14 December 2017
EMA/CHMP/383892/2017

Work plan for the Respiratory Drafting Group (RDG) for 2018

Chairperson: Karolina Törneke

Status of the work plan: December 2017 – Adopted

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Face-to-face meetings are planned for the following dates:

- 22-23 March 2018
- 18-19 October 2018

The above mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

2. Guidelines

2.1. EU Guidelines under revision

Action: Lead

Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis (CHMP/EWP/9147/08)

Target date	Draft guideline to be released for 6 month public consultation Q2-Q3 2018
Comments	Revision to bring the guideline in line with the current clinical knowledge and developments.

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Guideline on the 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 Disease (COPD) in adults and for use in the treatment of asthma in children and adolescents (CPMP/EWP/4151/00 Rev. 1)

Target date	Draft guideline to be released for 6 month public consultation Q3 2018
Comments	Consultation of other Working Parties (e.g. Quality Working Party, Pharmacokinetics Working Party) and PDCO

Action: Lead

Concept paper on acute respiratory distress disease

Target date	Draft concept paper to be released for 6 month public consultation Q1-Q2 2019
Comments	New guideline to develop in line with current scientific knowledge and recent scientific advices

2.2. ICH Guidelines

None

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Support to Scientific Advice and Protocol Assistance in the field of respiratory diseases upon request

3.2. Evaluation and supervision activities

Contribution to product assessment and post-authorisation issues in the field of respiratory diseases upon request

4. Input in European activities

4.1. Training for the network and knowledge building

None

5. Input in International activities (beyond ICH guidelines)

None

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

None

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/08/WC500095453.pdf