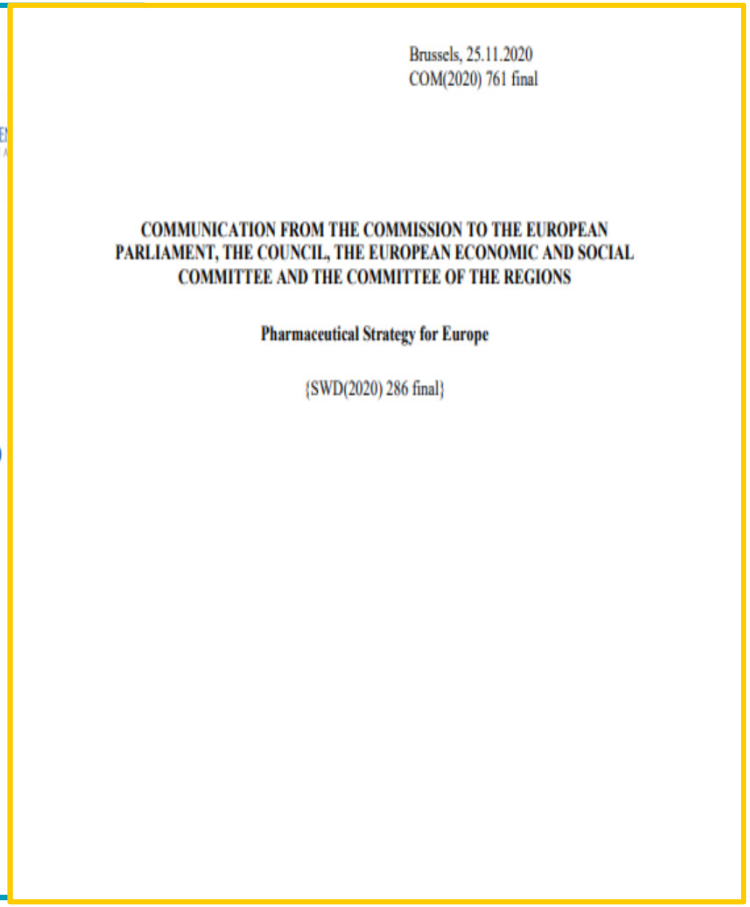
Working Parties new Operational Model

High level principles and proposals

5th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

Presented by Tony Humphreys on 3rd December 2020
Head of Scientific Committees Regulatory Science Strategy Division

EU strategic reflection on the pharmaceutical ecosystem



Review objectives

Reinforce governance to align mandates, work plans and tasks of the experts with the **needs of the network** and introducing a clear thread of accountability vis-à-vis of strategic priorities

Allow a strategic direction for the outputs of the groups as a collective to cascade down to each group to reinforce consistency, quality assurance, training and retention of best experts

Prepare for regulatory science challenges and introduce more **flexibility** and granularity in identifying specialised expertise for individuals tasks and drafting groups

Establish agile links between experts working on the same topic within and across domains and extending collaboration to other specialists as needed

Optimise the operations of the Working Parties to achieve **maximum productivity** linked to **efficient resource utilisation** addressing changes in composition and working methodology as required

Final High level principles (1/2)

I
- Working Parties and SAGs exists for the benefit[1] of the entire network and its public and animal health mission and need to add value to the assessment/advice process

II
- The number of representatives, meeting days and ways of working should be determined by current and future needs of the network

II
I
- The most rational architecture and governance should be agreed to maximise utility of outcomes and best use of resources

IV
- Co-ordinating bodies with oversight on scientific and operational matters will ensure accountability and coordination of outputs to maximise benefits for the Network

[1]"Hard" benefits: operational, tactical, and strategic "Soft" benefits: Training and harmonisation

Final High level principles (2/2)

V

- A clear strategic direction for key elements (e.g. scientific priorities, interaction with stakeholders) is necessary to ensure coordinated outputs, scientific quality and adoption of timely outputs

VI

- A level of harmonisation on rules of procedures, workload organisation, good administrative practices etc. is desired to optimise use of resources and to facilitate quality control/assurance

VII

- A high degree of transparency of outputs, use of resources and rational for scientific priorities is desirable, for the Network itself and for the Public

Objective 1 – Architecture

Reinforce governance to align mandates, work plans and tasks of the experts with the needs of the network

- Reconfirm the need for all the working parties and renew/refresh their mandates
- Reclassify all working parties within scope of review into Standing Working Parties and Temporary Drafting Groups:
  - lead by WP member(s) and/ or Committee member(s) (if direct report)
  - complemented with experts from the network (from NCAs, from SAGs, from academia)
  - reflected in WP work plan; with well-defined objectives, deliverables, and timelines
- Reorganise in five principal "Domains" i.e. Quality, Non-Clinical, Methodology, Clinical and Vet

Objective 1 – Operational oversight

Reinforce governance to align mandates, work plans and tasks of the experts with the needs of the network

- Introducing a new strategic oversight for each of the domains
- Strategic priorities and work plan oversight for the planning cycle are proposed to be handled by SciCoBo, including additional needs of other Committees (CAT, PRAC, PDCO, COMP and CMDh) with increased meeting frequency /dedicated meetings as needed

Objective 2 – Work plans

Allow a strategic direction for the outputs

- Generate a 3-year rolling strategic plan at domain level and linked to EMRN Strategy to 2025/EMA RSS to 2025.
- Work plans should address training delivery to the wider network as part of structured offering via the EU-NTC platform
- Introduce systematic and structured Stakeholder Engagement[2] at domain level to underpin strategic priority planning and individual guideline generation/revision

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

Objective 3 – Architecture

Prepare for Regulatory Science Challenges and introduce more flexibility and granularity in identifying specialised expertise for individual tasks and drafting groups.

- Introduce new concepts of grouping experts into Special Interest Communities (SIC) enabled by online collaborative tools and/or workspaces

Objective 4 – Composition and Leadership

Establish agile links between experts working on the same topic within and across Domains and extending collaboration to other specialists as needed.

- Further open the boundaries of the existing working parties to allow mixing of expertise to foster the multidisciplinary approach in the context of Temporary Drafting Groups
- Extend the current role of experts from SAGs to support guideline development

Guideline generation process

Step 1: Strategic planning

- The phase prior to initiating guidelines, involves prioritizing, work planning, and tracking of guidelines.
- During this review, the Review Group suggests using the new Domain structure to allocate resources and to make the guideline development and review processes more efficient.

Step 2: Initiating guidelines

- One of the first phases in the guideline lifecycle is the initiation process, where Domains would decide whether to develop a guideline document or revise an existing guideline.
- In reviewing the different guideline initiation processes, the Working Group focused on improving efficiency and transparency and proposed a two-tier approach.

A. **New Guidelines:** Guidelines for new regulatory requirements, new complex scientific issues or substantial changes
B. **Revised guidelines:** Addressing existing practices or minor changes in interpretation or policy

Next steps

High level implementation plan to Dec MB for endorsement

2021 operational implementation (Covid dependent)

Continued work to prepare implementation on guideline recommendations

Develop stakeholder engagement recommendations

Thank you for listening

Further information

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