

In compliance with the Act No 378/2007 on Pharmaceuticals and its implementing Regulation No 228/2008 on Marketing authorisation USKVBL requests for ensuring quality, safety and efficacy of Immunological veterinary medicinal products (IVMP) observance rules that are detailed described in some legal regulations concerning the marketing authorisation area.

### General guidelines (See Czech version)

- USKVBL/REG-3/2009 Rev.2 - Templates for preparation of SPC, labelling and package leaflet
- USKVBL/REG - 1/2010 Rev.1 - Detailed information on the draft texts for small single-dose immediate packaging units of IVMP in a language other than Czech

### Guidelines for particular parts of dossier

For the preparation of the quality, safety and efficacy part of the dossier for IVMP for the purposes of marketing authorisation applications, the requirements of European Pharmacopoeia published by EDQM together with recommendations of guidelines published on the European Medicines Agency (EMA) web-site should be taken into consideration (see the link below).

In addition to the overview of EMA guidelines below, the EMA also publishes and updates the list of reflection and position papers on the clarification of requirements in different areas of IVLP assessment.

### **Overview of EMA Guidelines for Immunological Veterinary Medicinal Products:**

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000194.jsp&murl=menus/regulations/](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000194.jsp&murl=menus/regulations/)

[regulations.jsp&mid=WC0b01ac058002dd33](http://regulations.jsp&mid=WC0b01ac058002dd33)

Name of the Guideline	Reference number	Effective from	Note
Guideline on requirements for immunological veterinary medicinal products	EMA/CVMP/001/00	01/12/1997	NEW
Environmental risk assessment of biological medicinal products	EMA/CVMP/007/00	01/12/1997	
Guideline on data requirements for the composition of authorised equine influenza vaccines	EMA/CVMP/008/00	01/12/1997	
Use of adjuvanted veterinary vaccines	EMA/CVMP/043/97	01/12/1998	
DNA vaccines non-amplifiable for use	EMA/CVMP/071/98	01/12/1998	
Duration of protection achieved by vaccines	EMA/CVMP/082/99	05/2001	
EU requirements for batch and mini-batch potency for developmental safety	EMA/CVMP/152/02	17/06/2002	
Field trials with veterinary vaccines	EMA/CVMP/852/99	01/12/2001	
Requirements and control of the production of immunological veterinary products	EMA/CVMP/743/00 Rev. 2	01/12/2005	
Requirements for the production and control of alleged products for use in animals	EMA/CVMP/004/04	08/06/2005	
Live recombinant vector vaccines for use	EMA/CVMP/004/04	08/06/2005	
User safety for immunological products	EMA/CVMP/004/04	08/06/2005	
Requirements for an authorisation of vaccines for use in birds against	EMA/CVMP/004/04	08/06/2005	
Requirements for an authorisation of vaccines for emergency use against	EMA/CVMP/004/04	08/06/2005	
Data requirements for immunological products intended for use in birds	EMA/CVMP/004/04	08/06/2005	
Requirements for combined immunological veterinary medicinal products	EMA/CVMP/004/04	08/06/2005	
The procedure to be followed when a vaccine product is suspected to be contaminated	EMA/CVMP/004/04	08/06/2005	
Data requirements for multivalent vaccines against avian influenza (AI), blue	EMA/CVMP/004/04	08/06/2005	
Data requirements for the use of seeds (MS) already used in authorised	EMA/CVMP/004/04	08/06/2005	
Design of studies to evaluate the efficacy of vaccines	EMA/CVMP/004/04	08/06/2005	
Data requirements to support the use of veterinary vaccines	EMA/CVMP/004/04	08/06/2005	
VICH GL17 Stability testing of biological medicinal products	EMA/CVMP/004/04	08/06/2005	
VICH GL25 Biologicals: testing of biological medicinal products	EMA/CVMP/004/04	08/06/2005	
VICH GL26 Biologicals: testing of biological medicinal products	EMA/CVMP/004/04	08/06/2005	
VICH GL34 Biologicals: testing of biological medicinal products	EMA/CVMP/004/04	08/06/2005	
VICH GL40 Test procedures for the detection of contamination	EMA/CVMP/004/04	08/06/2005	
VICH GL41 Target animal studies for vaccines in target animals for absence	EMA/CVMP/004/04	08/06/2005	
VICH GL44 Target animal studies for vaccines in target animals for absence	EMA/CVMP/004/04	08/06/2005	
VICH GL50 Harmonisation of safety testing for injectable vaccines	EMA/CVMP/004/04	08/06/2005	
VICH GL55 Harmonisation of safety testing for injectable vaccines	EMA/CVMP/004/04	08/06/2005	