15 December 2022
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Human Medicines Division

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

Chairperson:	vacant
Vice chair:	Caroline Auriche (acting chair)

Work plan period: June 2022 – December 2024 (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, in particular for auto-immune disease, diseases of the bones and joints and diseases from areas gastroenterology, respiratory 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

- Drafting of Guidance on development strategies for allergen products intended for allergies with low prevalence.
- Drafting of a Reflection paper on development of medicinal products to prevent and treat acute kidney injury.
- Finalisation of the Reflection papers on chronic non-infectious liver diseases (NASH, PBC, PSC)
- Drafting of a Guideline on therapeutic similarity of orally inhaled products
- Drafting of a Concept paper on therapeutic equivalence for nasal products
- Drafting a Question and Answer document on the change of propellants in orally inhaled spray formulations
- Revision of the Guideline on cystic fibrosis
- Revision of the guideline on respiratory distress syndrome
- Revision of the guideline on the investigations of medicinal products in the term and preterm neonate
- Review of existing guidelines in the remit of RIWP and horizon scanning to identify the need for guideline updates.
- Horizon scanning and identification on the need for new guidelines with the help of existing data sources (scientific advice requests).

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 working party activities
- Liaising 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) will be consulted before a draft for public consultation 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 will be released.
- On the Reflection paper on regulatory requirements for the development of medicinal products for Non Alcoholic Steatohepatitis (NASH)) Cardiovascular Working Party (CVWP) and Methodological Working Party (MWP) will be consulted before the final Guideline will be released.
- On the Reflection Paper on regulatory requirements for the development of medicinal products for Primary Biliary Cirrhosis (PBC) and Primary Sclerosing Cholangitis (PSC) Methodological Working Party (MWP) will be consulted before the final Guideline will be released..
- On the Guideline on development strategies for allergen products intended for allergies with low prevalence PDCO will be consulted before the draft Guideline will be released
- On the Guideline on the investigation of medicinal products in the term and preterm neonate 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 2023

4. Guidelines

4.1. EU Guidelines

Action: Lead

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

Target date	Draft revised guideline to be published for public consultation by Q2 2024.
Comments	Revision of existing guideline. Public consultation on the concept paper ended 12/2018

Action: Lead

Reflection paper on development of medicinal products to prevent and treat acute kidney injury

Target date	Draft reflection paper to be published for external consultation by Q1 2024.
Comments	New reflection paper, Public consultation on the concept paper ended 07/2019

Action: Lead

Guideline on development strategies for allergen products intended for allergies with low prevalence

Target date	Draft guideline to be published for public consultation by Q4 2023.
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 Q4 2023.
Comments	New Reflection Paper. Public consultation on the Draft reflection paper ended 31/08/2019.

Action: Lead

Reflection paper on regulatory requirements for the development of medicinal products for Primary Biliary Cirrhosis (PBC) and Primary Sclerosing Cholangitis (PSC)

Target date	Final Guideline to be published by Q4 2023.
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 Q4 2023
Comments	Revision of existing Guideline. Public consultation on the concept paper ended 30/06/2017

Action: Lead

Question and Answer document on the change of propellants in orally inhaled spray formulations

Target date	Q&A to be published by Q1 2023.
Comments	

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 Q4 2023
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 2023
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	Concept paper to be released for public consultation by Q2 2023
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

- None

6.2. Collaboration with Interested parties and other stakeholders

None

7. European collaborations

None

8. International activities

None