4 December 2023
EMA/531728/2023
Health Threats and Vaccine Strategy (AF-HTV)

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

Chairperson: Mair Powell

Vice chair: vacant

Work plan period: January 2022 – December 2024

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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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[1] Regulatory Science Strategy to 2025:

1.1. Short-term goals

- Preparation of an addendum to the Guideline on Clinical Development of new vaccines to address clinical trials in immunocompromised persons
- Start revision of the Guideline on Influenza Vaccines, Non-clinical and Clinical Module

1.2. Long-term 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: activities/projects to deliver the strategic goals

2.1. Guideline activities

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

This guideline covers all the general principles of the clinical development and evaluation of vaccines. It includes guidance on situations in which it may not be feasible to conduct clinical efficacy trials and there may be no immune surrogate for protection that can be applied to immunogenicity data to infer vaccine protection.

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.

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

[1] European Medicines Regulatory Network, the EU Network

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 more clear and 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

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.

2.2. Training activities

- Training of assessors identified as being, or likely to be, involved in the clinical evaluation of vaccines. A proposed programme would commence with a 2-day training programme, providing a) plenary sessions covering overviews of principles and guidelines followed by b) exercises conducted in in breakout groups ending in plenary presentations from each group and discussions. The material would be taken from recent scientific advice and applications. This grounding session would be followed by a further 5 sessions, each based on exercises and questions sent in advance. The trainers would be VWP members ± co-opted external experts to cover specific topics.

2.3. Communication and stakeholder activities

- Attendance to Vaccine Cluster virtual meetings on efficacy and safety issues related to vaccines on an ad hoc basis.

3. Operational Objectives

The VWP will provide product-related support upon request from innovation task force (ITF), SAWP, CMDh and Committees.

Priorities for 2024

4. Guidelines

4.1. EU Guidelines

Action: co-lead

Guideline on Influenza Vaccines, Non-clinical and Clinical Module

Target date	First draft ready for public consultation by end of 2024
Comments	This is a revision of the existing guideline to be co-led with the Emergency Task Force (ETF).

Action: Contribution

Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU

Target date	First draft ready for public consultation by end of 2024
Comments	This is a revision of the existing guideline led by PRAC with the contribution of the VWP

Action: co-lead

Addendum to the Guideline on clinical development of new vaccines

Target date	First draft ready for public consultation by end of 2024
Comments	This is an addendum to the existing guideline on trials in immunocompromised persons to be co-led with the Emergency Task Force (ETF).

5. Training for the network and knowledge building

Training of vaccines assessors planned for 2024

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

None

6.2. Collaboration with interest parties and other stakeholders

None

7. International activities

Vaccine Cluster teleconference on an ad hoc basis.