

Reference number: OGYÉI/46147-7/2023
Administrator: Dr. KESZÉG Magdolna
Subject: amendment of Wholesale
Distribution Authorisation

**PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató
Korlátolt Felelősségű Társaság**

H-1106 Budapest

Kabai u.1.

Tax number: 13999034-2-42

RESOLUTION

Based on the empowerment in **Subsection (1) of Section 11 of Act XCV of 2005** on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products, in the procedure initiated upon request of **PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató Korlátolt Felelősségű Társaság** (registered seat: H-1106 Budapest Kabai u. 1.) (hereinafter referred to as “**Applicant**”), under reference number **OGYÉI/46147/2023**, with the **National Centre for Public Health and Pharmacy** (hereinafter referred to as “**NCPHP**”), for the amendment of the Wholesale Distribution Authorisation, the following simplified

r e s o l u t i o n

is passed hereby.

At the same time as this Decision becomes final, the Applicant’s Wholesale Distribution Authorisation, consolidated with the previous amendments, is hereby

a m e n d e d

as set out in the Annex to this Resolution.

In accordance with **Subsection (2) of Section 81 of Act CL of 2016 on General Public Administration Procedures** (hereinafter referred to as the “**Public Administration Procedure Act**”), I have brought my above decision in a simplified format, as NCPHP has fully approved the request, and there is no counterclaimant.

Pursuant to **Subsection (6) of Section 26 of the Medicines Act**, the present resolution is not subject to any further appeal in the context of the administrative procedures. However, within 30 days of the notification of the contested administrative action alleging the impairment of a right based on **Subsection (1) of Section 114 of Act CL of 2016 on General Public Administration Procedures** (hereinafter referred to as the “**Public Administration Procedure Act**”) an administrative appeal may be lodged against the final decision to the court specified in **Subsection (1) of Section 13 of Act I of 2017** on the Code of Administrative Court Procedure.

The application must be submitted to NCPHP, addressed to the competent court. The NCPHP has made the decision contained in this resolution on the basis of the powers granted in **Subsection (1) of Section 20 of the Medicines Act**, pursuant to the designation specified in **Section 15 of Government Decree No. 333/2023 (VII.20.)** on the National Center for Public Health and Pharmacy.

Dated: in Budapest, at the time indicated in the time stamp.

Issued by:

Acting on behalf of
Chief Medical Officer
Dr. MÜLLER Cecília:


Dr. LUKÁCS
Ferenc
József

Digitally signed by:
Dr. LUKÁCS Ferenc
József
Date:
2023.09.15
13:39:16 +02'00'

Head of department
Dr. LUKÁCS Ferenc József

[coat of arms of Hungary]
NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY
Department of Regulatory Control

Wholesale Distribution Authorisation (WDA)

1. Authorisation number	HU-D-PHRO
2. Name of authorisation holder	PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató Korlátolt Felelősségű Társaság
3. Legally registered address of authorisation holder	H-1106 Budapest, Kabai u. 1.
4. Address(es) of site(s)	
HU-D-PHRO01	H-1106 Budapest, Kabai u. 1.
HU-D-PHRO02	H-1151 Budapest, Károlyi Sándor u. 121. "Building 'O' / Storage 2"
HU-D-PHRO03	H-6640 Csongrád, Kenderföldek utca 3 "Storage 3 and Storage 4 at room temperature; cold store 1 and cold store 2"
5. Legal basis of authorisation	Act XCV of 2005 Decree No. 53/2004 (VI.2.) of the Minister of Health, Social and Family Affairs Gov. Decree 449/2017 (XII. 27.)
6. Signature	Dr. LUKÁCS Ferenc József Digitally signed by: Dr. LUKÁCS Ferenc József Date: 15.09.2023 13:40:10 +02'00'
7. Person granting the wholesaling authorisation	Dr. LUKÁCS Ferenc Head of Inspectorate 
8. Date	Dated: in Budapest, at the time indicated in the time stamp.

PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató Korlátolt Felelősségű Társaság
Site 1: H-1106 Budapest, Kabai u. 1.

Scope of the Wholesale Distribution Authorisation

1	Medicinal products
	1.1 With a Marketing Authorization in EEA country (s) 1.2 Without a Marketing Authorization in EEA and intended for EEA market 1.3 Without a Marketing Authorization in EEA and intended for exportation
2	Authorised Wholesale Distribution Operation
	2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export
3	Medicinal products with additional requirements
	3.1 Products according to Art. 83 of 2001/83/ EC 3.1.1 Narcotic or psychotropic products 3.1.3 Immunological medicinal products 3.3 Cold chain products 3.4 Other products: See in restriction part

Any restriction or clarifying remarks related to the scope of these wholesaling operations.

Authorised Wholesale Distribution Operation

2.2. Holding:

2.2.1. Room temperature (15-25°C) store-house storage locations:

Storage no. I-II: from 01-01-01 to 09-99-07 from 12-01-01 to 29-99-07

Storage no. III from 30-01-01 to 48-99-07 from 50-01-01 to 50-18-03 from 53-01-01 to 55-06-07
from 55-17-06 to 55-99-07

2.2.2. Drugs with special storage conditions 8-15°C, storage locations:

Cold store sites: Storage no. I-II from 10-01-01 to 10-99-07 except: 10-01-06, 10-02-06, 10-03-06, 10-04-06

2.2.3. Cold chain (2-8°C) store-house storage locations: Storage no. I-II: from 11-01-01 to 11-99-07

Storage no. III: from 49-01-01 to 49-13-07 from 49-16-05 to 49-99-07

3. Medicinal products with additional requirements

3.4 Other products:

3.4.1 Homeopathic medicinal products

3.4.2 Materials for preparation of “magistral formula” (human medicinal products)

Additional provisions based on national requirements.

Name(s) of responsible person(s)

Dr. KRIEGER Éva	degree certificate number: 65/2005 (Pharmacist)
Dr. KOCSMÁRSZKY József	degree certificate number: 47/1987 (Pharmacist)
Dr. HORVÁTH László	degree certificate number: 135/1975 (Pharmacist)
Dr. BARTA Réka	degree certificate number: 8/2020/GY (Pharmacist)
Dr. ROZMANICZ Gergő	degree certificate number: 97/SE-GYTK-GYO/2016 (Pharmacist)

PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató Korlátolt Felelősségű Társaság

Site 2: H-1151 Budapest, Károlyi Sándor u. 121. "Building 'O' / Stotage 2"

Scope of the Wholesale Distribution Authorisation

1	Medicinal products
	1.1 With a Marketing Authorization in EEA country (s) 1.2 Without a Marketing Authorization in EEA and intended for EEA market 1.3 Without a Marketing Authorization in EEA and intended for exportation
2	Authorised Wholesale Distribution Operation
	2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export
3	Medicinal products with additional requirements
	3.1 Products according to Art. 83 of 2001/83/ EC 3.1.2 Medicinal products derived from blood 3.1.3 Immunological medicinal products 3.3 Cold chain products 3.4 Other products: See in restriction part

Any restriction or clarifying remarks related to the scope of these wholesaling operations.

Authorised Wholesale Distribution Operation

2.2. Holding:

2.2.1. Room temperature (15-25°C) store-house

2.2.2 Drugs with special storage conditions 8-15°C

2.2.3 Cold chain (2-8°C) store-house

3. Medicinal products with additional requirements

3.4 Other products:

3.4.1 Homeopathic medicinal products

3.4.2 Materials for preparation of "magistral formula" (human medicinal products)

3.4.3 Herbal and animal drugs

3.4.4 Dialysing solutions (s.c. CAPD solutions) applying for continuous ambulant peritoneal dialysis.

Additional provisions based on national requirements.

Name(s) of responsible person(s)

Dr. KRIEGER Éva	degree certificate number: 65/2005 (Pharmacist)
Dr. KOCSMÁRSZKY József	degree certificate number: 47/1987 (Pharmacist)
Dr. HORVÁTH László	degree certificate number: 135/1975 (Pharmacist)
Dr. BARTA Réka	degree certificate number: 8/2020/GY (Pharmacist)
Dr. ROZMANICZ Gergő	degree certificate number: 97/SE-GYTK-GYO/2016 (Pharmacist)

PHARMAROAD Gyógyszerkereskedelmi, Kereskedelmi és Szolgáltató Korlátolt Felelősségű Társaság
Site 3: H-6640 Csongrád, Kenderföldek utca 3 /Storage 4 at room temperature and Storage 3 in cold store 1 and cold store 2

Scope of the Wholesale Distribution Authorisation
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1	Medicinal products
	1.4 With a Marketing Authorization in EEA country (s) 1.5 Without a Marketing Authorization in EEA and intended for EEA market 1.6 Without a Marketing Authorization in EEA and intended for exportation
2	Authorised Wholesale Distribution Operation
	2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export
3	Medicinal products with additional requirements
	3.1 Products according to Art. 83 of 2001/83/ EC 3.1.2 Medicinal products derived from blood 3.1.3 Immunological medicinal products 3.3 Cold chain products 3.4 Other products: See in restriction part

Any restriction or clarifying remarks related to the scope of these wholesaling operations.

Authorised Wholesale Distribution Operation

- 2.2. Holding:
 2.2.1. Room temperature (15-25°C) store-house
 2.2.2. Cold chain (2-8°C) store-house

3. Medicinal products with additional requirements

- 3.4 Other products:
 3.4.1 Homeopathic medicinal products
 3.4.2 Materials for preparation of “magistral formula” (human medicinal products)
 3.4.3 Dialysing solutions (s.c. CAPD solutions) applying for continuous ambulant peritoneal dialysis.

Additional provisions based on national requirements.

Name(s) of responsible person(s)

Dr. RAPOS-TARI Ildikó

degree certificate number: 59/2006 (Pharmacist)

SZÁNTAINÉ Dr. TARI Judit

degree certificate number: 60/2006 (Pharmacist)