EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2017
EMA/CHMP/625937/2017

Work plan for the Central Nervous System Working Party (CNSWP) for 2018

Chairperson: Karl Broich

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:

- 16 March 2018
- 26 September 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 the investigation of suicidal ideation and behaviour

Target date	Draft reflection paper to be released for 3 month public consultation Q3 2018
Comments	New reflection paper to reflect on current scientific developments

2.2. EU Guidelines under revision

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Action: Lead

Guideline on clinical investigation of medicinal products for treatment of migraine, CPMP/EWP/788/2001 Rev. 2

Target date Draft guideline to be released Q4 2018

Comments Revision to bring the Guideline in line with the recent scientific developments

Guideline on clinical investigation of medicinal products in the treatment of depression, CHMP/185423/2010 Rev. 3

Target date Draft guideline to be released for 6 month public consultation Q4 2018

Comments Revision to bring the Guideline in line with the recent scientific developments

Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder, EMA/CHMP/735080/2015

Target date Draft guideline to be released for 6 month public consultation Q4 2018

Comments Revision to bring the Guideline in line with the recent scientific developments

Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders, CPMP/EWP/566/1998 Rev. 2 Corr

Target date Draft guideline to be released Q3 2018

Comments Revision to bring the Guideline in line with the recent scientific developments

Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias (EMA/CHMP/539931/2014)

Target date Final guideline to be released Q1 2018

Comments Revision to bring the Guideline in line with the recent scientific developments

2.3. ICH Guidelines

N/A

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Support to Scientific Advice and Protocol Assistance in the field of neurology and psychiatry 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 neurology and psychiatry 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 neurology and psychiatry; 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 neurology and psychiatry; e.g. following publication of new or revised guideline, as appropriate
- Interaction with relevant research consortia within the neurology and psychiatry 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 neurology and psychiatry guidelines, as appropriate
- Cooperation with other regulators and international organisations in the field of dementia e.g. support to global action against dementia activities

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

6.1. Workshops

EMA public workshop during consultation on the Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

Date to be defined.

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