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Therapies for Immune and Inflammatory diseases
Human Medicines Division

Draft 3-year rolling work plan for the Rheumatology and Immunology Working Party (RIWP)

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

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1. Strategic goals

The strategic goal of the Rheumatology/Immunology WP is the support of medicines development and evaluation of products in internal medicine, including auto-immune diseases, diseases of the bones and joints and diseases from areas of gastroenterology, respiratory system and nephrology. Thus, its strategic goals are mainly related to the Strategic Focus Area "Availability and Accessibility of Medicines" of the "European medicines agencies network strategy to 2025".

2. Tactical goals

2.1. Guidance activities

- Revision of the Guideline on clinical investigation of medicinal products for the treatment of Psoriatic Arthritis
- Drafting of Guidance on the investigation of medicinal products in Systemic Sclerosis
- Drafting of Guidance on development strategies for allergen products intended for allergies with low prevalence.
- Revision of the Guideline on therapeutic equivalence of orally inhaled products
- Drafting guidance on therapeutic equivalence for nasal products
- Revision of the Guideline on clinical investigation of medicinal products for the treatment of cystic fibrosis
- Revision of the guideline on clinical investigation of medicinal products for the treatment of acute respiratory distress syndrome
- Revision of the guideline on the investigations of medicinal products in the term and preterm neonates
- Review of existing guidelines in the remit of RIWP and horizon scanning to identify the need for guideline updates.

(A) Activities ongoing/to be finalised in 2025

Action: Lead

Guideline on the clinical investigation of medicinal products for the treatment of psoriatic arthritis

Target date	Draft revised Guideline to be published for public consultation by Q4 2025
Comments	Revision of an existing guideline

Action: Lead

Guideline on the clinical investigation of medicinal products in the term and preterm neonates

Target date	Draft revised guideline to be published for public consultation by Q2 2025.
Comments	Revision of existing guideline.

Action: Lead

Guideline on allergen products development for immunotherapy and allergy diagnoses in moderate to low-sized study populations

Target date	Final guideline to be published by Q2 2025.
Comments	New guideline. Public consultation on the draft guideline ended 31/05/2024

Action: Lead

Guideline on requirements for clinical documentation for orally inhaled products **(OIP)** including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary diseases

Target date	Final updated guideline to be published for by Q2 2025
Comments	Revision of existing Guideline. Public consultation on the draft updated Guideline ended 30/10/2024

Action: Lead

Guideline on requirements for clinical documentation for demonstration of therapeutic equivalence for nasal products

Target date	Draft Guideline to be published for public consultation by Q4 2025
Comments	New Guideline.

Action: Lead

Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis

Target date	Draft updated Guideline to be published for public consultation by Q3 2025
Comments	Revision of existing Guideline.

Action: Lead

Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome

Target date	Draft updated Guideline to be released for public consultation by Q1 2025
Comments	Revision of the existing Guideline.

Action: Lead

Guidance document on the clinical investigation of medicinal products for the treatment of Systemic sclerosis

Target date	Concept paper to be published for public consultation by Q2 2025

Comments	New Guidance document

(B) Activities to be started in 2025

Drafting a paediatric addendum to the guidelines on the clinical investigation of medicinal products in ulcerative colitis and Crohn's disease.

(C) Activities to be started in 2026-2027

Drafting guidance on the clinical investigation of medicinal products for the treatment of Idiopathic Pulmonary Fibrosis (IPF)

2.2. Training and workshop activities

The RIWP will be providing trainings to the network to be organised as needed (e.g., when guidelines are finalised or updated) and workshops as needed to support the drafting of Guidelines.

2.3. Communication and Stakeholder activities

Participation in stakeholder activities will be decided on a case-by-case basis.

2.4. Multidisciplinary collaboration

- On the Guideline on therapeutic similarity of orally inhaled products (OIP): Quality Working Party (QWP) and Methodological Working Party (MWP) will be consulted before a final Guideline will be released.
- On the new Guideline on therapeutic equivalence for nasal products QWP and MWP will be consulted before a final Guideline will be released.
- On the Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis: Infectious Disease Working Party (IDWP), MWP and PDCO will be consulted before a draft updated Guideline for public consultation is released.
- On the Guideline on the investigation of medicinal products in the term and preterm neonates: multidisciplinary consultations are planned including PDCO.
- On the guideline on acute respiratory distress syndrome with regular consultations with Emergency Task Force (ETF) and planned discussion with PDCO and MWP.

3. Operational goals

RIWP will provide product related support upon request from Committees and SAWP.

4. List of Abbreviations

N/A, abbreviations are spelled out where mentioned first in the document