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Human Medicines Division

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

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Work plan period: 2024 – 2026

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Table of contents

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: activities/projects to deliver the strategic goals

2.1. Guideline 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.
- Finalisation of the Reflection papers on NASH
- 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 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.

2.2. Training activities

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

2.3. Communication and Stakeholder activities

- European and international co-operation relating to the working party activities
- Liaison with interested parties, such as industry, patient organisations and healthcare professional organisations

2.4. Multi-disciplinary 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 the final Guideline will be released.
- On the new Guideline on therapeutic equivalence for nasal products Quality Working Party (QWP) will be consulted before a the 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), Methodological Working Party (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.

3. Operational goals: medicinal product-specific activities

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

Priorities for 2024

4. Guidelines

4.1. EU Guidelines

Action: Lead

Clinical investigation of medicinal products for the treatment of psoriatic arthritis

Target date	Concept paper to be published for public consultation by Q4 2024
Comments	Revision of an existing guideline,

Action: Lead

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

Target date	Draft revised guideline to be published for public consultation by Q4 2024.
Comments	Revision of existing guideline. Public consultation on the concept paper ended 12/2018

Action: Lead

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

Target date	Draft guideline to be published for public consultation by Q1 2024.
Comments	New guideline. Public consultation on the concept paper ended 06/2019

Action: Lead

Reflection paper on regulatory requirements for the development of medicinal products for Non Alcoholic Steatohepatitis (NASH)

Target date	Final Guideline to be published by Q1 2024.
Comments	New Reflection Paper. Public consultation on the Draft reflection paper ended 31/08/2019.

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	Draft revised guideline to be published for public consultation by Q1 2024
Comments	Revision of existing Guideline. Public consultation on the concept paper ended 30/06/2017

Action: Lead

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

Target date	Concept paper to be published for public consultation by Q3 2024
Comments	New Guideline

Action: Lead

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

Target date	Draft revised Guideline to be published for public consultation by Q4 2024
Comments	Revision of existing Guideline. Public consultation on the concept paper ended 31/10/2016

Action: Lead

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

Target date	Draft revised Guideline to be released for public consultation by Q4 2024
Comments	Revision of the existing Guideline.

4.2. ICH Guidelines

None

5. Training for the network and knowledge building

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

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

6.1. Workshops

Dedicated stakeholder interactions may be organized in the process of guidance drafting if needed.

6.2. Collaboration with Interested parties and other stakeholders

To be organized on a "as needed" basis

7. European collaborations

None

8. International activities

None