

Information sheet "Marketing Authorisation Procedure pursuant to section 11 Animal Health Act (Tiergesundheitsgesetz; TierGesG)"

updated: October 2017

Pursuant to section 11 sub-section 2 Animal Health Act, in vitro diagnostics for the detection of notifiable and reportable animal diseases generally may only be placed on the market or administered after an official marketing authorisation has been granted.

The competent authority for granting marketing authorisations (licensing authority) for those in vitro diagnostics is the Friedrich-Loeffler-Institut (FLI), Federal Research Institute for Animal Health. The marketing authorisation procedure pursuant to sections 20 ff of the Regulation on Animal Vaccines (Tierimpfstoff-Verordnung) is initiated after submission of an application by the pharmaceutical entrepreneur.

The pharmaceutical entrepreneur is the person placing the product on the market under his own name (manufacturer, distributor). The pharmaceutical entrepreneur must have his registered place of business in a member state or in a contracting state of the Agreement on the European Economic Area.

For information on the data to be submitted and on the requirements to be met, please refer to the information sheets "Marketing Authorisation Application", "Summary of Product Characteristics" and "Labelling requirements".

The **marketing authorisation application** must be labelled with the words "Amtliche Zulassung nach § 11 Absatz 2 TierGesG" ("Official marketing authorisation procedure pursuant to section 11 TierGesG") and with the words "Testkit bei ... eingereicht am ..." ("test kit filed with on"). The application must be sent to the following address:

Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health
Licensing Authority (Zulassungsstelle)
Südufer 10
D-17493 Greifswald-Insel Riems

Phone: +49-38351-71240
Fax: +49-38351-71151
E-mail: jana.heidrich@fli.de

The experimental testing required for a decision on the marketing authorisation will be done in the respective test laboratory of the Friedrich-Loeffler-Institut. The address of the laboratory can be found in the information sheet "Test laboratories".

The **duplicate of the marketing authorisation application** with the respective documentation and the **samples of the product** required for testing (in sufficient quantity and quality pursuant to section 32 sub-section 2 of the Regulation on Animal Vaccines) must be sent to the test laboratory for the respective disease in Jena. **For products that are to be tested at the test laboratories on the Isle of Riems, the above-mentioned documents and samples should be addressed and sent directly to the Licensing Authority Insel Riems (Dr. Heidrich).**

The fees for a decision on a marketing authorisation are specified in the Regulation on the Administrative Costs for Animal Vaccines (Tierimpfstoff-Kostenverordnung). The fee for a decision on a marketing authorisation for products is 2,500 € or 3,750 € respectively. The cost of batch release amounts to 340 € or 510 € respectively.