15 December 2022
EMA/CHMP/919105/2022
Human Medicines Division

Consolidated 3-year work plan for the Central Nervous System Working Party (CNSWP)

Chairperson: Andre Elferink

Work plan period: January 2022 – December 2024 (with a first review point after one year)

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Table of contents

1. Strategic goals

1.1. Short term goals

- Release of the draft Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders. Organise the stakeholders workshop to assist the finalisation of this document.
- Release of the draft Guideline on clinical investigation of medicinal products for treatment of migraine, draft Guideline on clinical investigation of medicinal products in the treatment of depression and draft Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder.
- Provide specialised input in neurology and psychiatry fields on request of CHMP or other EMA Committees.
- Review the need publishing new guidelines in the area of neuroscience.

1.2. Long term goals

- Develop consistent principles for feasible, efficient and robust data generation in the asymptomatic phase of neurodegenerative disorders. With an ageing population in the EU, and the observed progress in scientific research on the topic that could potentially allow prevention of symptomatic diseases, a consistent approach to studying the asymptomatic phases of neurodegenerative disorders is highly needed.
- Work towards building a framework that stimulates the development and use of innovative methods of outcome measurement in neuroscience (including use of digital technology tools), accompanied by increased patient-centricity. As an important part of this activity, the working party should collaborate to define psychometric principles for validating outcome measurement tools in psychiatric and neurological conditions in the context of remote trials, Patient Reported Outcomes and outcome measurement based on electronic devices.
- Ensure that consistent methods are applied for obtaining a reliable interpretation to data from trials affected by the COVID19 pandemic. In this context, neurological and psychiatric conditions deserve a particular attention given the nature of both the disease and the outcome measurement tools.
- Prepare the expert network for both the challenges and opportunities in situations when disease definitions are uncertain and subject to change. There is an increased need of clear regulatory views on transdiagnostic and/or symptom specific indications in neuroscience.
- Expand connections and links to academic and clinical experts specialising in the field of neuroscience Tactical goals: activities/projects to deliver the strategic goals

1.3. Guideline activities

- Guideline on clinical investigation of medicinal products for treatment of migraine, CPMP/EWP/788/2001 Rev. 2
- Guideline on clinical investigation of medicinal products in the treatment of depression, CHMP/185423/2010 Rev. 3
- Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder, EMA/CHMP/735080/2015

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

1.4. Training activities

- The CNSWP has pioneered collaboration with EuNTC to provide assessor training as new guidelines are released and this will be continued going forward.
- The cooperation with the European College of Neuropsychopharmacology (ECNP), European Academy of Neurology (EAN), International Society for CNS Clinical Trials and Methodology (ISCTM) and other societies is an opportunity for the members of the CNSWP to increase their knowledge of the work done by the Academia and the Industry as well as a platform to provide Regulatory perspective on the new developments.

1.5. Communication and Stakeholder activities

- Contribution to International Society for CNS Clinical Trials and Methodology (ISCTM) teleconferences.
- Participation in teleconferences with FDA to exchange experience, especially in the context of new guidelines.
- Participation and contribution to FDA workshops in neurology and psychiatry.
- Interaction with interested parties e.g., learned societies (International Headache Society, International League against Epilepsy) under the supervision of the CHMP.

1.6. Multi-disciplinary collaboration

- Organisation of a dedicated workshop, likely connected to the guideline revisions

2. Operational goals: medicinal product-specific activities

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

Priorities for 2023

3. Guidelines

3.1. EU Guidelines[1]

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 for public consultation Q4 2023
Comments	Guideline developed in collaboration with PDCO and Methodology Working Party (MWP)

Action: Lead

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 for public consultation Q1 2023
Comments	Guideline developed in collaboration with PDCO and Methodology Working Party (MWP).

Action: Lead

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 2023
Comments	Guideline developed in collaboration with PDCO, Methodology Working Party (MWP) and Scientific Advice Working Party (SAWP).

Action: Lead

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 Q1 2023
Comments	Guideline developed in collaboration with PDCO and Methodology Working Party (MWP).

3.2. ICH Guidelines

N/A

4. Training for the network and knowledge building

- Organise assessor trainings on all newly created guidelines, once released.
- Maintain awareness of issues arising in order to identify the need for review and update of Guidelines and development of additional guidance documents

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

5.1. Workshops

- Organise a workshop with stakeholders in relation with epilepsy guideline.

5.2. Collaboration with Interested parties and other stakeholders

- Consultation of additional experts on a Guidelines under development.
- Interactions with learned societies in the field of neurology and psychiatry.