CHIEF PHARMACEUTICAL INSPECTORATE

[*the national emblem of the Republic of Poland*]
Chief Pharmaceutical Inspector

Done at Warsaw on 09 October 2018---

Reference: NOH.5100.66.2018.1124.MG.4---

DECISION

Pursuant to Article 74.1 and 74.2 in relation to Article 72.1 of the Pharmaceutical Law of 6 September 2001 (uniform text Journal of Laws – year 2017, item 2211, as amended) and Article 104.1 of the Code of Administrative Procedure of 14 June 1960 (uniform text – Journal of Laws – year 2017, item 1257),---

THE CHIEF PHARMACEUTICAL INSPECTOR
hereby grants
PHARMACEUTICAL WHOLESALE AUTHORISATION

1. Authorisation number:---
   NOH.5100.66.2018.1124.MG.4---

2. Name of authorisation holder:---
   Swisscare Pharma spółka z ograniczoną odpowiedzialnością spółka komandytowa [*limited partnership under Polish Law*]---
   Court Register of Companies registration no. (KRS): 0000692424---
   Statistical Registration no. (Regon): 368101894---

3. Legal registered address of authorization holder:---
   ul. Jarosława Iwaszkiewicza 37; 82-300 Elbląg, Poland---

4. Address of wholesale site:---
   ul. Rzgowska 100/102, 93-153 Łódź, Poland---

5. Scope of authorisation:---
   Medicinal products for human use: according to Schedule 1---

6. Legal basis of authorisation:---
   Article 74.1 and 74.2 in relation to Article 72.1 of the Pharmaceutical Law of 6 September 2001 (uniform text: Journal of Laws – year 2017, item 2211, as amended)---

7. Name of the Chief Pharmaceutical Inspector:---
   Paweł Piotrowski---

8. Signature:---
   (-Joanna Szajnik-Solska) [*signed*]---

9. Date:---
   9 October 2018---

RAFAŁ KORZENIEWSKI TŁUMACZ PRZYSIĘGŁY JĘZYKA ANGIELSKIEGO NR TP/6303/05

CHIEF PHARMACEUTICAL INSPECTORATE

I. The basic requirements for carrying out pharmaceutical wholesale business and duties of an entrepreneur running a pharmaceutical wholesale site:---

1. The undertaking of the activity specified in the Authorisation and the running of the business must be in compliance with the Pharmaceutical Law of 6 September 2001 (Journal of Laws - year 2017, item 2211, as amended)[3]and other provisions, in particular, the entrepreneur is required to:---
- purchase medicinal products only from authorised entities, entrepreneurs licensed to manufacture or import medicinal products or entrepreneurs conducting economic activities involving wholesale, after having verified the validity of their relevant concessions;---
- have, including storage, only medicinal products obtained from entities entitled to provide them;---
- supply medicinal products only to authorised entities;---
- observe the Good Distribution Practice guidelines.---

2. In the event that the entrepreneur has not started the pharmaceutical wholesale site within four months of the date of obtaining the Authorisation or has not conducted the activities under the Authorisation for a period of at least six months, the Authorisation may be withdrawn in accordance with Article 81.2.3 of the Pharmaceutical Law of 6 September 2001.

II. The Authorisation is valid for an indefinite time.---

III. The Authorisation does not include trade that falls within the scope of the Act on Counteracting Drug Addiction of 29 July 2005 (uniform text - Journal of Laws - year 2018, item 1030)---

Grounds:

According to Article 107.4 of the Code of Administrative Procedure, the Chief Pharmaceutical Inspector shall not provide justification for this decision as it grants all of the requests made by the Applicant.---

Note:

Pursuant to Article 127.3 of the Code of Administrative Procedure of 14 June 1960 (hereinafter referred to as CAP) this decision cannot be appealed against, however, the Applicant may apply to the Chief Pharmaceutical Inspector for a review of the request within 14 days of the receipt of this Decision.---
Further, pursuant to Article 52.3 of the Act of 30 August 2002 - Law on Proceedings before Administrative Courts, a party may file a complaint against this Decision without first using the right to request for review; the complaint should be filed with the Province Administrative Court in Warsaw within 30 days from the receipt of this Decision through the agency of the Chief Pharmaceutical Inspector.---
Entry fee for filing a complaint is PLN 3000.---
A party may apply for exemption from court costs and the grant of[1]legal assistance according to the provisions set forth in the Law on Proceedings before Administrative Courts[2](Articles 239-262).---
In accordance with Article 127a.1 of the Administrative Code, until the deadline for filing for a review of the case expires, the party may waive the right to file a request for such a review before the authority that issued the Decision.---
The decision becomes final and valid on the day the public administration body has received the statement of waiver of the right to file a request for review.---
[*stamp:*] 'On behalf of Chief Pharmaceutical Inspector – Joanna Szajnik-Solska – Supervision Department Director'---
(-) [*signed*]---

[*a round seal with the national emblem of the Republic of Poland and the following inscription: Główny Inspektor Farmaceutyczny / Chief Pharmaceutical Inspector*]---

Schedule 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORIZATION
NOH.5100.66.2018.1124. MG.4

1. MEDICINAL PRODUCTS---
1.1 with a Marketing Authorisation in the Republic of Poland---
1.2 intended for marketing in European Union member states, member states of the European Free Trade Association (EFTA) – parties to the European Economic Area (EEA) Agreement, outside the Republic of Poland---
1.3 intended for export 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 and supply of medicinal products of other economic entities---
2.4 export---
3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS---

3.1 products specified in Article 83 of Directive 2001/83/EC f the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Official Journal L 311, 28/11/2001 P. 0067 - 0128, as amended; Official Journal EU Polish Special Edition, Chapter 13, vol. 27, p. 69)---

3.1.1 medicinal products derived from blood---
3.1.2 immunological medicinal products---
3.3 cold chain 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 specified in due Pharmacopoeia---
3.4.5 herbs---
3.4.6 goods defined in Article 72.5 the Pharmaceutical Law of 6 September 2001---
3.4.7 goods defined in Article 72.6 the Pharmaceutical Law of 6 September 2001---

[*stamp:*] 'On behalf of Chief Pharmaceutical Inspector – Joanna Szajnik-Solska – Supervision Department Director'---
(-) [*signed*]---

[*a round seal with the national emblem of the Republic of Poland and the following inscription: Główny Inspektor Farmaceutyczny / Chief Pharmaceutical Inspector/*]---

Recipients:---
1. Adam Kliś, LLM, attorney for Swisscare Pharma Sp. z o.o. Sp. k.,---
2. files---

I hereby certify that this is a true and correct translation of the original document in the Polish language.

Translator's Register entry no. 1104/2018 *Elbląg, 17 October 2018*

Rafał Korzeniewski, MA, Ministry-Registered Translator and Interpreter for the English Language
Ministry of Justice registration no. TP/6303/05