14 December 2017
EMA/CHMP/517878/2017

Work plan for the Infectious Diseases Working Party (IDWP) for 2018

Chairperson: María Jesús Fernández Cortizo

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:

- 19-20 June 2018
- 08-09 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

Target date Finalise by Q4 2018

Comments Draft GL published in October 2017 for 6 months consultation until April 2018.

Joint work with the Vaccine Working Party (VWP)

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2.2. EU Guidelines under revision

Action: Lead

Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements (EMA/CHMP/351889/2013)

Target date Finalise by Q4 2018

Comments Release draft GL for consultation by end of Q1 2018

Preparation of a revised guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 rev 2)

Target date Finalise by Q1 2019

Comments Release draft concept paper for consultation by end of Q1 2018

Clinical evaluation of direct acting antiviral agents intended for treatment of chronic hepatitis C (CHMP/EWP/30039/2008)

Target date Finalise by Q2 2018

Comments Continuation of 2017 work for early 2018

Action: Specialised input

Guideline on the clinical investigation of medicinal products for the treatment of cystic fibrosis (EMEA/CHMP/EWP/9147/2008-corr*)

Leading group Respiratory Drafting Group (RDG)

Target date Finalisation during 2019

Comments Release draft GL for public consultation by Q3 2018; joint work with the RDG

2.3. ICH Guidelines

Not applicable

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, protocol assistance, paediatric investigation plan evaluation and orphan designation on general and product specific matters related to infectious diseases

Note: Contribution to scientific advice on anti-infectives via monthly virtual meetings

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 referral discussions upon request from CHMP/PRAC

Note: To 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 anti-infectives 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

- Interactions with European Centre for Disease Prevention and Control (ECDC) via IDWP meetings or teleconferences, as needed.
- Contribution to Innovative Medicines Initiative (IMI) calls and projects.
- Contribution to the work of the Antimicrobial Advice Ad Hoc Expert Group (AMEG).

5. Input in International activities (beyond ICH guidelines)

- Antimicrobials IDWP/FDA cluster on information sharing with a subset for antibacterial and antivirals.
- Discussion with FDA in the context of the antimicrobials Cluster virtual meetings per year (plus ad hoc meetings based on Transatlantic Task Force on Antimicrobial Resistance (TAFTAR) agreement on AMR) on efficacy and safety issues related to anti-infectives, matters of public interest and emerging issues pertaining to infectious diseases.
- Discussion with FDA for in parallel scientific advice procedures intended for selected products.

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

6.1. Workshops

Organise a workshop with stakeholders in relation Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections in Q2 2018

6.2. Other activities with stakeholders and external parties

- Support to any ongoing or upcoming activities / scientific discussions related to antimicrobial resistance
- Contribution to briefing meetings related to infectious diseases with external parties (pharmaceutical companies, academia, public/private partnership or patients' associations)
- Contribution to any other requests from the European Commission for a scientific opinion, as deemed appropriate
- Interaction with research groups in the area of anti-infectives

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