International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/24/046
September 2024

FOR VICH SC ONLY

STATUS OF THE REVIEW OF VICH GUIDELINES – 2024

This table has been developed to show, before each VICH Steering Committee meeting, the status of the VICH GLs and highlight the need for review if required.
At the forthcoming 43rd meeting the SC has to consider 3 GLs which have been either implemented or reviewed in 2019; these GLs (GL36, GL50 and GL56) are highlighted in red below.

15 GLs are currently under revision (*highlighted in yellow*).
The revision of 5 GLs has been put on hold (*highlighted in blue*).
33 further GLs have been reviewed (or revised) in the last 5 years without further need for action.
3 GLs have been implemented after 2019.

To date 59 GLs have been implemented in the regions before September 2024, and 2 new GLs are at step 4 of the development process. The list of these guidelines is detailed in the document VICH/99/036 – Status of VICH Guidelines and Work plan, which is updated whenever required. The last version of this document can be found on the Steering Committee page of the VICH Website.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

STATUS OF THE REVIEW OF VICH GUIDELINES

Adopted VICH Guidelines

Re	Topic	TITLE OF GUIDELINES	Expert Working Group in charge	Step Status	Step 2 (EWG consensus) Signed on:	Step 3 (SC approval of release for consultation) Signed on:	Step 5 (EWG consensus) signed on:	Step 6 (SC approval) signed on:	Implementation date	STATUS	Topic leader for the initial GL	Date of last consideration
GL1	Validation definitions	Validation of analytical procedures: definition and terminology	Quality	Step 7	Mar. 1997	Aug.1997	Oct. 1998	Oct. 98	Oct. 1999	No Action before ICH	AHI	Nov 21
GL2	Validation methodology	Validation of analytical procedures : methodology	Quality	Step 7	Mar. 1997	Aug.1997	Oct. 1998	Oct. 98	Oct. 1999	No Action before ICH	AHI	Nov 21
GL3 Rev. 1	Stability 1	Stability testing of new drug substances and products	Quality	Step 9	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000 - **Revised Nov 2011**	No Action	FDA	Nov 23
GL4	Stability 2	Stability testing for new dosage forms	Quality	Step 7	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000	No Action	FDA	Nov 21
GL5	Stability 3	Stability testing : photostability testing of new drug substances and products	Quality	Step 7	Sep. 1997	Feb. 1998	Mar. 1999	May 1999	May 2000	No Action	FDA	Nov 21
GL6	Ecotox Phase I	Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1	Ecotoxicity	Step 7	Sep. 1998	Oct. 1998	Nov. 1999	June 2000	Jul. 2001 (to be implemented in Japan upon completion of phase 2)	No Action	AHI	Nov 21

GL7	Anthelmintics General	Efficacy of anthelmintics: general requirements	Anthelmintics	Step 7	Aug. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001	Under revision	EU	
GL8	Stability premixes	Stability testing for medicated premixes	Quality	Step 7	Jul. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001	Under revision	FDA	
GL9	GCP	Good Clinical Practices	GCP	Step 7	Sep. 1998	Oct. 1998	Nov. 1999	June 2000	Jul. 2001	No Action	AHE	Nov 21
GL10 Rev. 1	Impurities substances	Impurities in new veterinary drug substances	Quality	Step 9	Oct. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001 - **Revised Nov 2011**	No Action	EU	Nov 22
GL11 Rev. 1	Impurities products	Impurities in new veterinary medicinal products	Quality	Step 9	Oct. 1998	Oct. 1998	Nov. 1999	Nov. 1999	Dec.2000 – June 2001 - **Revised Nov 2011**	No Action	EU	Nov 22
GL 12	Anthelmintics bovine	Efficacy of anthelmintics: specific recommendations for bovines	Anthelmintics	Step 7	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001	Under revision	EU	
GL13	Anthelmintics ovine	Efficacy of anthelmintics: specific recommendations for ovines	Anthelmintics	Step 7	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001	Under revision	EU	
GL14	Anthelmintics caprine	Efficacy of anthelmintics: specific recommendations for caprines	Anthelmintics	Step 7	Nov. 1998	Feb. 1999	Nov. 1999	Nov. 1999	Dec.2000 – June 2001	Under revision	EU	
GL15	Anthelmintics equine	Efficacy of anthelmintics: specific recommendations for equines	Anthelmintics	Step 7	Mar. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002	Under revision	EU	
GL16	Anthelmintics porcine	Efficacy of anthelmintics: specific recommendations for porcines	Anthelmintics	Step 7	Mar. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002	Under revision	EU	
GL17	Stability: Biotechnologicals/biologicals	Stability testing of new biotechnological/biological products	Quality	Step 7	Apr. 1999	July 1999	Mar. 2000	Jun. 2000	Jul. 2001	No Action	JMAFF	Nov 21

GL18 Rev. 2	Impurities: Residual Solvents	Impurities: residual solvents in new veterinary medicinal products, active substances and excipients	Quality	Step 7	Apr. 1999	July 1999	Mar. 2000	Jun. 2000	Jul. 2001 **Rev Sept 2014**	**Revised April 23**	EU	Impl. April 24
GL19	Anthelmintics canine	Efficacy of anthelmintics: specific recommendations for canine	Anthelmintics	Step 7	Nov. 1999	Nov. 1999	Feb. 2001	Jun. 2001	Jul. 2002	Under revision	EU	
GL20	Anthelmintics feline	Efficacy of anthelmintics: specific recommendations for feline	Anthelmintics	Step 7	Feb. 2000	Jun. 2000	Feb. 2001	Jun. 2001	Jul. 2002	Under revision	EU	
GL21	Anthelmintics poultry	Efficacy of anthelmintics: specific recommendations for poultry	Anthelmintics	Step 7	Feb. 2000	Jun. 2000	Feb. 2001	Jun. 2001	Jul. 2002	Under revision	EU	
GL22	Safety reproduction	Studies to evaluate the safety of residues of veterinary drug in human food: reproduction studies	Safety	Step 7	Apr. 2000	Jun. 2000	May 2001	Jun. 2001	Aug. 2002	Under revision	AHE	
GL23 Rev. 1	Safety genotoxicity	Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing	Safety	Step 7	Apr. 2000	Jun. 2000	May 2001	Jun. 2001	Aug. 2002 2001 (to be implemented in Japan upon completion of phase 2)	Under revision	EU	
GL24	Pharmacovigilance	Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)	Pharmacovigilance	Step 7	Apr. 2000	(Jun. 2000) Re-signed Nov 2005	(May 2001) Sept. 2007	Oct 2007	Decemb er 2015	On hold	EU	Nov 23
GL25	Biologicals	Testing of residual formaldehyde	Biologicals	Step 7	Jul. 2000	Nov. 2000	Feb. 2002	Apr. 2002	May 2003	No Action	AHI	Nov 21

GL26	Biologicals	Testing of residual moisture	Biologicals	Step 7	Jul. 2000	Nov. 2000	Feb. 2002	Apr. 2002	May 2003	No Action	AHI	Nov 21
GL27	Antimicrobial Resistance	Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance	Antimicrobial Resistance	Step 7	May 2001	Jun. 2001	Aug. 2003	Oct. 2003	15 December 2004	On hold	EU	
GL28 Rev. 1	Safety carcinogenicity	Studies to evaluate the safety of residues of veterinary drug in human food: carcinogenicity testing	Safety	Step 9	May 2001	Jun. 2001	Aug. 2002	Oct. 2002	Oct. 2003 - **Revised Mar 2005**	No Action	EU	Nov 22
GL29	Pharmacovigilance: PSU	Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	Pharmacovigilance	Step 7	May 2001	Jun. 2001	May 2006	June 2006	June 2007	On hold	AHI	
GL30	Pharmacovigilance: list of terms	Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms	Pharmacovigilance	Step 7	May 2006	June 2006	(Sept. 2007) **Re-signed** June 2010	June 2010	December 2015	Ongoing maintenance of lists	EU	
GL31	Safety: Repeat-dose toxicity test	Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose toxicity testing	Safety	Step 7	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003	Later Action	EU	Nov 21
GL32	Safety: Developmental toxicity test	Studies to evaluate the safety of residues of veterinary drugs in human food: Developmental toxicity testing	Safety	Step 7	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003 (Exc. EU)	Later Action	EU	Nov 21
GL33 Rev. 2	Safety: General approach to testing	Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing	Safety	Step 9	Dec. 2001	Apr. 2002	Oct. 2002	Oct. 2002	Oct. 2003 - **Revised Feb 2009**	On hold	FDA	Feb 17

GL34	Biologicals: Mycoplasma	Test for the detection of Mycoplasma contamination	Biologicals	Step 7	Dec. 2001	(Sept. 2007) **Re-signed** Nov. 2011	Jan. 2013	Feb. 2013	Feb. 2014	No Action	USDA	Nov 21
GL35 Rev. 1	Pharmacovigilance: ESTD	Pharmacovigilance: Electronic Standards for Transfer of Data	Pharmacovigilance	Step 7	(May 2002) **Re-signed** June 2010	(Sept. 2007) **Re-signed** June 2010	Feb. 2013	Feb. 2013	December 2015	**Revised March 23**	AHI	Impl. Mar 24
GL36 Rev. 2	Safety: microbiological ADI	Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to establish a microbiological ADI	Safety	Step 7	May 2002 by Task Force	May 2003	March 2004	May 2004	May 2005 - **Revised Feb. 2019**	No Action	FDA	Feb 19
GL37	Safety: repeat dose chronic toxicity	Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose Chronic Toxicity Testing	Safety	Step 7	May 2002 by Task Force	May 2003	March 2004	May 2004	May 2005	No Action	AHE	Nov 22
GL38	Ecotoxicity Phase II	Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II	Ecotoxicity	Step 7	July 2003	Oct. 2003	Sept. 2004	Oct. 2004	Oct. 2005	No Action	AHI	Nov 21
GL39	Quality: specifications	Test Procedures and Acceptance Criteria for new Veterinary Drug Substances and New medicinal Products: Chemical Substances	Quality	Step 7	July 2004	August 2004	Sept. 2005	Nov. 2005	Nov. 2006 - Reviewed Nov 2009	No Action	JMAFF	Nov 22
GL40	Quality: specifications	Test Procedures and Acceptance Criteria for new Biotechnological/Biological Veterinary Medicinal Products	Quality	Step 7	July 2004	August 2004	Sept. 2005	Nov. 2005	Nov. 2006	No Action	JMAFF	Nov 22
GL41	TAS: reversion to virulence	Examination of live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence	TAS	Step 7	Sept. 2004	Oct. 2004	June 2007	July 2007	July 2008	No Action	JVPA	Nov 21
GL42 Rev. 1	Pharmacovigilance: Data elements	Pharmacovigilance: Data Elements for Submission of Adverse Events Reports	Pharmacovigilance	Step 7	Oct. 2005	Nov. 2005	Sept. 2007 **Re-signed** June 2010	Oct 2007 **Re-signed** June 2010	December 2015	**Revised March 23**	EU	Impl. Mar 24

GL43	TAS: Pharmaceuticals	Target Animal Safety for Pharmaceuticals	TAS	Step 7	Sept. 2006	Dec. 2006	June 2009	July 2009	July 2010	No Action	JVPA	Nov 21
GL44	TAS: Biologicals	Target Animal Safety for Veterinary live and inactivated Vaccines	TAS	Step 7	June 2007	August 2007	June 2009	July 2009	July 2010	No Action	JVPA	Nov 21
GL45	Quality: Bracketing and Matrixing	Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Quality	Step 7	Nov. 2007	Feb. 2008	Feb. 2010	April 2010	April 2011	No Action	AHE	Nov 22
GL 46	MRK: Nature of Residues	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Metabolism Study to determine the Quantity and Identify the Nature of Residues	MRK	Step 7	July 2009	Nov. 2009	Dec 2010	February 2011	February 2012	On hold	FDA	
GL 47	MRK: Comparative Metabolism Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Comparative Metabolism Studies in Laboratory Animals	MRK	Step 7	July 2009	Nov. 2009	Dec 2010	February 2011	February 2012	Under revision	AHI	
GL 48 Rev. 1	MRK: Marker Residue Depletion Studies	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods	MRK	Step 7	July 2009	Nov. 2009	Dec 2010	February 2011	February 2012 **Revised Jan. 2015**	No Action	AHE	Nov 20
GL 49 Rev. 1	MRK: Method used in Residue Depletion Studies	Guidelines for the Validation of Analytical Methods used in Residue Depletion Studies	MRK	Step 7	July 2009	Nov. 2009	Dec 2010	February 2011	February 2012 **Revised Jan. 2015**	Under revision	AHI	
GL 50 Rev. 1	Biologicals: TABST	Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use	Biologicals	Step 7	Sept. 2011	Nov. 2011	Feb. 2013	Feb. 2013	February 2014 **Revised Feb. 2016**	No Action	EU	Nov 21
GL51	Quality: Stability data	Statistical evaluation of stability data	Quality	Step 7	Nov. 2011	Nov. 2011	Feb. 2013	Feb. 2013	February 2014	No Action	FDA	Nov 19
GL52	Bioequivalence: Blood level	Blood Level Bioequivalence Study	Bioequivalence	Step 7	Oct. 2013	Nov. 2013	June 2015	August 2015	August 2016	No Action	FDA	Nov 21

GL53	Electronic File Format	Electronic exchange of documents: File format requirements	EFF	Step 7	Nov. 2013	January 2014	January 2015	Feb. 2015	February 2016	No Action	AHE	Nov 21
GL54	Safety: Acute Reference Dose (ARfD)	Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)	Safety	Step 7	Dec. 2014	Feb 2015	Sept 2016	November 2016	November 2017	No Action	FDA	Nov 22
GL 55	Biologicals: TABST Live vaccines	Harmonization of criteria to waive target animal batch safety testing for live vaccines	Biologicals	Step 7	Sept 2015	Oct 2015 Re-signed in Feb 2016	April 17	May 2017	May 2018	No Action	EU	
GL 56	MRK: Residues in Honey	Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods	MRK	Step 7	Oct. 2016	January 2017	June 2018	June 2018	June 2019		EU	
GL 57	MRK: Residues in Fish	Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: Marker residue depletion studies to establish product withdrawal periods in aquatic species	MRK	Step 7	Nov. 2017	Dec. 2017	February 2019	February 2019	February 2020		AHI	
GL 58	Stability: Climatic Zones III and IV	Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	Quality	Step 7	June 2018	June 2018	October 2019	November 2019	November 2020		FDA	
GL 59	Biologicals: LABST Veterinary vaccines	Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use	Biologicals	Step 7	June 2019	Oct. 19	October 2020	November 2020	November 2021		JMAFF	
GL 60	Quality: GMP for API	Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products	Quality	Step 4	August 2023	Sept. 23					FDA	
GL 61	Quality: Pharmaceutical Development	Pharmaceutical Development for veterinary medicinal products	Quality	Step 4	January 24	February 24					FDA	