14 December 2017
EMA/CHMP/350919/2017

Work plan for the Gastroenterology Drafting Group for 2018

Chairperson: Mark Ainsworth

Status of the work plan December: 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:

- January 2018
- 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. New EU Guidelines

Action: Lead

Reflection paper on chronic non-infectious liver diseases

Target date	Draft reflection paper to be released for public consultation Q3 2018
Comments	A targeted consultation with stakeholders is planned to support the drafting process

Action: Specialised input

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Demonstration of therapeutic equivalence for locally applied and locally acting products in the gastrointestinal tract

Leading group Pharmacokinetics Working Party

Target date Final guideline to be adopted by the CHMP Q4 2018

Comments Involvement of the Gastroenterology Drafting Group is planned before finalisation

2.2. EU Guidelines under revision

Action: Lead

Guideline on the development of new medicinal products for the treatment of Crohn's disease, CPMP/EWP/2284/99 Rev. 2

Target date Final guideline to be released Q1 2018

Comments None

Note for guidance on the development of new medicinal products for the treatment of ulcerative colitis, CHMP/EWP/18463/2006 Rev. 1

Target date Final guideline to be released Q1 2018

Comments None

2.3. ICH Guidelines

None

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

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

3.2. Evaluation and supervision activities

Contribution to product assessment for Initial Marketing Authorisation Applications and post-authorisation procedures in the field of gastroenterolgy upon request

4. Input in European activities

4.1. Training for the network and knowledge building

- Organisation of training sessions for the regulatory network in the field of gastroenterology; e.g. following publication of new or revised guideline, as appropriate

- Maintain awareness of issues arising in order to identify the need for review and update of Guidelines and development of additional guidance documents

4.2. Interactions with learned societies and specialised organisations

- Interaction with interested parties; learned societies, public health stakeholders (e.g. public health professionals) under the supervision of the CHMP
- Organisation of focused sessions with learned societies in the field of gastroenterolgy; e.g. following publication of new or revised guideline, as appropriate
- Interaction with relevant research consortia within the gastroenterology field under the supervision of the CHMP, as appropriate

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

Interactions with the FDA and other medicinal products regulatory authorities via teleconferences regarding the development of gastroenterology guidelines, as appropriate.

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

6.1. Workshops

None

6.2. Other activities with stakeholders and external parties

Targeted stakeholder interaction on development of therapies in chronic non-infectious liver diseases is planned in the course of the drafting process.

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