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Consolidated 3-year rolling work plan for the Vaccine Working Party (VWP)

Chair: Mair Powell

Vice-Chair: vacant

Work plan period: January 2025 – December 2027

Dates of Meetings: Monthly.

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1. Strategic goals

The Vaccine Working Party (VWP) is a working party established to address vaccine-related topics in relation to clinical development and non-clinical development (the latter with focus on pharmacology studies supporting demonstration of protection and immunogenicity). Fulfilment of broad long-term goals linked to the EMA/EMRN Regulatory Science Strategy to 2025:

1.1. Short-term strategic goals

- Finalisation of an addendum to the Guideline on Clinical Development of new vaccines to address clinical trials in immunocompromised persons
- Finalisation of the revision of the Guideline on Influenza Vaccines, Non-clinical and Clinical Module
- Writing a concept paper for new guideline on vaccines against orthopoxviruses, Non-clinical and Clinical module

1.2. Long-term strategic goals

- Catalysing the integration of science and technology in medicines' development:
    - Support development of biomarkers
    - Diversify and integrate the provision of regulatory advice along the development continuum
- Driving collaborative evidence generation – improving the scientific quality of evaluations:
    - Leverage non-clinical models and 3Rs principles
    - Develop network competence and specialist collaborations to engage with big data
- Enabling and leveraging research and innovation in regulatory science:
    - leverage collaborations between academia and network scientists to address regulatory science research questions
    - Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

2. Tactical goals

2.1. Guidance activities

Addendum to the Guideline on Clinical Development of new vaccines, EMEA/CHMP/VWP/164653/05

The revised guideline was adopted by CHMP and published in 2022.

In 2023 it was felt necessary to develop an addendum concerning on clinical trials to assess the safety, immunogenicity and efficacy of vaccines in immunocompromised individuals as this is currently missing.

The addendum has gone through a 3-months public consultation in the second part of 2024.

Addendum finalisation is aimed by end of 2024.

Guideline on Influenza Vaccines, Non-clinical and Clinical Module, EMA/CHMP/VWP/457259/2014

This guideline entered into force in 2017. Since then, several requests for CHMP scientific advice as well as new MAAs have pointed to the need to update and clarify certain sections of this guidance to make it clearer and more comprehensive on specific matters. A concept paper to describe the proposed changes has been finalised and published for public consultation in 2023.

Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU, EMA/PRAC/222346/2014

This guidance focuses on the requirements for annual enhanced safety surveillance to rapidly detect any increased local and systemic reactogenicity, or other unexpected adverse immune response that may arise during the influenza vaccine product life-cycle. It also outlines principles to be followed for improved continuous routine surveillance for influenza vaccines.

Based on the experience gathered so far, there is the need to revise the current requirements to improve the quality and quantity of the data collected for regulatory appraisal.

The work on the revision of the interim guidance on ESS started has started in the last quarter of 2024 and will continue in 2025.

Guidance on the development of vaccines against orthopoxviruses (NEW)

Considering the latest developments in terms of vaccines against orthopoxviruses, there is the need to generate a new guidance which provides clear directions to developers and informs on the requirements for the development of vaccines also with novel platforms.

A concept paper on this matter is intended to be produced in 2025.

2.2. Training and workshop activities

Training of assessors identified as being, or likely to be, involved in the clinical evaluation of vaccines. The material would be taken from recent scientific advice and applications. The trainings will be given face to face or remotely or by a hybrid approach.

The training is intended to cover the following topics:

- basic principles for clinical vaccine development
- immunogenicity data to support licensure
- vaccine efficacy studies
- vaccine effectiveness studies
- vaccine safety pre- and post-licensure

- understanding of the regulatory remit and how regulatory decisions are used by PHAs (including NITAGs where appointed) and the WHO (for prequalification)

The trainers would be VWP members ± co-opted external experts to cover specific topics.

The training is considered a priority and expected to take place during 2025.

2.3. Communication and Stakeholder activities

Attendance to Vaccine Cluster virtual meetings with international regulators on efficacy and safety issues related to vaccines on an *ad hoc* basis.

2.4. Multidisciplinary collaboration

The VWP will provide product-related support upon request from emergency task force (ETF) innovation task force (ITF), Scientific advice working party (SAWP), Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) and Scientific Advice Working Party (SAWP) and relevant Committees.

The VWP intends to work in close collaboration with methodologists and biostatisticians to develop guidance documents concerning statistical issues related to the analysis and interpretation of vaccine immunogenicity trials.

3. Operational goals

The VWP will provide product-related support upon request from the ETF, ITF, SAWP and EMA Committees.

VWP plans to have one face-to-face meeting per year. For 2025 it is planned to take place during April-May.

4. List of Abbreviations

CMDh Coordination Group for Mutual Recognition and Decentralised Procedures – Human

ETF emergency task force

ITF innovation task force

SAWP Scientific Advice Working Party