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SWORN TRANSLATION FROM POLISH

CHIEF PHARMACEUTICAL INSPECTORATE

[the national emblem of the Republic of Poland]
Chief Pharmaceutical Inspector
NZOH.5100.92.2020.KMAN.1

Warsaw, on [*handwritten*: 21/07/2020]

DECISION

Pursuant to Article 74 (2) of the Pharmaceutical Law of 6 September 2001 (i.e. Journal of Laws of 2020, item 944) and Article 155 of the Code of Administrative Procedure of 14 June 1960 (i.e. Journal of Laws of 2020, item 256 as amended)

THE CHIEF PHARMACEUTICAL INSPECTOR

hereby changes the authorization with ref. no.: GIF-N-4111/11/AR/10 of 5 February 2010 to run a pharmaceutical wholesale business located in Warsaw at ul. Chełmżyńska 249, granted to InPharm sp. z o.o., by adding point 2.3 to the scope of authorization in Amendment No. 1;

AND GIVES IT THE FOLLOWING WORDING:
WHOLESALE DISTRIBUTION AUTHORIZATION

1. Authorization number
   GIF-N-4111/11/AR/10
2. Name of authorization holder
   InPharm spółka z ograniczoną odpowiedzialnością *[limited liability company]*
   KRS *[National Court Register]* no: 0000255451,
   Regon *[statistical identification number]:* 140487485
3. Legally registered address of authorization holder
   ul. Strumykowa 28/11, 03-138 Warsaw
4. Address of site
   ul. Chełmżyńska 249, 04-458 Warsaw
5. Scope of authorization
   Medicinal products for human use: Amendment 1
6. Legal basis of authorization
   Article 74 (1) and (2) in conjunction with Article 72 (1) of the Pharmaceutical Law of 06 September 2001
7. Name of the Chief Pharmaceutical Inspector
   Paweł Piotrowski
8. Signature
   [rectangular blue stamp reading:]
   Chief Pharmaceutical Inspector
   Paweł Piotrowski
   [illegible signature]
9. Date
   [*handwritten:* 21/07/2020]

I. Basic conditions for running a pharmaceutical wholesale business and obligations imposed on an entrepreneur in connection with the running of a pharmaceutical wholesale business:

1. The taking up and carrying out of the activities specified in the authorization must comply with the Pharmaceutical Law of 06 September 2001 and other regulations; in particular the entrepreneur is obliged to:

- procure medicinal products only from a marketing authorization holder, a business authorized to manufacture or import medicinal products, or a business carrying out activities consisting in the wholesale trade, after verification of the validity of the relevant authorization;
- possess, including store, only medicinal products obtained from entities entitled to supply them;
- supply medicinal products only to entitled entities;
- comply with the Good Distribution Practice.

2. If the entrepreneur has not started running a pharmaceutical wholesale business within 4 months from the date of obtaining the authorization or will not run the business covered by the authorization for a period of at least six months, the authorization may be withdrawn - pursuant to Article 81 (2) (3) of the Pharmaceutical Law of 06 September 2001.

II. The authorization is valid for an indefinite period.

III. The authorization does not cover trading to the extent specified in the Act on Counteracting Drug Addiction of 29 July 2005 (i.e. Journal of Laws of 2019, item 852).

Justification:

Pursuant to Article 107 § 4 of the Code of Administrative Procedure (i.e. Journal of Laws of 2020, item 256, as amended), the Chief Pharmaceutical Inspector exercised the option of not justifying this decision, as it grants the request of the party in its entirety.

Instructions:

Pursuant to Article 127 § 3 of the Code of Administrative Procedure of 14 June 1960 (i.e. Journal of Laws of 2020, item 256 as amended; hereinafter referred to as: CAP) the decision is not subject to appeal, however, a party may request the Chief Pharmaceutical Inspector to re-examine the case within 14 days from the service of this decision.
Moreover, pursuant to Article 52 § 3 of the Law on Proceedings before Administrative Courts of 30 August 2002 , a party may file a complaint against this decision without exercising the right to file an application for re-examination of the case - the complaint shall be filed with the Provincial Administrative Court in Warsaw within 30 days from the date of service of the decision via the Chief Pharmaceutical Inspector. The complaint fee is PLN 3000. A party may apply for exemption from court costs and the right to assistance under the rules set out in the Law on Proceedings before Administrative Courts (Articles 239-262).
Pursuant to Article 127a §1 of CAP, during the time for filing an application for re-examination of the case a party may wave their right to file it against the authority which issued the decision.
As of the date on which the party serves a statement waiving the right to file an application for reconsideration of the case on the public administration body, the decision shall become final and binding.

[round red seal with the national emblem of the Republic of Poland in its midst and a circumscription reading:]
CHIEF PHARMACEUTICAL INSPECTOR

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Chief Pharmaceutical Inspector
Paweł Piotrowski
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CHIEF PHARMACEUTICAL INSPECTORATE

Amendment No. 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORIZATION
GIF-N-4111/11/AR/10

1. MEDICINAL PRODUCTS

1.1 intended for trading in the Republic of Poland (with a Marketing Authorization in EEA country)

1.2 intended for trading in Member States of the European Union, member states of the European Free Trade Association (EFTA) - Parties to the Agreement on the European Economic Area, outside the Republic of Poland (Intended for EEA market)

1.3 intended for exportation

2. SCOPE OF AUTHORIZED WHOLESALE DISTRIBUTION OPERATIONS

2.1 purchase and sale of medicinal products (Procurement)

2.2 storage and supply of own medicinal products (Holding)

2.3 storage and supply of medicinal products belonging to another trader (Supply)

2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 products referred to in Article 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 (OJ EC L 311, 28.11.2001, p. 67, as amended; OJ EU Official Journal Polish special edition, chapter 13, item 27, p. 69) (Products according to Article 83 of 2001/83/EC)

3.1.1 Medicinal products derived from blood

3.1.2 Immunological medicinal products

3.3 Cold chain medicinal products (requiring low temperature handling)

3.3.1 Below 15° C

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 as defined in the relevant Pharmacopoeia

3.4.5 Herbs

3.4.6 Goods referred to in Article 72 (5) of the Pharmaceutical Law of 06 September 2001

3.4.7 Supplies referred to in Article 72 (6) of the Pharmaceutical Law of 06 September 2001

[round red seal with the national emblem of the Republic of Poland in its midst and a circumscription reading:]
CHIEF PHARMACEUTICAL INSPECTOR

[rectangular blue stamp reading:]
Chief Pharmaceutical Inspector
Paweł Piotrowski
[illegible signature]

Copies to:

1. InPharm sp. zo.o., ul. Strumykowa 28/11, 03-138 Warsaw
2. to file

CHIEF PHARMACEUTICAL INSPECTORATE

I, Agnieszka Maniakowska, the undersigned sworn translator of the English language, entered into the register of sworn translators maintained by the Minister of Justice under number TP 94/11, hereby declare the above English text to be a true and faithful translation of the attached copy of a document presented to me. In witness whereof, I confirm this by my own signature and seal.

R/D No. 278/2020

Legionowo, 04 August 2020