14 December 2017
EMA/CHMP/VWP/515395/2017

Work plan for the Vaccines Working Party (VWP) for 2018

Chairperson: Mair Powell

Status of the work plan: December 2017 – Adopted

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Face-to-face meetings are planned for the following dates:

- 7-8 June 2018
- 22-23 November 2018

The above mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

2. Guidelines

2.1. New EU Guidelines

Action: Lead

Guideline on the evaluation of medicinal products indicated for the treatment and prophylaxis of respiratory syncytial virus (RSV) infections, EMA/CHMP/257022/2017

Target date	Finalise by Q4 2018
Comments	First draft published in October 2017 for 6 months consultation until April 2018
	Joint work with the Infectious Disease Working Party (IDWP)

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Action: Specialised input

None

2.2. EU Guidelines under revision

Action: Lead

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

Target date	Finalise first draft by Q1 2018 followed by 6 months public consultation
Comments	None

Action: Specialised input

Interim Guidance on Enhanced Safety Surveillance for seasonal influenza vaccines in the EU EMA/PRAC/222346/2014

Leading group	PRAC
Target date	Finalise by Q4 2018
Comments	Joint revision with the PRAC – to be published as Appendix to the Influenza Guideline Non-Clinical and Clinical Module

2.3. ICH Guidelines

None

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Preparation of scientific reports on matters of public interest and emerging issues pertaining to infectious diseases
- Contribution to innovation task force (ITF) advice, scientific advice (monthly virtual meetings), protocol assistance, paediatric investigation plan evaluation and orphan designation on general and product specific matters related to infectious diseases

3.2. Evaluation and supervision activities

- Contribution/recommendation to CHMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP or PRAC.
- Input on non-centralised products (NAPs) evaluation/referral procedures upon request of CMDh.
- Contribution to evaluation of medicinal products intended exclusively for markets outside EU (Art. 58 procedures for scientific opinions in the context of cooperation with the WHO)
- Contribution to referral discussions upon request from CHMP/PRAC

Note: requests will be addressed via monthly virtual meetings or at one of the face to face meetings depending on timing.

4. Input in European activities

4.1. Training for the network and knowledge building

Maintain awareness of issues arising in the context of vaccines for infectious diseases in order to identify the need for review and update of Guidelines and development of additional guidance documents.

4.2. Other input in European activities

- Regular interactions with European Centre for Disease Prevention and Control (ECDC) via VWP meetings or teleconferences, as needed.
- Interaction with Innovative Medicines Initiative (IMI) consortia on specific projects (e.g. PERISCOPE, ADVANCE, FluCOP), and/or other EU funded consortia (e.g. related to universal influenza vaccines).

5. Input in International activities (beyond ICH guidelines)

- Discussion with FDA and HC in the context of three Vaccine Cluster virtual meetings per year on efficacy and safety issues related to vaccines, matters of public interest and emerging issues pertaining to infectious diseases.
- Regular contact and discussion with WHO either during VWP meetings through WHO observers or via ad-hoc virtual meetings (e.g. Ebola/Zika-related activities, pandemic influenza, polio endgame activities, WHO R&D blueprint, lot release, specific topics).

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

6.1. Workshops

None

6.2. Other activities with stakeholders and external parties

Ad hoc meetings with Interested Parties: European Federation of Pharmaceutical Industries and Associations (EFPIA), Vaccines Europe

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/08/WC500095453.pdf