AUTHENTICATED TRANSLATION FROM THE POLISH LANGUAGE

[A document containing four pages has been submitted for translation. The document was partially drafted in two language versions – only the Polish version has been translated. The translator's remarks are inserted in square brackets in italics]

Warsaw, 07 May 2021

[Polish national emblem] CHIEF PHARMACEUTICAL INSPECTOR

NZOH.5100.21.2021.MG.2

DECISION

Under Art. 74(2) of the Pharmaceutical Law of 6 September 2001 (consolidated text: Journal of Laws of 2020, item 944, as amended) and Art. 155 of the Code of Administrative Procedure of 14 June 1960 (consolidated text: Journal of Laws of 2021, item 735)

THE CHIEF PHARMACEUTICAL INSPECTOR

amends the authorisation ref. no. GIF-N-4111/7/AR/10 of 26 January 2010 for running the pharmaceutical wholesale centre located in Łódź, ul. Obywatelska 128/152, granted to entrepreneur Genesis Pharm Sp. z o.o. Sp. k. by adding Point 3.1.3 to the scope of the authorisation and by modifying the entry in point *"Any restrictions or clarifying remarks related to the scope of these wholesaling operations"* in Annex no. 1;

AND WORDING IT AS FOLLOWS:

WHOLESALE DISTRIBUTION AUTHORISATION

1. Authorisation number
GIF-N-4111/7/AR/10

2. Name of authorisation holder
Genesis Pharm spółka z ograniczoną odpowiedzialnością spółka komandytowa
KRS *[National Court Register]*: 0000854684
REGON *[National Official Business Register]*: 100680279

3. Legally registered address of authorisation holder
ul. Obywatelska 128/152; 94-104 Łódź

4. Address of site
ul. Obywatelska 128/152; 94-104 Łódź

5. Scope of authorisation
medicinal products for human use: Annex no. 1

6. Legal basis of authorisation
Art. 74(1) and (2) in conjunction with Art. 72(1) of the Pharmaceutical Law of 6 September 2001

7.Name of Chief Pharmaceutical Inspector
Ewa Krajewska

8. Signature

p.p. Chief Pharmaceutical Inspector
Joanna Szajnik-Solska
Head of the Supervision Department
/signed electronically/

9. Date

2021-05-10

I. The basic terms of running a pharmaceutical wholesale centre and the obligations imposed on the entrepreneur in connection with running a pharmaceutical wholesale centre:
1. Taking up the activity specified in the authorisation and maintaining it has to be compliant with the Pharmaceutical Law of 6 September 2001 and other regulations; in particular, the entrepreneur is obliged to:

- procure medicinal products solely from the entity responsible, an entrepreneur holding an authorisation for manufacturing or importing medicinal products or an entrepreneur running business consisting in wholesale, having checked the validity of the relevant authorisation;
- possess, including the storage of, only the medicinal products procured from entities authorised to supply them;
- supply medicinal products solely to authorised entities;
- observe the requirements of the Good Distribution Practice.

2. If the entrepreneur did not start running a pharmaceutical wholesale centre within 4 months from the date of obtaining the authorisation or does not run the business activity covered by the authorisation for at least six months, the authorisation can be withdrawn – under Art. 81(2)(3) of the Pharmaceutical Law.
II. The authorisation is valid for an indeterminate term.
III. The authorisation does not cover marketing in the scope specified in the Drug Addiction Counteracting Act of 29 July 2005 (consolidated text: Journal of Laws of 2020, item 2050).

Substantiation:

Under Art. 107(4) of the Code of Administrative Procedure, the Chief Pharmaceutical Inspector resigned from substantiating this decision as it allows the request of the party in full.

Advisement:

Under Art. 127(3) of the Code of Administrative Procedure of 14 June 1960 (consolidated text: Journal of Laws of 2021, item 735; hereinafter referred to as "CAP"), the decision cannot be appealed from, but the party can apply to the Chief Pharmaceutical Inspector for re-examination of the case within 14 days from the service of this decision.
Moreover, under Art. 52(3) of the Law on Procedure before Administrative Courts of 30 August 2002, the party can lodge a complaint against this decision without exercising the right to apply for re-examination of the case – the complaint is to be lodged with the Voivodeship Administrative Court in Warsaw within 30 days from the date of service of the decision, through the Chief Pharmaceutical Inspector. The complaint fee is PLN 200. The party can apply for exemption from court fees and grant of the right to aid on the terms specified in the Law on Procedure before Administrative Courts (Art. 239-262).
Under Art. 127a(1) of CAP, the party – during the time limit for submittal of the application for re-examination of the case – can waive its submittal to the authority which issued the decision. As of the day of service of the notice of waiver of submittal of the application for re-examination of the case to the public administration authority, the decision becomes final and non-appealable.

p.p. Chief Pharmaceutical Inspector
Joanna Szajnik-Solska
Head of the Supervision Department
/signed electronically/

Annex no. 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION
GIF-N-4111/7/AR/10

1. MEDICINAL PRODUCTS
1.1. with a Marketing Authorisation in the Republic of Poland
1.2. intended for marketing in the member states of the European Union, the member states of the European Free Trade Association (EFTA) – parties to the European Economic Area Agreement, outside the Republic of Poland
1.3. intended for exportation to third countries
2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS
2.1. purchase and sale of medicinal products
2.2. storage and supply of own medicinal products
2.3. storage of supply of medicinal products belonging to another entrepreneur
2.4. export
3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS
3.1. products specified in Art. 83 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (EC Official Journal L 311 of 28.11.2001, p. 67, as amended; EU Official Journal, Polish special issue, Chapter 13, vol. 27, p. 69)
3.1.1. medicinal products derived from blood
3.1.2. immunological medicinal products
3.1.3. radiopharmaceuticals (including radionuclide kits)
3.3. cold chain products (requiring low temperature throughout the distribution process)
3.3.2 below 8°C
3.4. other: please specify
3.4.1. cytotoxic medicinal products
3.4.4. medicinal products with very strong effect, specified in the relevant Pharmacopoeia
3.4.6. goods defined in Art. 72(5) of the Pharmaceutical Law of 6 September 2001
3.4.7. goods defined in Art. 72(6) of the Pharmaceutical Law of 6 September 2001

Any restrictions or clarifying remarks related to the scope of these wholesaling operations:

Scope of wholesale to the exclusion of medicinal products derived from blood requiring storage at the temperature below 2°C; Point 3.1.3. marketing of kits for making radiopharmaceutical preparations only (non-radioactive substances).

p.p. Chief Pharmaceutical Inspector
Joanna Szajnik-Solska
Head of the Supervision Department
/signed electronically/

Received by:
1. Genesis Pharm Sp. z o.o. Sp. k., ul. Obywatelska 128/152, 94-104 Łódź
2. to file

I certify that this is a true copy of the following electronic document:

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I, Anna Wocka, a Sworn Translator of the English language, entered in the Register of Sworn Translators kept by the Minister of Justice under no. TP/109/13, hereby certify that the above is a true and accurate translation of the document drawn up in Polish and presented to me.

Mysłowice, 26.05.2021

Repertory: 565/2021

Anna Wocka