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Human Medicines Division

Consolidated 3-year work plan for the Infectious Disease Working Party (IDWP)

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Work plan period: January 2022 – December 2024 (with a first review point after one year)

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1. Strategic goals

The Infectious Disease Working Party (IDWP) is a working party established to address issues related to the clinical and the non-clinical development of anti-infective medicinal products. In the field of the non-clinical development, this is limited to studies addressing the primary pharmacology.

Short term goals

- Finalisation of the following guidelines
  - Draft Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections, (CPMP/EWP/558/95 Rev. 3). (Completed)
  - Draft 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/213862/2016). (Completed)
- Start revision of the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1)
- Planning a training programme covering the main principles of the existing guidelines on anti-infective agents and of those which are to be developed and/or updated during the work plan period.
- Review the need for publishing new guidelines in the field of anti-infective agents or updating the existing ones in discussion with the key stakeholders.
- Identification of the European and international key stakeholders in the field of infectious diseases.
- Provide specialised input in the field of anti-infective agents on request of the regulatory network.

Long term goals

Fulfilment of broad long-term goals is linked to the EMA/EMRN Regulatory Science Strategy to 2025[1].

- Antimicrobial resistance (AMR)

  The high-level objectives which are more closely related with the activity and capability of the IDWP are listed below.
  - Contribute to the rational use of anti-infective agents, including given reconsideration to the priority list of antibiotics for which an update of their Product Information is needed, as well as by closely collaborating with the with the veterinary sector at the Agency in a One Health approach.
  - Evolve regulatory guidance and support alternative approaches to new anti-infective drug development as well as innovative approaches for prevention and treatment of bacterial infectious diseases following the EU One Health Action Plan against AMR[2].
  - Foster international regulators dialogue to promote convergence and streamline the development plans of new anti-infective agents and alternatives to traditional antimicrobials.

[1] European Medicines Agency, "EMA Regulatory Science to 2025. Strategic reflection," European Medicines Agency, Amsterdam, The Netherlands, EMA/110706/2020, 2020. [Online]. Available: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

[2] European Commission, "A European One Health Action Plan against Antimicrobial Resistance (AMR)," Jun. 2017. [Online]. Available :https://ec.europa.eu/health/system/files/2020-01/amr_2017_action-plan_0.pdf

- Contribution to the activities of the Innovation Task Force (ITF), as well as to the assessment of scientific advice and protocol assistance, paediatric investigation plan, and orphan designation on general and product specific matters related to infectious diseases on an ad-hoc basis.
- Contribution to the activities of the Emergency Task Force (ETF) on health threats preparedness and regulatory science on an ad-hoc basis.
- Ensure sufficient network competences to accommodate rapid evolution of the regulatory system.
- Improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, in particular improving the use of non-clinical models and optimise the capabilities in modelling, simulation, and extrapolation.
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions.
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.
- Enhance collaboration on in vitro diagnostics with notified bodies and academic groups.
- Drafting of new guidelines or updating the existing ones (not all of them may be launched and finalised during the work plan period).
- Interaction and engagement with the key stakeholders in the field of infectious diseases.

2. Tactical goals: activities/projects to deliver the strategic goals

2.1. Guideline activities

- Development of the guideline on the evaluation of medicinal products indicated for treatment of influenza (Concept Paper EMA/CHMP/EWP/808940/2016).
- Update of the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1).
- Update of the Guideline on the clinical evaluation of medicinal products intended for treatment of hepatitis B virus infection (CHMP/EWP/6172/03) and development of a Guideline on the clinical evaluation of medicinal products intended for the treatment of hepatitis D virus infection.
- Update of the Reflection paper on the non-clinical and clinical development for medicinal products indicated for HIV pre-exposure prophylaxis (PrEP) (EMA/171264/2012).

2.2. Training activities

- A face to face or virtual training programme for the work plan period, covering the principles of the existing guidelines and of those which will be updated and/or developed with the support of EU network Training Centre (EU NTC). The aim is to provide a) plenary sessions covering overviews of principles and guidelines followed by b) exercises conducted in breakout groups ending in plenary presentations from each group and discussions. The material would be taken from recent scientific advice and applications. The trainers would be IDWP members or co-opted external experts to cover specific topics.
- Provision of lectures on specific issues to be recorded and reproduced as needed by interested members of the IDWP and/or external experts to cover specific topics.

2.3. Communication and Stakeholder activities

- Organisation of and/or participation in specific forums, meetings or workshops dedicated to anti-infective agents to discuss with other regulators, academia, industry, professional societies, patient organizations, and advocacy communities' issues that may have impact regulatory guidance and/or regulatory decisions.
- Establish interactions with all/some of the key stakeholders identified as relevant for the IDWP.
- Attendance to the virtual meetings with other regulators to discuss efficacy and safety issues related to anti-infective agents.
- Interactions with WHO experts and groups as well as with the European Centre for Disease Prevention and Control (ECDC) via IDWP meetings or teleconferences, and contribution to Innovative Medicines Initiative (IMI) calls and projects on an ad-hoc basis.
- Collaboration with the CVMP Antimicrobials Working Party (AWP) under the new legislative landscape of the Regulation (EU) 2019/6 on veterinary medicinal products on an ad-hoc basis[3].

3. Operational goals: medicinal product-specific activities

The IDWP will provide product-related support upon request from the ETF, ITF, EMA Committees, Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) and Scientific Advice Working Party (SAWP).

[3] Official Journal of the European Union, Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. 2019: https://eur-lex.europa.eu/eli/reg/2019/6/oj.

Priorities for 2023

4. Guidelines

4.1. EU Guidelines

Action: Lead

Update of the Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease (CHMP/EWP/1343/01 Rev. 1)[4]

Target date	Finalisation by the end of 2023, publication 2024
Comments	Update needed to address changes in clinical practice and requests made in some recent scientific advices.

Action: Contribution

Update of the Guideline on the clinical investigation of medicinal products for the treatment of cystic fibrosis (EMEA/CHMP/EWP/9147/2008-corr*)[5]

Target date	To be determined by the lead working party
Comments	IDWP input limited to the clinical development of inhaled anti-bacterial agents

Action: Contribution

CVMP/Antimicrobials Working Party (AWP) Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health.[6]

Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals (AMR Risk Assessment guideline).[7]

Target date	To be determined by the AWP/CVMP
Comments	IDWP input as requested by the AWP/CVMP

5. Training for the network and knowledge building

Schedule and perform a training programme, covering the main principles of the existing guidelines on antibacterial agents, including the use of popPK-PD and the paediatric development.

[4] Clinical evaluation of antifungal agents for the treatment and prophylaxis invasive fungal disease -Scientific guideline | European Medicines Agency (europa.eu)
[5] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-development-medicinal-products-treatment-cystic-fibrosis-first-version_en.pdf
[6] Use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health - Scientific guideline | European Medicines Agency (europa.eu)
[7] Assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals - Scientific guideline | European Medicines Agency (europa.eu)

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

6.1. Workshops

None

6.2. Collaboration with interested parties and other stakeholders

Establish interactions with the EMA Patients' and Consumers' Working Party (PCWP).

7. European collaborations

Triggering an article 31 referral to update the Product Information of at least one of the antibiotics included in the priority list.

8. International activities

Attendance to the virtual meetings with the FDA and other regulatory agencies to discuss the requirements for the clinical development of specific conditions as well as product-specific issues related to anti-infective agents.