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SCIENCE MEDICINES HEALTH

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Infection Diseases Working Party/CHMP
Human Medicines Division
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Consolidated 3-year rolling work plan for the Infectious Diseases Working Party

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Work plan period: January 2025 – December 2027 (with a first review point after one year)

Dates of Meetings: Monthly (except August).



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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 primary pharmacology.

1.1. Short-term strategic goals

Short term goals

- Draft the Concept Paper on the need to update the *Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease* (CHMP/EWP/1343/01 Rev. 1).
- Develop the *Guideline on the evaluation of medicinal products indicated for treatment of influenza* (Concept Paper EMA/CHMP/EWP/808940/2016).
- Finalise the update of the *Guideline on the clinical evaluation of medicinal products intended for treatment of hepatitis B virus infection* (CHMP/EWP/6172/03).
- Draft a *Guideline on the non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the prevention and treatment of COVID-19* (Concept paper EMA/CHMP/70203/2024).
- 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.
- Develop a training programme for assessors identified as being, or likely to be, involved in the clinical evaluation of anti-infective medicinal products, 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.
- Interact with key European and International Stakeholders and regulators in the field of infectious diseases.
- Provide specialised input in the field of anti-infective agents on request of the regulatory network.
- Update the Paediatric Curriculum regarding the development of Fixed Dose Combinations (FDC) for the treatment of paediatric patients living with HIV-1, in collaboration with the PDCO expert group.

1.2. Long-term strategic goals

Fulfilment of broad long-term goals is linked to the EMA network strategy to 2028/¹

- Support the ETF in non-guideline activities relating to the development of new antimicrobials and the rational use of existing and new antimicrobials.

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 periodical reconsideration to the priority list of antibiotics for which an update of their Product Information is needed,

¹ [EMANS 2028](#)

support referral procedures as needed, as well as by closely collaborating with the veterinary sector at the Agency in a One Health approach.

- Contribute to drafting regulatory guidance and support alternative approaches to new anti-infective drug development as well as innovative approaches for prevention and treatment of bacterial and fungal infectious diseases following the EU One Health Action Plan against AMR².
- Contribute to the international regulator's dialogue to promote convergence and streamline the development plans of new anti-infective agents and alternatives to traditional antimicrobials.
- Contribute 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.
- Contribute 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.
- Improve the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, 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.
- Interact and engage with key stakeholders in the field of infectious diseases.

2. Tactical goals

2.1. Guidance activities

(A) Activities ongoing/to be finalised in 2025

- Update of the *Guideline on the clinical evaluation of medicinal products intended for treatment of hepatitis B virus infection* (CHMP/EWP/6172/03)³.

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

³ [Clinical evaluation of medicinal products intended for treatment of hepatitis B - Scientific guideline | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/clinical-evaluation/clinical-evaluation-guideline-hepatitis-b)

- Complete Concept paper for updating the *Guideline on clinical evaluation of anti-fungal agents for the treatment and prophylaxis of invasive fungal diseases* (CHMP/EWP/1343/01 Rev.1)⁴.
- Develop a *Guideline on the non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the prevention and treatment of COVID-19* (Concept paper EMA/CHMP/70203/2024).

(B) Activities to be started in 2025-2027

- Develop the *Guideline on the evaluation of medicinal products indicated for treatment of influenza* (Concept Paper EMA/CHMP/EWP/808940/2016).
- Develop a concept paper followed by a *Guideline on the clinical evaluation of medicinal products intended for the treatment of hepatitis D virus infection*.
- Update 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 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 and workshop activities

- Deliver 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 to the CHMP and PDCO. The trainers would be IDWP members or co-opted external experts to cover specific topics.
- Provide 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. (IDWP training- last lecture in Jan 2025)
- Schedule and perform a training programme covering main principles on anti-fungal and anti-viral agents once the respective guidelines have been finalised.
- Update the Paediatric Curriculum regarding the development of Fixed Dose Combinations (FDC) for the treatment of paediatric patients living with HIV-1, in collaboration with the PDCO expert group.

2.3. Communication and Stakeholder activities

- Organise and/or participate in specific forums, meetings or workshops dedicated to anti-infective agents to interact with key stakeholders as relevant for the IDWP.
- Attend the virtual meetings with other regulators to discuss efficacy and safety issues related to anti-infective agents.

⁴ [Guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease \(europa.eu\)](https://www.europa.eu)

- Interact 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.
- Collaborate 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 basis⁵.

2.3.1. European level

Interact with key European Stakeholder organisations having an interest in infectious diseases.

2.3.2. International level

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

2.4. Multidisciplinary collaboration

For activities pertaining to guidelines, a collaboration with the Emergency Task Force (ETF) will be established to facilitate close cooperation and leverage the ETF's scientific expertise in the drafting of guidelines.

The collaboration with the ETF will include joint development of the *Guideline on the non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the prevention and treatment of COVID-19* (Concept paper EMA/CHMP/70203/2024).

The ETF will contribute to drafting the concept paper and updating the *Guideline on clinical evaluation of anti-fungal agents for the treatment and prophylaxis of invasive fungal diseases* (CHMP/EWP/1343/01 Rev.1).

On an *ad hoc* basis the IDWP will collaborate with the veterinary sector at the Agency in a One Health approach.

3. Operational goals

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).

IDWP will interact with the relevant bodies also including academia regarding important topics in the field of infectious diseases.

IDWP plans to have one face-to-face meeting each year.

⁵ 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://eurlex.europa.eu/eli/reg/2019/6/oj>

4. List of Abbreviations

| | |
|--------|--|
| AWP | Antimicrobials Working Party |
| CHMP | Committee for Medicinal Products for Human Use |
| CMDh | Coordination Group for Mutual Recognition and Decentralised Procedures - Human |
| CVMP | Committee for Veterinary Medicinal Products |
| ECDC | European Centre for Disease Prevention and Control |
| EMA | European Medicines Agency |
| ETF | Emergency Task Force |
| EU NTC | European Union Network Training Centre |
| FDC | Fixed Dose Combinations |
| IDWP | Infectious Diseases Working Party |
| IMI | Innovative Medicines Initiative |
| ITF | Innovation Task Force |
| PDCO | Paediatric Committee |
| PrEP | Pre-exposure prophylaxis |
| SAWP | Scientific Advice Working Party |