swissmedic

Authorisation No. 511351-102608771

DECISION

Operating Authorisation for Medicinal Products

Subject

1. Application date: 25.03.2019, Number 102608771
2. Applicant: Rivopharm SA
3. Reason for application:
   Renewal
   Change of Qualified Person
4. Number of authorisation valid until now: 504552
5. Legal bases:
   Federal Act on Therapeutic Products (LATer; RS 812.21);
   Ordinance on Authorisation of Medicinal Products (OAMed; RS 812.212.1)
   Ordinance on Medicinal Products (OM; RS 812.212.21)
   Ordinance on Fees of the Swiss Agency for Therapeutic Products (OEm-Swissmedic; RS 812.214.5)

Swissmedic decides as follows:

1. Holder of the Operating Authorisation
   Rivopharm SA
   Centro Insema
   6928 Manno

2. The number of this authorisation is 511351-102608771

3. The authorisation is granted for the following activities:
   - Manufacture of medicinal products
   - Import of medicinal products
   - Wholesale trade in medicinal products
   - Export of medicinal products
   - Foreign trade in medicinal products

4. Number of authorised operating sites: 1

5. The provisions contained in the annexes are applicable.

6. This authorisation of unlimited duration is valid starting from 02.12.2019.

7. Fee: CHF 10,800.00

8. This authorisation replaces the authorisation indicated as the subject hereof, starting from the validity date indicated at point 6.

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Bern, 23.10.2019

Swissmedic, Swiss Agency for Therapeutic Products

(signature)

Claudia Gugler
Centralised distribution

Your contact:
Inspectorates and Authorisations Division
Secretariat telephone number: +41 58 462 04 55

Appeal procedure:
This decision may be the subject of an appeal, within a period of 30 days from its notification, to the Federal Administrative Court, Post Box, 9023 St-Gall, (art. 31 and 33 letter e of the Federal Act of 17 June 2005 on the Federal Administrative Court; RS 173.32). The statement of grounds of appeal shall include the conclusions, grounds and proof and bear the signature of the appellant or his/her representative; the decision appealed against and the documents invoked as evidence shall be attached thereto (art. 52 of the Federal Act of 20 December 1968 on Administrative Procedure; RS 172.021).

Copy for information to:
- the Chief Pharmacist for the Canton of Ticino
- the Regional Inspection Service for Southern Switzerland (IRM-S)

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Annex 1

Authorised operating site 1000456

Rivopharm SA
Centro Insema
6928 Manno

Qualified Person(s)

QP 1
Casale, Daniele
Dr. Master's Degree in Pharmaceutical Biotechnology

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Authorised activities / Conditions / Reservations

No.	*Description*	*Scope**	*QP*
1	**MANUFACTURE OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)**		
1.2	**Non-sterile products**		
1.2.1	Non-sterile products (manufacturing activities for the following pharmaceutical forms)		
1.2.1.1	Hard capsules	H/V, I	1
1.2.1.13	Tablets	H/V, I	1
1.2.2	Certification of batches (technical release)	H/V, I	1
1.5	**Packaging**		
1.5.1	Primary packaging	H/V, I	1
1.5.1.1	Hard capsules	H/V, I	1
1.5.1.13	Tablets	H/V	1
1.5.2	Secondary packaging		
1.6	**Quality control**		
1.6.2	Microbiological analyses without sterility test	H/V, I	1
1.6.3	Chemical / physical analyses	H/V, I	1
S.2	**IMPORT OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)**		
S.2.2	**Import of ready-to-use medicinal products, including release to market**		
S.2.2.1	Medicinal products (excluding immunological and blood products)	-	1
S.2.3	**Import of ready-to-use medicinal products, excluding release to market**		
S.2.3.1	Medicinal products (excluding immunological and blood products)	-	1
S.2.3.4	Import of ready-to-use medicinal products, excluding release to market is limited to:		
S.2.3.4.1	Import of products intended for re-export	-	1
S.2.3.4.2	Import of products under a mandate granted by the product approval holder	-	1
S.4	**WHOLESALE TRADE IN MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)**		
S.4.1	**Wholesale trade in non-ready-to-use medicinal products**		
S.4.1.1	Medicinal products (excluding immunological and blood products)	-	1
S.4.2	**Wholesale trade in ready-to-use medicinal products, including release to market**		
S.4.2.1	Medicinal products (excluding immunological and blood products)	-	1
S.5	**EXPORT OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)**		
S.5.2	**Export of ready-to-use medicinal products**		
S.5.2.1	Medicinal products (excluding immunological and blood products)	-	1

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No.	*Description*	*Scope**	*QP*
S.6	**FOREIGN TRADE IN MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)**		
S.6.1	**Foreign trade in non-ready-to-use medicinal products, without storage in Switzerland**		
S.6.1.1	Medicinal products (excluding immunological and blood products)	-	1
S.6.2	**Foreign trade in ready-to-use medicinal products, without storage in Switzerland**		
S.6.2.1	Medicinal products (excluding immunological and blood products)	-	1

* see last page

[QR code]

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Scope of validity of authorised activities (legend valid for all annexes)

H/V Medicinal products for human medicine (medicinal products for human use) and veterinary medicine (medicinal products for veterinary use). Medicinal products for clinical studies are not included.

V Exclusively, medicinal products for veterinary medicine (medicinal products for veterinary use).

I Medicinal products for human medicine (medicinal products for human use) for clinical studies.

- Scope not specified/delimited.

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