

**Information sheet "Labelling requirements" (sections 35 and 36 Regulation on Animal Vaccines)**  
updated: January 2015

**Labelling of container pursuant to section 35 of the Regulation on Animal Vaccines**

A product may only be marketed, if the container and - if used - the outer package contain the following information in **German language**, in an easily legible form and in a permanent manner:

- (1) No. 1. Name of the medicinal product, pharmaceutical form
2. Active substances (common name) by type and quantity per unit or dosage form
3. Batch identification with the abbreviation "Ch.-B." (if for test kits no common batch identification for all components is possible, all batch identifications must additionally be indicated on the outer package)
4. Marketing authorisation number with the abbreviation "Zul.-Nr."
5. Name and address of the pharmaceutical entrepreneur (= applicant)
6. Target animal species
7. Method and route of administration and, if required, dosage (vaccines only)
8. Withdrawal period, as far as the product is administered to animals used for food production (vaccines only)
9. Warnings, as far as imposed by the licensing authority
10. The words „ad us. vet.“ or „Für Tiere“ (“for animals”) (vaccines only)
11. The words „verschreibungspflichtig“ („subject to prescription“) or „nur auf tierärztliche Verschreibung abzugeben“ („ad us vet“) (vaccines only)
12. Content of the product by weight, volume or number of units
13. Expiry date
14. Storage conditions
15. Precautions (if required for disposal of unused product)
- (2) for sera: additionally animal species of origin of the serum and  
for vaccines: host system, which was used for reproduction of the agents
- (3) Containers which contain only one unit or less than ten ml need to be labelled on the outer package only

**Package leaflet pursuant to section 36 of the Regulation on Animal Vaccines**

A product may only be marketed with a package leaflet bearing the heading "Gebrauchsinformation" ("instructions for use"). The package leaflet must contain the following information in German language and in an easily legible form:

- (1) No. 1. Name and address of the pharmaceutical entrepreneur (= applicant)
2. Name of the medicinal product
3. Active substances by type and quantity
4. Method of administration
- (2) No. 1. Purpose of application
2. Instructions for work
3. Storage conditions
4. Expiry date
5. Target animal species
6. Type and quality of the sample material

Any additional information must be separated clearly from the information pursuant to section 36 sub-sections 1 and 2.

- (3) The package leaflet is not required if a product is marketed without outer package and if the information pursuant to sub-sections 1 and 2 is printed on the container.

In multilingual instructions for use, we recommend to indicate in addition the MA No. and the words "Die deutsche Gebrauchsinformation ist nach § 11 Absatz 2 TierGesG zugelassen" in the header of the instructions for use.