

Information sheet "Summary of Product Characteristics" (§ 21 Regulation on Animal Vaccines)

updated: January 2015

In addition, the marketing authorisation application pursuant to section 20 sub-section 4 (for products that are not for veterinary use) must contain a **Summary of Product Characteristics** in German language pursuant to **Annex 2**:

1. Name of the product
2. Constituents of the product by type and quantity and their specification by common or chemical name
3. Material to be used for testing, target animal species
4. Type of application, field of application
5. Contra-indications
6. Information on the correct application
7. Information on the safe use
8. Expiry date, if necessary after first opening of the container
9. Storage conditions
10. Information on the disposal of unused products
11. Name and address of the applicant and of the manufacturer
12. Marketing authorisation number
13. Date of marketing authorisation or renewal date
14. Date of revision of the summary of product characteristics

The documentation must be submitted in duplicate:

1. The original of the documentation (application, summary of product characteristics) labelled with the words "Amtliche Zulassung nach § 11 TierGesG" ("official marketing authorisation procedure pursuant to section 11 TierGesG") and with the words "Testkit bei ... eingereicht am ..." ("test kit filed with on...") must be sent to

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

2. The marketing authorisation documentation and the samples of the product must be sent to the test laboratory for the respective disease (see information sheet "Test laboratories").
3. The summary of product characteristics must additionally be enclosed as Microsoft Word file.