EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reorganisation of EMA working parties

Industry Standing Group 26th June 2023

Presented by Silvy da Rocha Dias
H-QA-EPG, Head of Office *ad interim*

Introduction

- Background on the re-organisation of the Working Parties
- New model for working parties
- Methodology WP

Implementation of the new WP model

- Project for the re-organisation of the working parties structure initiated in 2020 but paused due to BCP and Covid-19
  - Implementation plan presented at the 7th and 8th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicine
  - Non-Clinical, Clinical and Methodology domains are active
  - Quality domain is currently under revision and implementation phase

Main principles of the new WP operational model

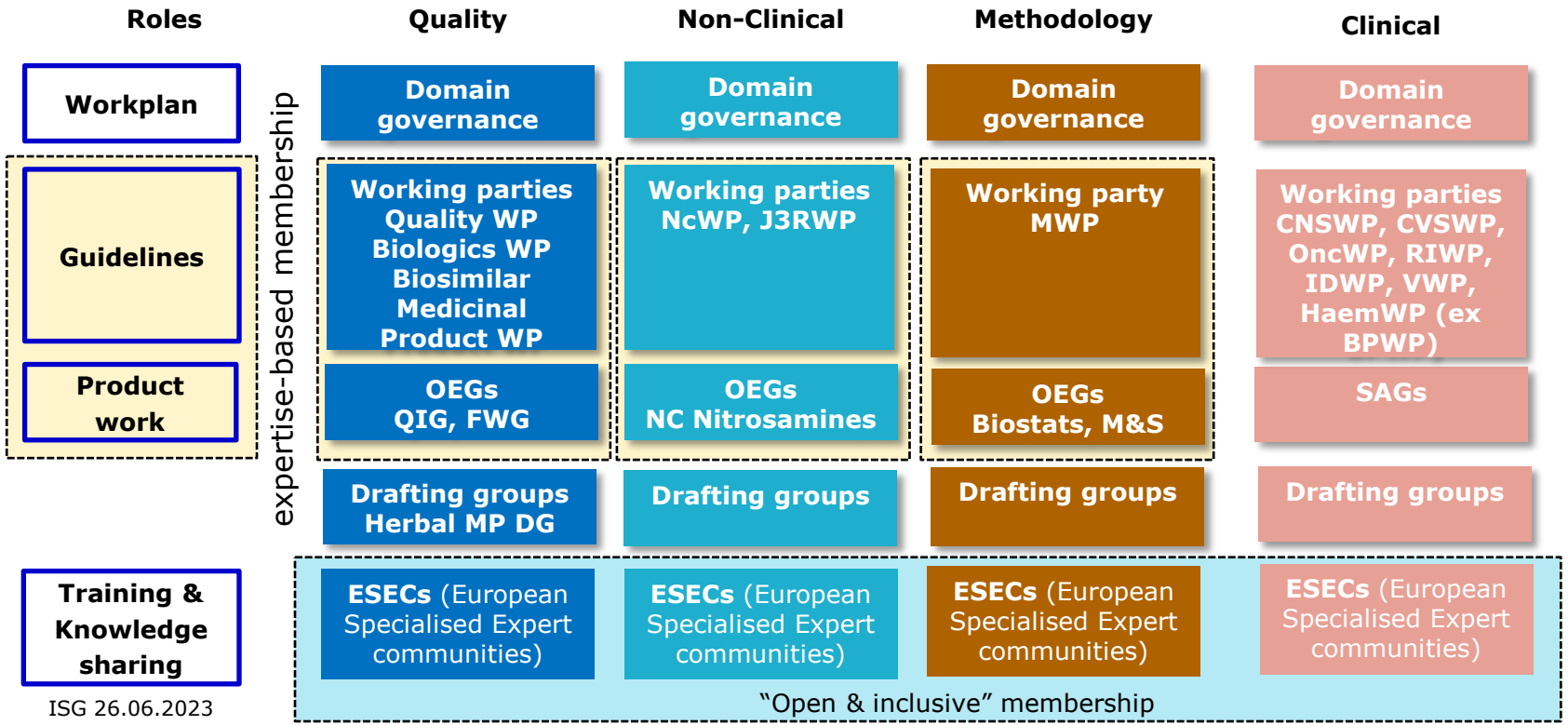
- Five main domains with a **new strategic oversight for each of the new domains** populated each by chairs of the relevant working parties
- WPs membership is based on best and available expertise from EU network
- Generation of a **3-year rolling strategic plan at domain level** and linked to EMRN Strategy to 2025 / EMA RSS to 2025.
- Introduce systematic and structured Stakeholder Engagement[1] at domain level to underpin strategic priority planning and individual guideline generation/revision

1 Industry, academia, healthcare professionals, patients and international regulators

Working parties, Operational Expert Groups, Drafting Groups and European Specialised Expert Communities

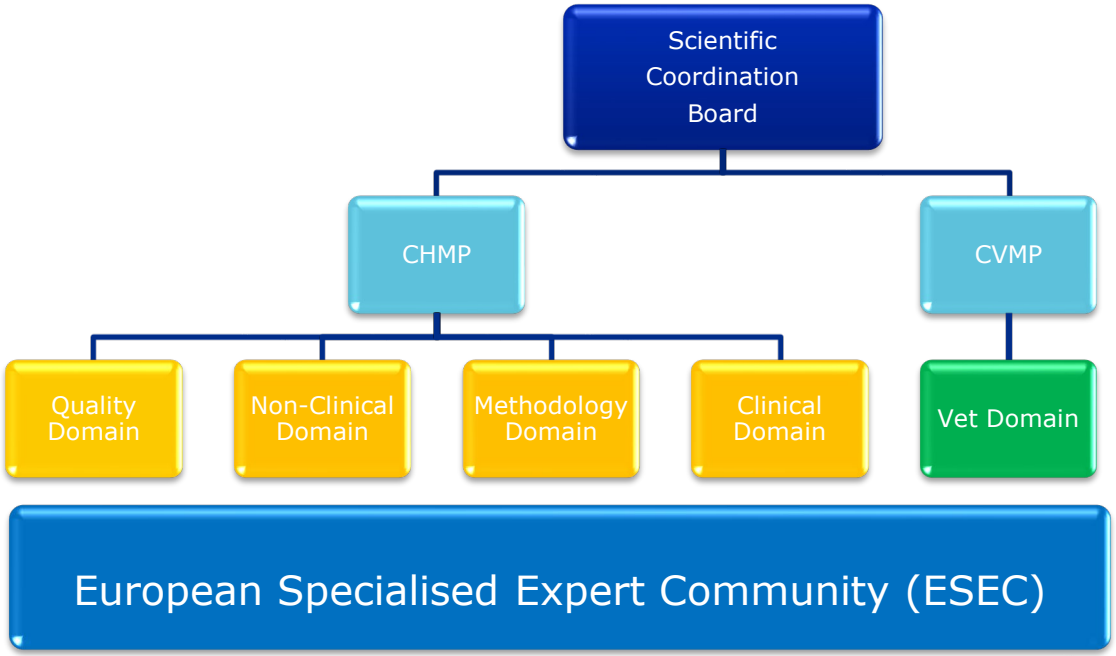
New structures of the operational model

Architecture of the new operational model



ESECs, a source of expertise for working party structures

- **Community of experts** with special knowledge in a given area;
- **Accessible** to experts from the NCAs, SAGs, CHMP members, academic organisations that are/will be contributing to the regulatory system
- **To be a member**: be nominated by a Committee member (NCA), sign a confidentiality agreement and needs to be included in the expert database.



Other groups

Excluded from reorganisation

- Healthcare Professionals' Working Party
- Patients' and Consumers' Working Party
- Scientific Advice Working Party
- Name Review group
- ASMF WG
- SmPC Advisory group
- Inspectors Working Groups

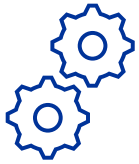
Integrated into WP or OEGs

- Safety Working Party
- Biostatistics Working Party
- Pharmacogenomic Working Party
- Pharmacokinetic Working Party
- Modelling and Simulation Working Group

Methodology Working Party

New structures of the operational model

Methodology Working Party



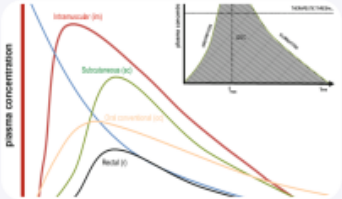
Operational Support

- ✓ Product-related support to Committees, Coordination groups and other WPs
- ✓ Guideline development

Expertise and Global leadership

- ✓ Partnership with international regulatory organisations
- ✓ Leadership in global collaborations
- ✓ Capacity building with academia and across NCAs
- ✓ Training and development of the European Regulatory Network

Four main areas of specialty for the MWP



Clinical Pharmacology

- Includes product – specific bioequivalence
- Modelling and simulation Q&A documents

Real World Evidence

- Reflection Paper on AI also foreseen

Clinical Trial Modernisation

- Implementing ICH guidance
- Trials of the future

Pharmaco - genomics

- Be ready for IVD legislation and implementation
- Update guidance

Key stakeholder engagement according to the workplan

Key Stakeholders

Industry – by sector (pharma, biotech, associations, etc…)

Global regulators – individually and as a group

EU projects – includes ACT-EU, BDSG

[Consolidated 3-year work plan for the Methodology Working Party (MWP) (europa.eu)]

Stakeholder engagement at Domain level

New structures of the operational model

Key stakeholder engagement for workplans

Domain

- Presentation and consultation period on the 3-year rolling strategic workplan generated at the domain level

Key stakeholders

- Industry, academia/learned societies, healthcare professional organisations, patient representatives, EU agencies

Working Party

- Specific scientific or regulatory issues as foreseen in the 3-year rolling strategic plan e.g. emerging trends, horizon scanning, framework revisions
- Guideline development

Key stakeholders

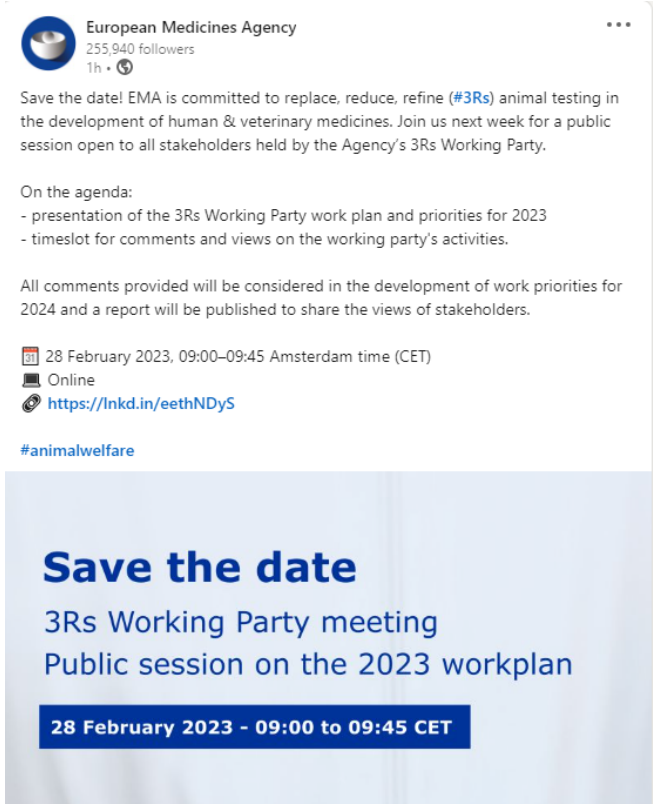
- Interested parties, industry, healthcare professional organisations, patient representatives
- NCAs, academia/learned societies, EU agencies, international organisations

3RsWP stakeholder meeting and public session

- **Two-day plenary meeting on the implementation of 3Rs principles** in the development and evaluation of human and veterinary medicinal products.

- Participants **included industry and trade associations, animal welfare organisations, research consortia and EU agencies.** The meeting was by invitation only.

- The aim of the public session was to **present the 3RsWP work plan and priorities for 2023** and **to give an opportunity to stakeholders to comment and provide their views on the working party's activities.**



Any questions?

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