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/

regulations.jsp&mid=WC0b01ac058002dd33

Name of the Guideline	Reference number	Effective from	Note
Guideline on requirements for the production and control of immunological veterinary medicinal pro	EMA/CVMP/IWP/206555/2010-Rev.1	01/06/2017	NEW!
Environmental risk assessment for immunological veterinary medicinal products	EMA/CVMP/074/95	01/02/1997	
Guideline on data requirements for changes to the strain composition of authorised equine influenza v	EMA/CVMP/IWP/97061/2013	01/05/2015	
Use of adjuvanted veterinary vaccines	EMA/CVMP/IWP/043/97	01/12/1998	
DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	EMA/CVMP/IWP/07/98	01/01/2001	
Duration of protection achieved by veterinary vaccines	EMA/CVMP/682/99	01/05/2001	
EU requirements for batches with maximum and minimum titre or batch potency for developmental sa	EMA/CVMP/552/02	17/06/2002	
Field trials with veterinary vaccines	EMA/CVMP/852/99	01/12/2001	
Requirements and controls applied to bovine serum used in the production of immunological veterina	EMA/CVMP/743/00 Rev.2	01/01/2006	
Requirements for the production and control of allergen products for use in animals	7BIm1a	01/09/1994	
Live recombinant vector vaccines for veterinary use	EMA/CVMP/004/04	08/06/2005	
User safety for immunological veterinary medicinal products	EMA/CVMP/IWP/54533/2006	01/11/2007	
Requirements for an authorisation under exceptional circumstances for vaccines for use in birds again	EMA/CVMP/IWP/222624/2006	01/06/2007	
Requirements for an authorisation under exceptional circumstances for vaccines for emergency use a	EMA/CVMP/IWP/220193/2008	01/06/2009	
Data requirements for immunological veterinary medicinal products intended for minor use or minor sp	EMEA/CVMP/IWP/123243/2006 Rev. 3	01/03/2017	NEW!
Requirements for combined vaccines and associations of immunological veterinary medicinal produc	EMEA/CVMP/IWP/594618/2010	01/10/2014	
The procedure to be followed when a batch of a vaccine finished product is suspected to be contamin	EMA/CVMP/IWP/205351/2006-Rev.1	01/03/2016	
Data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), blue	EMA/CVMP/IWP/105506/2007	01/07/2010	
Data requirements for the replacement of established master seeds (MS) already used in authorised	EMA/CVMP/IWP/125504/07	01/02/2010	
Design of studies to evaluate the safety and efficacy of fish vaccines	EMA/CVMP/IWP/314550/2010	01/05/2012	
Data requirements to support in-use stability claims for veterinary vaccines	EMEA/CVMP/IWP/250147/2008	01/06/2010	
VICH GL17 Stability testing of biotechnological/biological veterinary medicinal products	EMA/CVMP/VICH/501/99	01/06/2001	
VICH GL25 Biologicals: testing of residual formaldehyde	EMA/CVMP/VICH/095/01	01/05/2003	
VICH GL26 Biologicals: testing of residual moisture	EMA/CVMP/VICH/096/01	01/05/2003	
VICH GL34 Biologicals: testing for the detection of Mycoplasma contamination	EMA/CVMP/VICH/463/2002	28/02/2014	
VICH GL40 Test procedures and acceptance criteria for new biotechnological/biological veterinary m	EMEA/CVMP/VICH/811/04	01/11/2006	
VICH GL41 Target animal safety: examination of live veterinary vaccines in target animals for absenc	EMA/CVMP/VICH/1052/2004	01/07/2008	
VICH GL44 Target animal safety for veterinary live and inactivated vaccines	EMA/CVMP/VICH/359665/2005	01/07/2009	
VICH GL50 Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccin	EMA/CVMP/VICH/582610/2009	01/05/2018	new version: Revision 1
VICH GL55 Harmonisation of criteria to waive target animal batch safety testing for live vaccines for v	EMA/CVMP/VICH/136103/2015	01/05/2018	new version: Revision