Bundesministerium
für Gesundheit

Bundesministerium für Gesundheit, 53107 Bonn

To whom it may concern

Bonn 09. September 2015

Az.: 114 – 41045

Subject Regulation on medicinal products in Germany

In particular Authorisations and statement of GMP compliance

Marketing authorisation

Under the German Drug Law, approval ("Marketing Authorisation") of conventional medicinal products for human use is granted by the:

Bundesinstitut
für Arzneimittel und Medizinprodukte (BfArM)
Federal Institute for Drugs and Medical Devices
Kurt-Georg-Kiesinger-Allee 3, D - 53175 Bonn
Phone: (+49) 228 207 30,
FAX (+ 49) 228 207 5207
Email: poststelle@bfarm.de; www.bfarm.de

Paul – Ehrlich – Institut
Bundesinstitut für Impfstoffe und
Biomedizinische Arzneimittel
Federal Institute for vaccines and biological medicinal products
Paul-Ehrlich-Straße 51-59, D- 63225 Langen
Phone: (+49) 6103 / 77 - 0
FAX: (+49) 6103 / 77 - 1234
E-mail: pei@pei.de; www.pei.de
- for blood products, sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, allergens, gene transfer medicinal products, somatic cell therapy products, xenogenic cell therapy products, advanced therapy medicinal products and blood components manufactured using genetic engineering.

Supervision of companies

In the Federal Republic of Germany, the 16 Federal States ("Laender") are responsible for monitoring compliance with GMP including supervision of manufacture, import and export of medicinal products. The activities of the 25 competent authorities on the regional level (Laender authorities, called *Bezirksregierung, Regierungspräsidium, Regierung, Senat, Behörde or Landesamt*) in the 16 Federal States are managed by the corresponding Ministry of Health in each of the 16 Laender.

A central co-ordination unit ("ZLG") of the Federal Laender was established to co-ordinate the executive tasks in the framework of GMP:

Zentrale Koordinierungsstelle der Laender
für den Gesundheitsschutz bei Arzneimitteln (ZLG)
Sebastianstraße 189, D - 53115 Bonn
Phone (+49) 228 977 94 0, FAX (+49) 228 977 94 44; www.zlg@zlg.nrw.de

Manufacturing license

In Germany, a manufacturing license may only be granted by the competent Laender authorities if appropriately qualified persons and suitable premises and equipment for manufacturing, testing and storage of the medicinal products are available, and if the manufacturer is able to ensure that the products are manufactured and tested in accordance with the current state of science and technology, especially the principles and guidelines of good manufacturing practice (GMP) for medicinal products as laid down by Community Law and which are comparable to other international GMP-guidelines such as WHO. Further more the manufacturing license may be issued only after an inspection of the manufacturer has been performed by the competent Laender authority. These requirements follow Articles 40 ff. of Directive 2001/83/EC and Directive 2003/94/EC which can be found under http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm. The manufacturing license regularly does not specify an expiry date

Contacts list with competent authorities participating in the WHO certification scheme

Combined certificates, referring to the marketing authorisation and the manufacturing license, are subject of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In Germany, such product related certificates are issued by the competent Laender authorities or the *Federal Institutes*. Jurisdiction of the latter is determined by the location of the manufacturing site or the site which is responsible for the batch release of imported products into the European Community.

A complete list of the German Health Authorities participating in the WHO certification scheme can be found here:

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/

Dr. Ralf Halfmann
(Federal Ministry for Health of Division Marketing Authorisation and Quality of Medicinal Products)

Authentication

The certificate with the seal of the Bundesministerium für Gesundheit is herewith authenticated.

By order

Maria Wobbe