

- Licence**
- **for manufacturing of medicinal products**
  - **for the importation of medicinal products**
  - **for the wholesale trade of medicinal products**
  - **for the exportation of medicinal products**
  - **for the foreign trade in medicinal products**

**Subject**

- Amendment of the licence issued by Swissmedic on 24 February 2010 to the company Bioforce AG, Grünaustrasse, 9325 Roggwil; Company no. 1005730.
- Number 504628 was assigned to this license.
- This license is based on application number 0102500396.

**Taking into consideration**

- application number 0102500396 submitted by Bioforce AG, dated 11 April 2013, for modification of the scope and change of the Qualified Person,
- the proposals from the Regional Inspection Office of Eastern and Central Switzerland, dated 27 April 2010, 02 March 2012 and 06 November 2012,
- the fact that the evaluation of the submitted application is subject to a fee,

**and based on**

- Articles 6 (manufacturing), 19 (importation, exportation and foreign trade), 28 (wholesale trade) and 34 (drawing of blood for transfusions or for the manufacturing of medicinal products) of the Swiss federal law on medicinal products and medical devices (Heilmittelgesetz), dated 15 December 2000 (HMG; SR [Swiss law] 812.21),
- Articles 3 (manufacturing), 7 (importation, wholesale trade and exportation), 12 (foreign trade), 15 (drawing of blood for transfusions or for the manufacturing of medicinal products), 27 and 28 of the Swiss Ordinance with regard to medicinal product authorisations (Arzneimittel-Bewilligungsverordnung), dated 17 October 2001 (AMBV; SR 812.212.1), and
- Article 3, paragraph 1, and Article 4, paragraph 1, in conjunction with Letter a, Item IV of Appendix V to the Swiss Ordinance with regard to medicinal product fees (Heilmittel-Gebührenverordnung) (HGebV; SR 812.214.5),

the following has been decided:

**1. Licence holder**

**Bioforce AG**  
Grünaustrasse  
9325 Roggwil  
No. 1005730

**2. The licence is granted for the following activities:**

- Manufacturing of medicinal products (number of business locations: 1)
- Importation of medicinal products (number of business locations: 1)
- Wholesale trade of medicinal products (number of business locations: 1)
- Exportation of medicinal products (number of business locations: 1)
- Foreign trade in medicinal products (number of business locations: 1)

Bioforce AG, 9325 Roggwil TG  
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3. The provisions mentioned in the appendices are applicable.
4. The licence is valid from **22 April 2013** until **17 March 2015**.
5. The fees due amount to Fr. 1,000.00 and are to be settled by the applicant.
6. This licence replaces the licence mentioned in the subject with effect from the date of validity mentioned under point 4.

Bern, 22 April 2013

Swissmedic, Swiss Agency for Therapeutic Products  
Department for Licences

Department Head Certificates and Licenses

**Head of the Unit for Companies and Certificates**

*[signed]*

*[signed]*

**Dr. Georges Meseguer**

Dr. Andreas Czank

**Information on legal remedies:**

It is possible to lodge an appeal against this decision within a period of 30 days from the receipt of notification of the decision. Such an appeal must be submitted to the Swiss Federal Administrative Court (Bundesverwaltungsgericht), Postfach, 9023 St. Gallen (Art. 31 and 33, letter e, of the federal law dated 17 June 2005 on the Swiss Federal Administrative Court; SR 173.32).

The appeal must indicate the desired outcome, justifications for this outcome, including evidence, and the appeal must bear the signature of the complainant or of his/her representative. The contested decision and the documents referred to as evidence must be enclosed with the appeal (Art. 52 of the federal law dated 20 December 1968 with regard to administrative procedures; SR 172.021).

A copy of this licence has been sent for information to:

- Regional Inspection Office of Eastern and Central Switzerland
- The Head Pharmacist of the Canton of Thurgau

## **Appendix 1: Manufacturing of medicinal products**

### **Business location:**

**Bioforce AG**  
Grünaustrasse  
9325 Roggwil

### **Qualified Person:**

Dr. Rohr, Gabriela Elisabeth  
Certified Chemist [Swiss qualification level]

### **Licensed activities / conditions / restrictions:**

#### **Manufacturing of active pharmaceutical ingredients**

- Products manufactured in an aseptic manner are excluded
- Products which undergo final sterilisation are excluded
- Processing of biological products is excluded
- Processing of highly active or allergenic active ingredients is excluded

#### **Manufacturing of intermediate products and ready-to-use medicinal products (with the exception of labile blood products)**

- In the form of fluid medicinal preparations
- Products manufactured in an aseptic manner are excluded
- Products which undergo final sterilisation are excluded
- Processing of biological products is excluded
- Manufacturing of highly active or allergenic active ingredients is excluded

#### **Manufacturing of intermediate products and ready-to-use medicinal products (with the exception of labile blood products)**

- In the form of semi-solid medicinal preparations
- Products manufactured in an aseptic manner are excluded
- Products which undergo final sterilisation are excluded
- Processing of biological products is excluded
- Processing of highly active or allergenic active ingredients is excluded

#### **Manufacturing of intermediate products and ready-to-use medicinal products (with the exception of labile blood products)**

- In the form of solid medicinal preparations
  - Products manufactured in an aseptic manner are excluded
  - Products which undergo final sterilisation are excluded
  - Processing of biological products is excluded
  - Processing of highly active or allergenic active ingredients is excluded

#### **Manufacturing of medicinal products for clinical trials (active pharmaceutical ingredients)**

#### **Manufacturing of medicinal products for clinical trials (intermediate products and ready-to-use products)**

**Manufacturing of medicinal products on the basis of a magistral formula, officinal formula or a pharmacist's own formula in the sense of Article 9, paragraph 2, letters a, b and c of the HMG [Swiss Law on Medicinal Products and Medical Devices] on behalf of the holder of a cantonal authorisation for retail trade in accordance with Article 30 of the HMG for dispensing by the ordering party.**

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## **Appendix 2: Importation of medicinal products**

### **Business location:**

Bioforce AG  
Grünaustrasse  
9325 Roggwil

### **Qualified Person:**

Dr. Rohr, Gabriela Elisabeth  
Certified Chemist [Swiss qualification level]

### **Licensed activities / conditions / restrictions:**

**Importation of ready-to-use medicinal products (excluding immunological medicinal products, blood and blood products), including market release.**

**Importation of ready-to-use medicinal products (excluding immunological medicinal products, blood and blood products), excluding market release, restricted to importation exclusively for re-exportation.**

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### **Appendix 3: Wholesale trade of medicinal products**

#### **Business location:**

Bioforce AG  
Grünaustrasse  
9325 Roggwil

#### **Qualified Person:**

Dr. Rohr, Gabriela Elisabeth  
Certified Chemist [Swiss qualification level]

#### **Licensed activities / conditions / restrictions:**

**Wholesale trade of non-ready-to-use medicinal products (excluding immunological medicinal products and blood products)**

**Wholesale trade of ready-to-use medicinal products (excluding immunological medicinal products, blood and blood products) in Switzerland, including market release**

*Bioforce AG, 9325 Roggwil TG  
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## **Appendix 4: Exportation of medicinal products**

### **Business location:**

Bioforce AG  
Grünaustrasse  
9325 Roggwil

### **Qualified Person:**

Dr. Rohr, Gabriela Elisabeth  
Certified Chemist [Swiss qualification level]

### **Licensed activities / conditions / restrictions:**

**Exportation of ready-to-use medicinal products (excluding immunological medicinal products, blood and blood products)**

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## **Appendix 5: Foreign trade in medicinal products**

### **Business location:**

Bioforce AG  
Grünaustrasse  
9325 Roggwil

### **Qualified Person:**

Dr. Rohr, Gabriela Elisabeth  
Certified Chemist [Swiss qualification level]

### **Authorised activities / conditions / restrictions:**

**Foreign trade in non-ready-to-use medicinal products (excluding immunological medicinal products and blood products), without storage in Switzerland**

**Foreign trade in ready-to-use medicinal products (excluding immunological medicinal products, blood and blood products), without storage in Switzerland**