granted and, therefore, it has decided to change the authorization to distribute medicinal products as specified above in the decision.

After this decision to change the authorization to distribute medicinal products becomes final and conclusive, the authorization to distribute medicinal products issued to CZ Pharma s.r.o. with the registered office at V Zátiší 157, 281 66 Jevany, ID No. 281 77 738, under file No. sukls52146/2013 as of 10th May 2013, changed on the basis of the decision on a change file No. sukls133519/2013 as of 25th September 2013, file No. sukls216518/2013 as of 6th January 2014, file No. sukls58391/2014 as of 23rd May 2014, file No. sukls145043/2016 as of 6th June 2016, file No. sukls13436/2017 as of 6th February 2017, file No. sukls165269/2017 as of 6th October 2017, file No. sukls43379/2020 as of 18th March 2020, file No. sukls88907/2020 as of 14th April 2020, and file No. sukls103639/2022 as of 1st July 2022 will be valid in the following scope:

Name and surname of a natural person / business name or name of a legal person	Olikla s.r.o.
Place of business / registered office	náměstí Smiřických 42, 281 63 Kostelec nad Černými Lesy
Identification number	281 77 738
Scope of activities	
Addresses of storage sites (warehouses) and names of qualified persons	Pražská 390, 285 06 Sázava (3 ground floor halls, total area of 565 m^2) Mgr. Alice Poláková
Addresses of contractual distribution points and names of qualified persons	Phoenix lékárenský velkoobchod, s.r.o., K pérovně 945/7, 102 00 Prague 10 – Hostivař, pursuant to the authorization to distribute medicinal products ref. No. 12719/6/INS/00 as of 1st August 2000 Mgr. Alice Poláková

Warning of Appeal

Pursuant to S. 81 et seq of the Act No. 500/2004 Sb., the Rules of Administrative Procedure, as amended, it is possible to lodge an appeal against this Decision with the State Institute for Drug Control within a 15-day period from the day of the Decision delivery. The Ministry of Health of the Czech Republic shall decide on the appeal.

Official stamp impression

PharmDr. Ivan Buzek
Head of Pharmacy and Distribution Department

Annex No. 1 - The scope of authorization to distribute pharmaceuticals (2 pages)

Annex No. 1/1 to the Decision file No. sukls244817/2022 as of 5th December 2022

SCOPE OF AUTHORIZATION TO DISTRIBUTE PHARMACEUTICALS

Name and address of the distribution point: Olikla s.r.o., Pražská 390, 285 06 Sázava

1. MEDICINAL PRODUCTS

1.1. ☒ With a decision on registration in an EEA country / EEA countries

1.2. ☐ Without a decision on registration in EEA and designated for the EEA market*

1.3. ☐ Without a decision on registration in EEA and designated for export

2. AUTHORIZED DISTRIBUTION ACTIVITIES

2.1. ☒ Purchase / Procurement

2.2. ☒ Storage

2.3. ☒ Supply

2.4. ☒ Export

2.5. ☐ Other activities: ---

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1. ☒ Medicinal products according to Art. 83 of Dir. 2001/83/EC[1]

3.1.1. ☒ Medicinal products derived from human blood

3.1.2. ☒ Immunological medicinal products

3.1.3. ☐ Radio-pharmaceuticals (including radionuclide kits)

3.2. ☐ Medicinal gases

3.3. ☒ Cold chain medicinal products (requiring handling at low temperatures)

3.4. ☐ Other medicinal products: ---

Any limitations or explanatory notes or stipulation of conditions relating to the scope of distribution activities:
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*Art. 5 of Dir. 2001/83/EC or No. 83 of Regulation EC/726/2004.

Official stamp impression

PharmDr. Ivan Buzek
Head of Pharmacy and Distribution Department

[1] To distribute medicinal products containing narcotic and psychotropic substances it is necessary to obtain not only this authorization, but also the authorization for handling which is issued by the Ministry of Health of CR under the Act No. 167/1998 Sb. on Addictive Substances and on Amendments to Certain Other Acts as amended

Annex No. 1/2 to the Decision file No. sukls244817/2022 as of 5th December 2022

SCOPE OF AUTHORIZATION TO DISTRIBUTE PHARMACEUTICALS

Name and address of the distribution point:
PHOENIX lékárenský velkoobchod, s.r.o., K pérovně 945/7, 102 00 Prague 10 – Hostivař

1. MEDICINAL PRODUCTS

1.4. ☒ With a decision on registration in an EEA country / EEA countries

1.5. ☐ Without a decision on registration in EEA and designated for the EEA market*

1.6. ☐ Without a decision on registration in EEA and designated for export

2. AUTHORIZED DISTRIBUTION ACTIVITIES

2.1. ☒ Purchase / Procurement

2.2. ☒ Storage

2.3. ☒ Supply

2.4. ☒ Export

2.5. ☐ Other activities: ---

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1. ☒ Medicinal products according to Art. 83 Dir. 2001/83/EC[1]

3.1.1. ☒ Medicinal products derived from human blood

3.1.2. ☒ Immunological medicinal products

3.1.3. ☐ Radio-pharmaceuticals (including radionuclide kits)

3.2. ☐ Medicinal gases

3.3. ☒ Cold chain medicinal products (requiring handling at low temperatures)

3.4. ☐ Other medicinal products: ---

Any limitations or explanatory notes or stipulation of conditions relating to the scope of distribution activities:
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*Art. 5 of Dir. 2001/83/EC or No. 83 of Regulation EC/726/2004.

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