



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Contact meeting on wider international harmonisation of VICH guidelines

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Overview of VICH guidelines available and examples of VICH  
guidelines implemented in the regions

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An agency of the European Union





# Content

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- VICH guidelines
- Examples:
  - Safety guidelines
  - Quality guidelines
- How they are implemented
- Implementation at the example of EU
- Review implementation at Steering Committee



# VICH guidelines available

- VICH has finalised up to date 47 guidelines:

Pre-approval			
	General		GL9
	Biologicals		GL50
		Quality	GLs 34, 25 & 26
		Safety	
		TAS	GLs 41 & 44
	Pharmaceuticals	Quality	GLs 1, 2, 3, 4, 5, 8, 10, 11, 17, 18 (R), 39, 40, 45
		Efficacy	
		Anthelmintics	GLs 7, 12, 13, 14, 15, 16, 19, 20 & 21
		Safety	
		Environmental Safety	GLs 6 & 38
		Metabolism and Residue	GLs 46, 47, 48, 49
		Toxicology	GLs 22, 23, 28, 31, 32, 33 & 37
		Target Animal Safety	GL 43
		Antimicrobial Safety	GLs 27 & 36
Post-approval			
	Pharmacovigilance		GLs 24, 29, 30, 35 & 42



# VICH guidelines available – Examples

## Quality

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- Biologicals:
  - GL 25, 26: Testing of residual formaldehyde, residual moisture
  - GL 34: Test for the detection of Mycoplasma contamination
- Pharmaceuticals:
  - GL 1: Validation of analytical procedures: definition and terminology
  - GL 2: Validation of analytical procedures : methodology
  - GLs 3, 4, 5, 8, 17: Stability new active substances and products, dosage form, photostability, premixes, new biotechnological / biological products
  - GLs 10, 11, 18: Impurities new active substances, products, residual solvents
  - GLs 39, 40: Test procedures and acceptance criteria for new active substances and products: Chemical Substances, Biotechnological/Biological Veterinary Medicinal Products
  - GL 45: Bracketing and matrixing design



# VICH guidelines available – Examples

## Safety

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- Pharmaceuticals:
  - GL 33: Safety: General approach to toxicity testing
  - GLs 31, 37: Repeat-dose toxicity test, Chronic toxicity
  - GL 22: Reproduction
  - GL 32: Developmental toxicity test
  - GL 23: Genotoxicity
  - GL 28: Carcinogenicity
  - GL 36: Establishment of a microbiological ADI
  - GL 27: data for new products for food producing animals with respect to antimicrobial resistance



# VICH guidelines available – Examples

## Safety (contd.)

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- Pharmaceuticals:
  - GL 43: Target animal safety pharmaceuticals
  - GLs 6, 38: Environmental impact assessment: phase I, phase II
- Metabolism and residue kinetics
  - GL 46: Nature of residues: Metabolism study to determine the quantity and identify the nature of residues
  - GL 47: Comparative metabolism studies in laboratory animals
  - GL 48: Marker residue depletion studies to establish product withdrawal periods
  - GL 49: Validation of analytical methods used in residue depletion studies



## Implementation of VICH guidelines (1/3)

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- When signing-off (= adopting) a VICH GL at step 6 for implementation, the VICH Steering Committee (SC) determines the time period in which VICH members need to implement the guideline
- Implementation period: usually 1 year, but can at occasions be longer
- Implementation: member country/region needs to put measures in place that the VICH guideline replaces existing guidelines and is applied when a new application for a veterinary medicinal product is submitted
- Process can be different dependant on exact role in regulatory framework a guideline has



## Implementation of VICH guidelines (2/3)

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### Example EU:

- Data requirements are laid down in legislation giving framework of studies required, e.g. principles/list of quality, safety and efficacy data for pharmaceuticals and immunologicals (vaccines)
- This legislation makes reference to supportive guidance to be developed by the scientific committee for veterinary medicines of the EMA: the Committee for Medicinal Products for Veterinary use (CVMP)
- The CVMP provides technical input into the development of VICH guidelines, and following sign-off by the SC adopts the VICH GL as CVMP guideline, with the appropriate implementation date



## Implementation of VICH guidelines (3/3)

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### Example EU:

- The EU co-ordinator is responsible also for informing the EU member states of the adopted VICH GLs and their implementation date
- In case the VICH GL would necessitate a change in the legislation outlining the data requirements (e.g. for GL 32: Developmental toxicity testing or GL 44: Target animal safety for vaccines) the legislation had to be changed first
- Such change of legislation can be a longer process than 1 year; flagged up by EU that implementation for GL 32 required longer time



## Review implementation at Steering Committee

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- The co-ordinators report regularly to the VICH secretariat the status of implementation of VICH GLs in their country/region
- At VICH SC meetings review of implementation and discussion of any issues arising, e.g. if there would be differences in interpretation of GLs
- Process intended to lead to true harmonisation of data requirements



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*Questions?*



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*Thank you for your attention!*

