EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Veterinary International Conference on Harmonization (VICH)

Latest developments and perspective

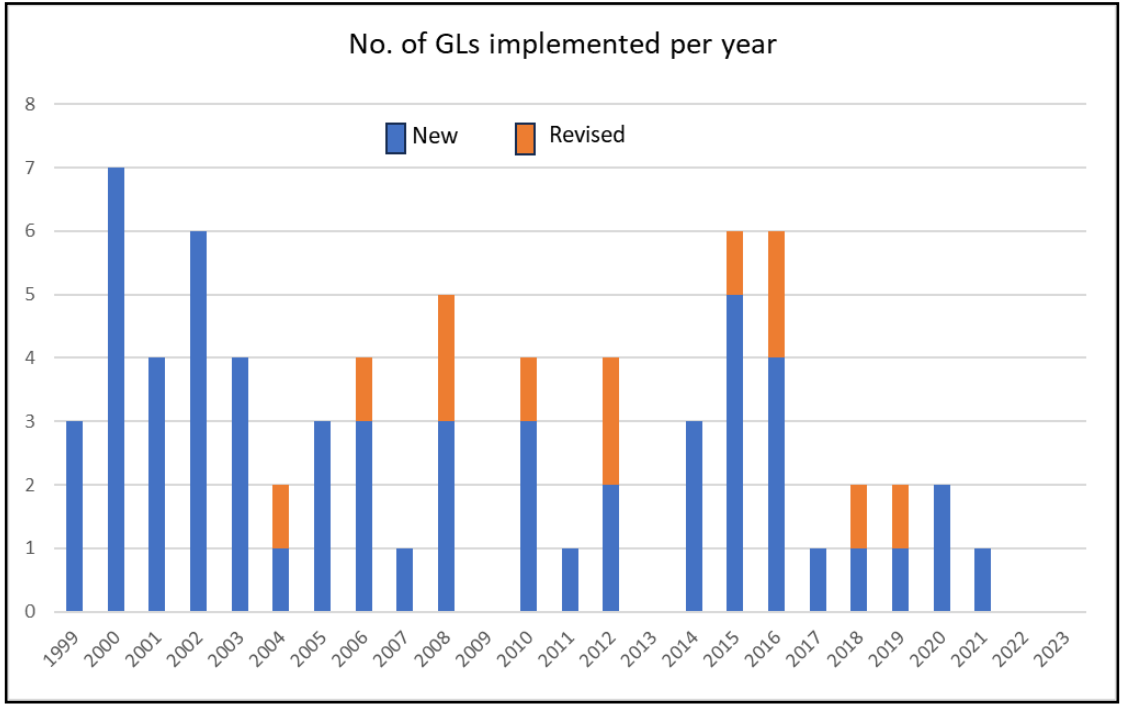
EMA Veterinary Medicines Info Day 2024

Presented by Nick Jarrett on 14 March 2024
VICH coordinator for EU and Head of Veterinary Pharmaceuticals, European Medicines Agency

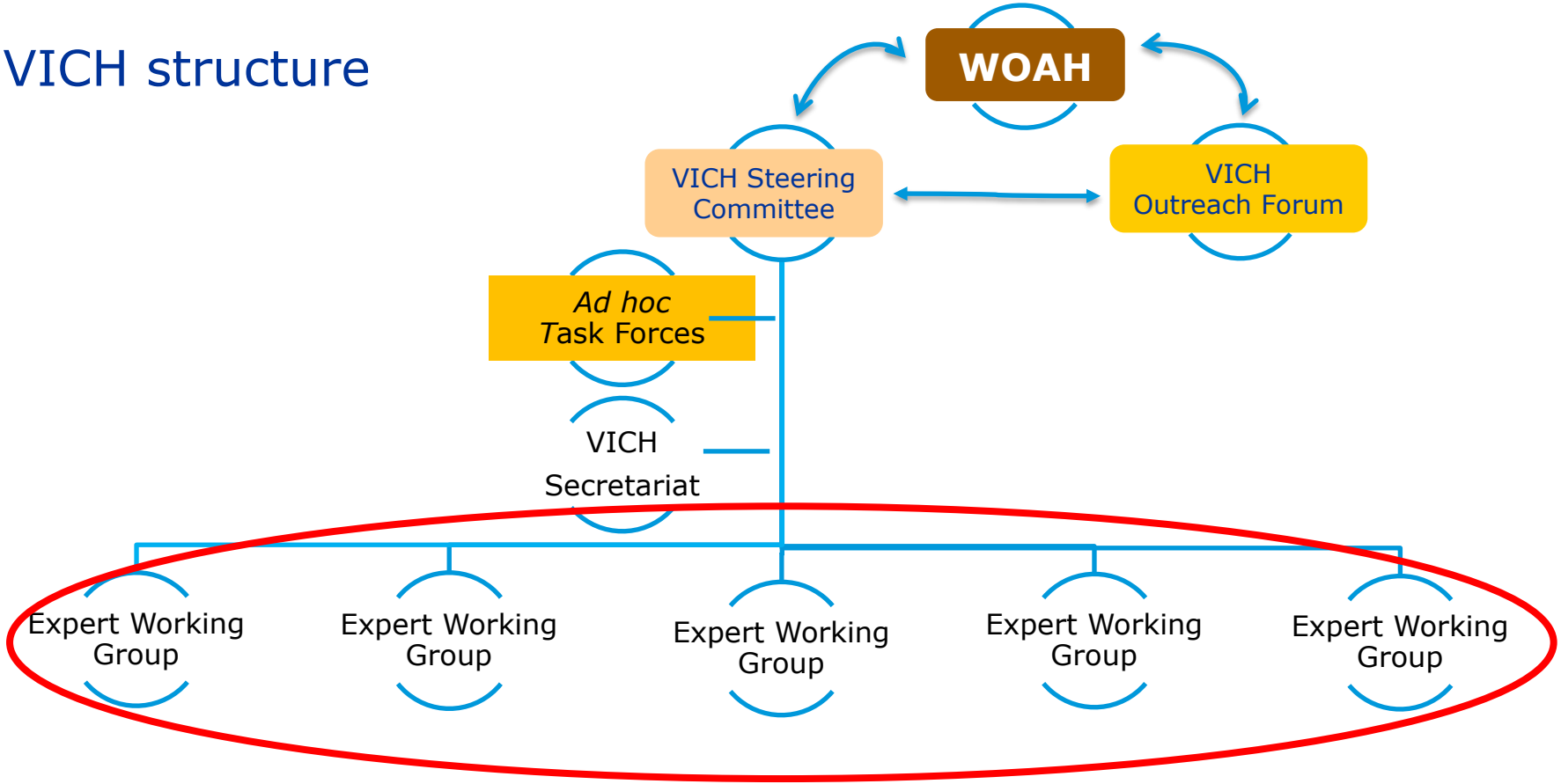
Guidelines

GL1: Validation of analytical procedures: definition and terminology
GL2: Validation of analytical procedures: methodology
GL3: Stability testing of new drug substances and products
GL4: Stability testing for new dosage forms
GL5: Photostability testing of new drug substances and products
GL6: EIA for VMPs phase 1
GL7: Efficacy of anthelmintics: general requirements
GL8: Stability testing for medicated premixes
GL9: GCP
GL10: Impurities in new veterinary drug substances
GL11: Impurities in new VMPs
GL12: Efficacy of anthelmintics: specific recommendations for bovines
GL13: Efficacy of anthelmintics: specific recommendations for ovines
GL14: Efficacy of anthelmintics: specific recommendations for caprines
GL15: Efficacy of anthelmintics: specific recommendations for equines
GL16: Efficacy of anthelmintics: specific recommendations for porcines
GL17: stability testing of new biotechnological/biological products
GL18: Impurities: residual solvents in new VMPs, active substances and excipients
GL19: Efficacy of anthelmintics: specific recommendations for canine
GL20: Efficacy of anthelmintics: specific recommendations for feline
GL21: Efficacy of anthelmintics: specific recommendations for poultry
GL22: Safety: Reproduction studies
GL23: Safety: genotoxicity studies
GL24: Pharmacovigilance: Management of Adverse Event Reports
GL25: Testing of residual formaldehyde
GL26: Testing of residual moisture
GL27: Pre-approval information for registration of VMPs for food producing animals with respect to antimicrobial resistance
GL28: Safety: Carcinogenicity testing
GL29: Pharmacovigilance: Management of PSURs
GL30: Pharmacovigilance: Controlled list of terms
GL31: Safety: Repeat dose toxicity testing
GL32: Safety Developmental toxicity testing
GL33: Safety: General approach to testing
GL34: Test for detection of Mycoplasma contamination
GL35: Pharmacovigilance: Electronic Standards for transfer of data
GL36: General approach to establish a microbiological ADI
GL37: Safety: repeat dose chronic toxicity testing
GL38: EIA – Phase II
GL39: Test procedure and acceptance criteria for new veterinary drug substances and new medicinal products: chemical substances
GL40: Test procedure and acceptance criteria for new biotechnological/biological VMPs
GL41: Examination of live veterinary vaccines in target animals for absence of reversion to virulence
GL42: Pharmacovigilance: data elements for submission of adverse events reports
GL43: Target animal safety for pharmaceuticals
GL44: Target animal safety for veterinary live and inactivated vaccines
GL45: Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
GL46: Metabolism study to determine the quantity and identify the nature of residues
GL47: Comparative metabolism studies in laboratory animals
GL48: Marker residue depletion studies to establish product withdrawal periods
GL49: Validation of analytical methods used in residue depletion studies
GL50: Harmonisation of criteria to waive TABST for inactivated vaccines for veterinary use
GL51: Statistical evaluation of stability data
GL52: Blood level bioequivalence study
GL53: Pharmacovigilance: Electronic exchange of documents: File format requirements
GL54: General approach to establish an acute reference dose
GL55: Harmonisation of criteria to waive TABST for live vaccines
GL56: Study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods
GL57: Marker residue depletion studies to establish product withdrawal periods in aquatic species
GL58: Stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV
GL59: Harmonisation of criteria to waive LABST for vaccines for veterinary use

Implementation of VICH Guidelines across two decades



VICH structure



VICH new guidelines under development

Topic	Status
GL60: GMP for active pharmaceutical ingredients used in VMPs	**Out for consultation** until 25 March 2024
GL61: Pharmaceutical development	Draft adopted by SC. Consultation until 15 August 2024
General principles for detection of extraneous viruses in mammalian veterinary vaccines	In drafting stage
Target animal safety of monoclonal antibody products	In drafting stage
Combination products	In drafting stage
Between strength biowaivers for immediate release solid oral dosage forms	In drafting stage
Principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals	Concept paper agreed in November 2023

VICH guidelines under review

Topic	Status
GL18: Residual solvents	**Published**. Implementation from April 2024
GL24: Management of adverse event reports GL29: Management of periodic safety update reports	On hold while EWG discusses signal detection and management
GL22: Reproduction studies	Out for consultation until 31 July 2024
GL23: Genotoxicity studies	Approaching sign off by EWG
GL7, 12-16, 19–21: Efficacy of anthelminthics	Post consultation. Approaching sign off
GL49: Validation of analytical methods used in residue depletion studies	In drafting stage
GL8: Stability testing of premixes	In drafting stage

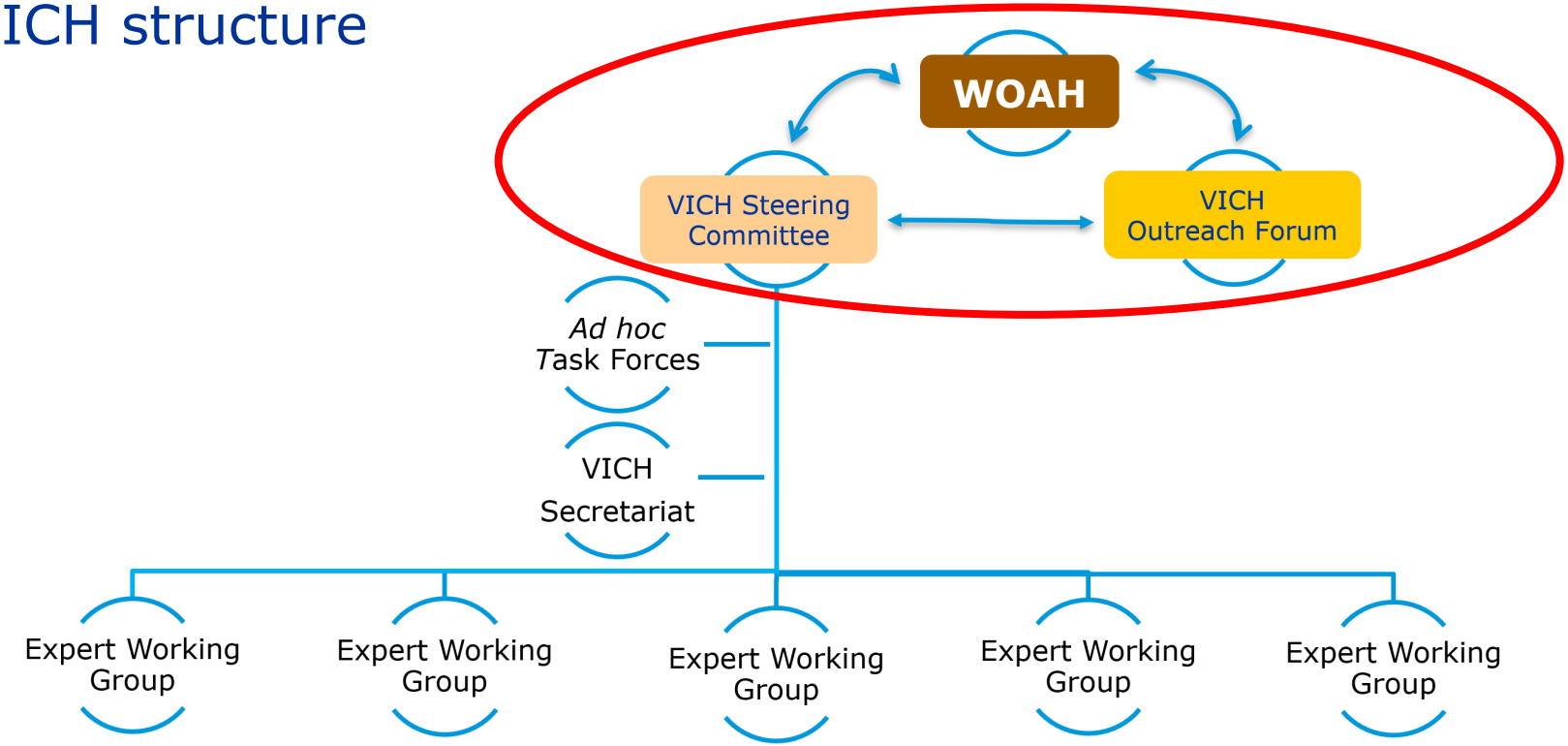
Potential future topics

Topic	Status
Review of GL34: Testing for the detection of Mycoplasma contamination	EU – CP under consultation
Review of GL27: Pre-approval information for registration of new VMPs for food producing animals with respect to AMR	EU – update and extend
Review of GL6: Environmental impact assessment – phase I	EU – follows from RP on ERA of ectoparasiticidal VMPs
Review of GL38: Environmental impact assessment – phase II	FDA
Review of GL47: Comparative metabolism studies in laboratory animals	FDA
New GLs to parallel: - ICH Q9 on Quality risk assessment - ICH Q10 on Pharmaceutical quality system - ICH Q12 on Pharmaceutical product lifecycle management	AhE
Further guidance on Q of medicated premixes	EWG

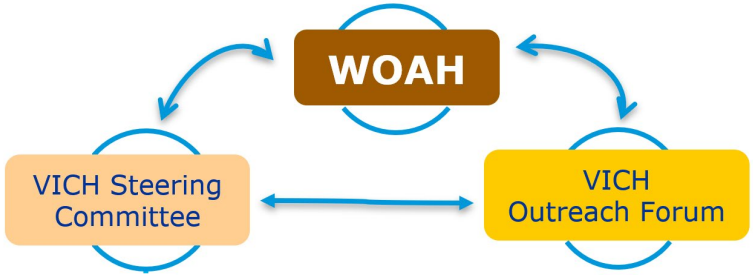
Global Regulatory Dossier Framework

- **To develop a common dossier structure for use across multiple jurisdictions**
- Numerous potential benefits including:
  - reducing administrative burden and facilitating global development plans
  - facilitating parallel assessments, maintenance of dossiers, and recognition of international dossiers
  - encouraging regulatory convergence
- Within scope of VICH? 
- **EU agree to engage but cannot commit to implement due to major hurdles**
  - legislation and e-submissions

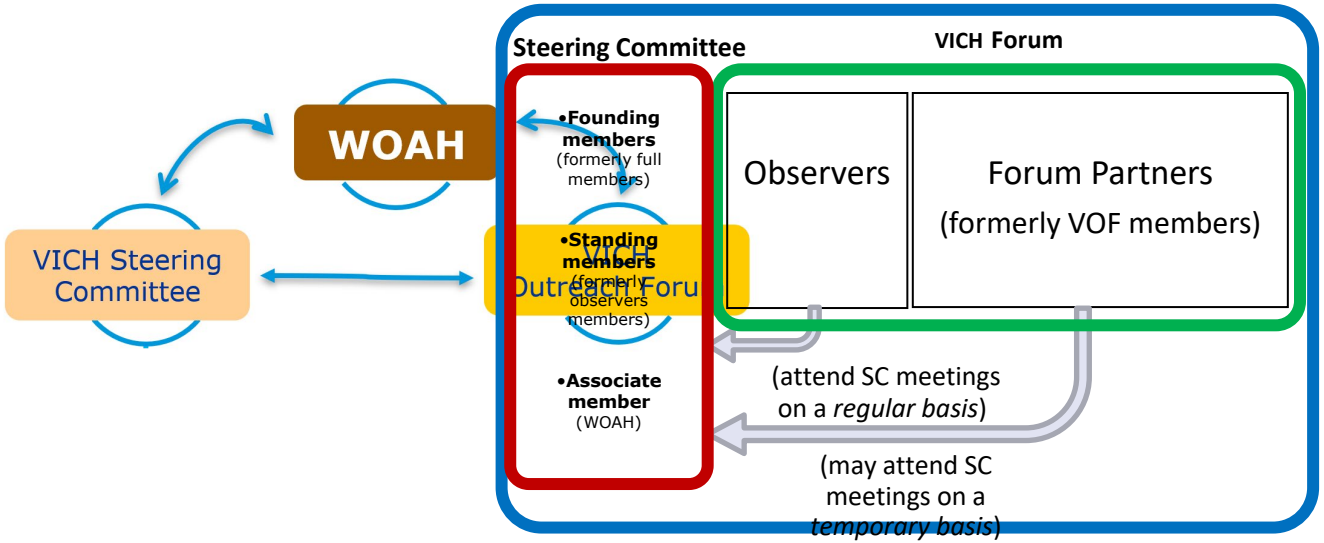
VICH structure



VICH structure overview



VICH structure overview

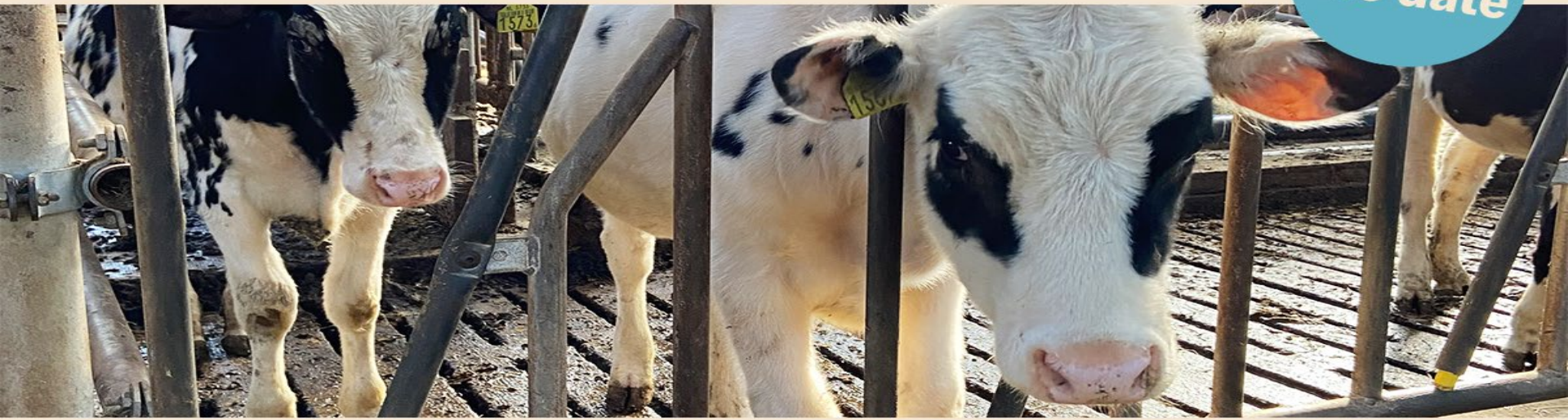


Allow continued growth of VICH and recognises importance of the Forum

- Bring SC and Forum closer together, providing opportunity for Forum Partners to further engage
- Provides opportunity to move between groups

VTCH

Save the date



NOV **13–14 November 2024**

In summary

- **Guidelines** – We continue to have a busy agenda
- **VICH Structure** – Changes to allow growth and recognise importance of Forum
- **Save the date** – 13-14 November 2024

Any questions?

Further information

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