

## Information sheet „Variation“ (Sections 28 and 29a Regulation on Animal Vaccines)

updated: October 2011

### Duties of the marketing authorisation holder (Article 28)

- (1) The applicant is obliged to inform the competent licensing authority of new facts without delay and to submit the respective data and documentation, if these new facts lead to changes in the data and documents pursuant to article 20 paragraph 4 (see information sheet “Marketing Authorisation Application”) or in the Summary of Product Characteristics pursuant to Article 21 (see information sheet „Summary of Product Characteristics“).
- (2) Furthermore, the applicant is obliged to inform the competent licensing authority without delay
  1. that he has placed the medicinal product into circulation, if no application for batch release by the authority is submitted,
  2. that he has withdrawn the product from the market either temporarily or permanently,
  3. on request of the competent authority, of the amounts of the medicinal product that he has supplied or exported.
- (3) Manufacturing and testing of the medicinal product by the marketing authorisation holder must comply with the current scientific and technical knowledge and must be kept updated accordingly. The competent licensing authority must be notified of the changes without delay and the respective data and documentation must be submitted.

### Variation to the marketing authorisation, application for new marketing authorisation (Article 29a)

- (1) The applicant is obliged to inform the competent licensing authority of new facts without delay and to submit the respective data and documentation, if these new facts lead to changes in the data and documents pursuant to article 20 paragraph 4 or in the Summary of Product Characteristics pursuant to Article 21.
- (2) The variation of
  1. the manufacturing procedure
  2. the field of application
  3. the shelf-life (prolongation)
  4. the labelling or
  5. the packaging insertmust be accepted from the competent licensing authority.
- (3) In case of a name change of the product, the product may be placed into circulation under the old name for two further years commencing on the 1st of January or the 1st of July following the promulgation of the name change in the Federal Gazette.
- (4) In case of a significant modification of the type or quantity of the active ingredients of the medicinal product, a new marketing authorisation application must be submitted.