

Approval Nr.: 511566-102615336

DIRECTIVE

Operating license for medicinal products

Facts of the matter:

1. Application from 12 July 2019, number 102615336
2. Applicant: Fisher Clinical Services GmbH
3. Reason for the application:
renewal
4. Number of the previous license: 506567-102582986
5. Legal basis:
Therapeutic Products Act (HMG; SR 812.21)
Medicinal Products Authorization regulation (AMBV; SR 812.212.1)
Medicinal Products regulation (VAM; SR 812.212.21)
Regulation of Switzerland Heilmittelinstituts about its fees (GebV-Swissmedic; SR 812.214.5)

Swissmedic decrees:

1. Operating license holder
Fisher Clinical Services GmbH
Steinbühlweg 69
4123 Allschwil
2. The license is given the number 511566-102615336.
3. The license is granted for the following activities:
 - Manufacture of medicinal products
 - Import of medicinal products
 - Wholesale of medicinal products
 - Export of medicinal products
4. Number of business locations: 2
5. The facts apply as described in the appendices.
6. The license is valid without restrictions from January 16, 2020.
7. fee: CHF 6300.00
8. From the date of validity in section 6, this license replaces the license mentioned in the circumstances.

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Bern, 16.01.2020

Swissmedic, Schweizerisches Heilmittelinstitut

Kathrin Aebischer
Central shipping

Your contact:

Department of Inspectorates and Approvals

Telephone office: +41 58 462 04 55

Right to appeal:

A complaint can be made against this disposition within 30 days of delivery. The complaint must be submitted to the Federal Administrative Court, PO Box, 9023 St. Gallen (Art. 31 and 33 letter e of the Federal Act of June 17, 2005 on the Federal Administrative Court; SR 173.32). The complaint must include the request, the reasons for it, with the evidence and the signature of the complainant or the representative; the contested disposition and the documents called as evidence must be enclosed (Art. 52 of the Federal Law of December 20, 1968 on the administrative procedure; SR 172.021).

Copies:

- Pharmacist of canton Basel-Landschaft
- Regional Medicines Inspectorate of Northwestern Switzerland (RHI)

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Appendix 1

Business location 100074

Fisher Clinical Services GmbH
Ringstrasse 9
4123 Allschwil

Responsible Person(s)

RP 1
Lindenblatt Tillmann
PhD, pharmacist

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Authorized Activities | Requirements | Restrictions

Nr.	Description	Scope*	RP
1	PRODUCTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
1.5	Packaging		
1.5.2	Secondary packaging	H/V, I	1
S.1.8	Blinding of drugs for clinical trials	-	1

*see last page

Your sign: Tillmann Lindenblatt

Our sign: nr

Clerk, phone number.: Rosmarie Neeser Zaugg, +41 58 462 04 55

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Appendix 2

Business location 1001662

Fisher Clinical Services GmbH
Steinbühlweg 69
4123 Allschwil

Responsible Person(s)

RP 1
Lindenblatt Tillmann
PhD, pharmacist

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Authorized Activities | Requirements | Restrictions

Nr.	Description	Scope*	RP
1	PRODUCTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
1.2	Non-sterile products		
1.2.1	Non-sterile products (manufacturing activities for the following dosage forms)		
1.2.1.1	Hard capsules	I	1
1.2.1.17	Other non-sterile products: overencapsulation	I	1
1.2.2	Batch release (technical release)	I	1
1.5	Packaging		
1.5.1	Primary packaging		
1.5.1.1	Hard capsules	HV, I	1
1.5.1.2	Soft capsules	HV, I	1
1.5.1.3	Chewing gum	I	1
1.5.1.8	Other solid dosage forms	I	1
1.5.1.13	Tablets	HV, I	1
1.5.2	Secondary packaging	HV, I	1
S.1.8	Blinding of drugs for clinical trials	-	1
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
S.2.1	Imports of medicinal products not ready for use		
S.2.1.1	Medicinal products (without immunological medicinal products and blood products)	-	1
S.2.1.2	Immunological medicinal products	-	1
S.2.1.3	Blood products	-	1
S.2.3	Import of ready-to-use medicinal products, excluding market release		
S.2.3.1	Medicinal products (without immunological medicinal products and blood products)	-	1
S.2.3.2	Immunological medicinal products	-	1
S.2.3.3	Blood products	-	1
S.2.3.4	The import of ready-to-use medicinal products, excluding of market release, is restricted to:		
S.2.3.4.1	the import for exclusive re-export	-	1
S.2.3.4.3	the import of preparations not approved in Switzerland on behalf of the ordering	-	1
S.2.3.4.4	the import of medicinal products for clinical trials on behalf of the sponsor for the subsequent distribution to the clinical trial sites	-	1
S.4	WHOLESALE WITH MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
S.4.1	Grosshandel mit nicht verwendungsfertigen Arzneimitteln		
S.4.1.1	Medicinal products (without immunological medicinal products and blood products)	-	1
S.4.1.2	Immunological medicinal products	-	1
S.4.1.3	Blood products	-	1
S.4.3	Wholesale of ready-to-use medicinal products, exclusive market release		
S.4.3.1	Medicinal products (without immunological medicinal products and blood products)	-	1
S.4.3.2	Immunological medicinal products	-	1
S.4.3.3	Blood products	-	1

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Nr.	Description	Scope*	FVP
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)		
S.5.1	Exports of medicinal products not ready for use		
S.5.1.1	Medicinal products (without immunological medicinal products and blood product)	-	1
S.5.1.2	Immunological medicinal products	-	1
S.5.1.3	Blood products	-	1
S.5.2	Export of ready-to-use medicinal products		
S.5.3.1	Medicinal products (without immunological medicinal products and blood product)	-	1
S.5.3.2	Immunological medicinal products	-	1
S.5.3.3	Blood products	-	1

*see last page

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Scope of the approved activities (for all appendices)

- H/V Medicinal products from human use (human medicinal products) and veterinary use (veterinary medicinal products),**
- V Exclusively medicinal products for veterinary use (veterinary medicinal products)**
- I Human medicinal product for clinical trials**
- no detailed definition**



Fisher Clinical Services

Fisher Clinical Services GmbH Switzerland
Steinbühlweg 69 CH-4123 Allschwil
Tel. 0041 61 485 23 00 Fax 0041 61 485 23 01

For the Translation

20. JAN. 2020