

Swissmedic- License

- **For the manufacture of drugs**
- **For the import of drugs**
- **For the wholesale of drugs**

Issue

- Renewal of the Swissmedic license dated September 14, 2006 for the company Bachem AG, Hauptstrasse 144, 4416 Bubendorf, Switzerland, company number 1008308

Considering

- The application of the company Bachem AG dated May 09, 2008 for renewal of license
- The request of the Regional Therapeutic Products Inspectorate for North-Western Switzerland (RHI-NW) dated January 03, 2008
- The fact that examination of the received application is subject to a fee

Based on

- Article 6 (manufacture), 19 (import, export and trade abroad), 28 (wholesaling), 34 (blood withdrawal for transfusions or for manufacturing drugs) of the Therapeutic Products Act dated December 15, 2000 (HMG; SR 812.21),
- Article 3 (manufacture), 7 (import, wholesaling and export), 12 (trade abroad), 15 (blood withdrawal for transfusions or for manufacturing drugs), 27 and 28 of the Drugs License Regulation dated October 17, 2001 (AMBV; SR 812.212.1) and
- Article 2 paragraph 1 and article 3 in conjunction with paragraph IV of the annex to the Therapeutic Products Fees Regulation dated June 22, 2006 (HGebV; SR 812.214.5)

it is regulated as follows:

1. Operating license owner:

Bachem AG
Hauptstrasse 144
4416 Bubendorf
Switzerland
No. 1008308

2. The license is granted for the following activities:
 - The manufacture of drugs (number of facilities: 1)
 - The import of drugs (number of facilities: 1)
 - The wholesale of drugs (number of facilities: 1)
3. The facts set forth in the annexes will apply.
4. The license is valid through **July 22, 2013**.
5. The fee is set to CHF 1'500 and is to be paid by the applicant.
6. This license supersedes the Swissmedic license of September 14, 2006.

Berne July 23, 2008

SWISSMEDIC, Swiss Agency for Therapeutic Products
Division grant of licenses

Head of department companies and certificates

(Signature)

Dr. Georges Meseguer

Assistant

(Signature)

Monika Wittich

An appeal against this decree can be filed within 30 days of delivery. The notice of appeal is to be filed with the Federal Administrative Court, post office box, 3000 Berne 14, Switzerland (art. 31 and 33 letter e of the federal law, dated June 17, 2005 concerning the federal administrative court; SR 173.32).

The notice of appeal shall set forth the request and the reason thereof including the indication of evidence and the signature of the complainant or the representative; the appealed regulation and the documents presented as evidence shall be attached (art. 52 of the federal law dated December 20, 1968 concerning the administrative procedure; SR 172.021).

Copy for information to:

- Regional Therapeutic Products Inspectorate for North- Western Switzerland
- Cantonal Pharmacist, Canton of Basel-Landschaft

Annex 1: Manufacture of drugs

Facility:

Bachem AG
Hauptstrasse 144
4416 Bubendorf
Switzerland
No. 1008308

Qualified Person:

Haas, Gerhard
Chemist, Ph.D.
Date of birth: April 26, 1960

Licensed activities / Conditions / Restrictions:

Manufacture of active pharmaceutical ingredients

Aseptically prepared products are excluded
Terminally sterilized products are excluded
The processing of biological products is excluded
The processing of highly active or allergenic substances is included

Manufacturing of drugs for clinical trials

Chemical, physical and biochemical quality control of drugs as an external analytical laboratory

Microbiological quality control of drugs as an external analytical laboratory

Sterility testing is excluded

Annex 2: Import of drugs

Facility:

Bachem AG
Hauptstrasse 144
4416 Bubendorf
Switzerland
No. 1008308

Qualified Person:

Haas, Gerhard
Chemist, Ph.D.
Date of birth: April 26, 1960

Licensed activities / Conditions / Restrictions:

Import of finished drugs (no immunological drugs, blood and blood products), except release for market use

Restricted to drugs for clinical studies

Annex 3: Wholesale of drugs

Facility:

Bachem AG
Hauptstrasse 144
4416 Bubendorf
Switzerland
No. 1008308

Qualified person:

Haas, Gerhard
Chemist, Ph.D.
Date of birth: April 26, 1960

Licensed activities / Conditions / Restrictions:

Wholesale of unfinished drugs (except immunological drugs and blood products)

Wholesale of finished drugs (except immunological drugs, blood and blood products) in Switzerland, except release for market use

Restricted to drugs for clinical trials