

Authorisation No. 506439 / Application No, 102575124

DECISION

- Authorisation**
- **Import of drugs**
 - **Wholesale trade of drugs**
 - **Export of drugs**
 - **Foreign trade of drugs**

Subject

- Renewal of authorisation number 506439 based on application number 102579118 of 10.10.2017 for the company Inceptua SA, Luxembourg, Bioggio Branch.

Whereas

- renewal application number 102575124 of 30.06.2017 submitted by the company Inceptua SA, Luxembourg, Bioggio Branch;
- the fact that examination of the application lodged is a fee-based service

and by virtue of

- article 6 (manufacture), 19 (import, export and foreign trade), 28 (wholesale trade), 34 (collection of blood for transfusions and for the manufacture of drugs) of the Therapeutic Agents Act of 15th December, 2000 (LATer; RS 812.21),
article 3 (manufacture), 7 (import, wholesale trade and export), 12 (foreign trade), 15 (collection of blood for transfusions or for the manufacture of drugs), articles 27 and 28 of the Regulations on the authorization of drugs of 17th October, 2001 (OAM; RS 812.212.1), and also
article 3, paragraph 1 and article 4, paragraph 1 in relation to sub-paragraph A, section IV of Appendix 1 on the Regulations on fees of the Swiss Agency for therapeutic agents (OEAT; RS 812.214.5),

the following decision has been taken:

1. Operating authorisation holder

Inceptua SA, Luxembourg, Succursale di Bioggio
Via Campagna 30
6934 Bioggio

Authorisation No. 506439 / Application No. 102575124

2. The authorisation is issued for the following activities:
 - import of drugs (number of facilities: 1)
 - wholesale trade of drugs (number of facilities: 1)
 - export of drugs (number of facilities: 1)
 - foreign trade of drugs (number of facilities: 1)
3. The provisions contained in the annexes are also applicable.
4. The authorisation is valid from **12.02.2018** to **11.02.2023**.
5. The fee is set at 2000. - CHF and the applicant is required to pay it.
6. This authorisation replaces the authorisation named in the above-mentioned subject from the validity date stated in point 4.

Bern, 16.01.2018

Swissmedic, Swiss Agency for therapeutic agents

(signature)

Claudia Gugler
Zentraler Versand / Envoi centralisé

Your contact:

Inspectorate and Authorisation Division
Office telephone no.: 058 462 04 55

Legal appeal:

An appeal against this decision may be lodged within 30 days from the date whereon notice thereof is given. The appeal should be lodged before the federal administrative Court, PO box 9023 San Gallo, (art. 31 and 33, subparagraph e) of the Federal Act of 17th June, 2005 on the Federal Administrative Court; RS 173.32).

The writ of appeal must contain the conclusions, the reasons, the statement of evidence and the signature of the appellant or his/her/its representative. The decision challenged and the exhibits submitted as evidence must be attached, if they are in the appellant's possession (art. 52 of the Federal Act of 20th December, 1968 on administrative procedure; RS 172.021).

Copy c.c.:

Southern Switzerland Regional Inspection Department
Ticino canton pharmacist

Authorisation No. 506439 / Application No. 102575124

Annex 1: Import of drugs

Authorised operating facility

Inceptua SA, Luxembourg, Bioggio Branch
Via Campagna 30
6934 Bioggio

Technical Manager

Elia Guidali
Trade Officer

Authorised activities / conditions / reservations

Import of ready-to-use drugs, excluding release for the market

- Immunological drugs and allergens are included
- Stable blood derivatives are excluded
- The import of ready-to-use drugs, excluding release for the market, is limited to
 - the import of products intended for re-export
 - the import of products on the order of the approval certificate holder
 - the import of non-approved preparations in Switzerland on the order of the health operator with import authorisation
 - the import of drugs for clinical trials on the order of the sponsor for subsequent distribution to the trial centres

Limitation:

The authorised activities do not include storage

Authorisation No. 506439 / Application No. 102575124

Annex 2: Wholesale trade of drugs

Authorised operating facility

Inceptua SA, Luxembourg, Bioggio Branch
Via Campagna 30
6934 Bioggio

Technical manager

Elia Guidali
Trade Officer

Authorised activities / conditions / reservations

Wholesale trade of ready-to-use drugs, excluding release for the market

- Immunological drugs and allergens are included
- Stable blood derivatives are excluded

Limitation:

The authorised activities do not include storage

Authorisation No. 506439 / Application No. 102575124

Annex 3: Export of drugs

Authorised operating facility

Inceptua SA, Luxembourg, Bioggio Branch
Via Campagna 30
6934 Bioggio

Technical manager

Elia Guidali
Trade Officer

Authorised activities / conditions / reservations

Export of ready-to-use drugs

- Immunological drugs and allergens are included
- Stable blood derivatives are excluded

Limitation:

The authorised activities do not include storage

Authorisation No. 506439 / Application No. 102575124

Annex 4: Foreign trade of drugs

Authorised operating facility

Inceptua SA, Luxembourg, Bioggio Branch
Via Campagna 30
6934 Bioggio

Technical Manager

Elia Guidali
Trade Officer

Authorised activities / conditions / reservations

Foreign trade of ready-to-use drugs, without storage in Switzerland

- Immunological drugs and allergens are included
- Stable blood derivatives are excluded

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For submission to the competent authorities

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Geschäftsbereich
Division
Domaine d'activité

Datum
Date
Date

02.02.2018

Dear Sir or Madam,

We hereby confirm that the attached translation from Italian into English has been carried out and checked to the best of our knowledge and belief.

Our order number: R12037732

Yours faithfully,

KERN AG
Global Language Solutions



Mayumi Decker
Project Manager



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Vorstand: Manfred Kern (Vorsitzender), Michael Kern, Dr. Thomas Kern **Aufsichtsrat:** Ruthild Birte Kern (Vorsitzende)

Sitz der Gesellschaft: Frankfurt am Main **Handelsregister:** Amtsgericht Frankfurt am Main HRB 48945 **USt-IdNr.:** DE811153381