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Consolidated 3-year rolling work plan for the CNS Working Party

Chair: Andre Elferink

Vice-Chair: Ewa Balkowiec-Iskra

Work plan period: January 2025 – December 2027 (with a first review point after one year)

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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1. Strategic goals

The Central Nervous System Working Party (CNS WP) aims at playing a role in the prevention and reduction of CNS diseases through supporting the development of new medicinal products in these fields. The following are the main strategic goals.

- Provide the requested and state-of-the-art support to the EMA Committees regarding the neurology and psychiatry fields.
- Deliver appropriate guidance documents to support and improve the development and authorisation of medicines regarding the CNS field based on the most recent scientific insights.
- Review the need for development of new guidelines/position papers in CNS field based on EMA scientific advice (SA)/protocol assistance (PA) and qualification procedures and also based on pipeline forecasts in this field.
- Raise the understanding of all aspects of CNS field and ensure transfer of experience to EU NTC network through developing appropriate training.
- Expand collaboration with learned societies in CNS field.
- Ensure that the innovative methods of outcome measurement are adequately described in guidelines in the field of CNS (including gene-therapy, artificial intelligence based methods and novel methods to measure outcome in rare diseases) to increase patient-centricity.
- Develop and expand connections and links to assessors from national agencies, academic and clinical experts specialising in the CNS field via the European Specialised Expert Community Cardiovascular Diseases (CNS ESEC).
- Maintain and expand the collaboration with international regulators.
- Build knowledge regarding new methodologies to measure and define clinical endpoints in the field (including endpoint collected in gene editing studies, artificial intelligence based methods and novel methods to measure outcome in rare diseases).

1.1. Short-term strategic goals

- Release of the draft and final guidelines and concept papers in line with the tactical goals plan.
- Provide specialised input in neurology and psychiatry fields on request of CHMP or other EMA Committees.
- Continuously review the need of publishing new guidelines in the area of neuroscience

1.2. Long-term strategic goals

2. To release the Final Guideline on clinical investigation of medicinal products for treatment of migraine

3. To release the Final Guideline on clinical investigation of medicinal products for the treatment and prevention of bipolar disorder

4. To release the Final Guideline on clinical investigation of medicinal products for the treatment of Parkinson's Disease

5. To release the Final Guideline on clinical investigation of medicinal products for the treatment of ALS

6. To release the final Guideline on clinical investigation of medicinal products for the treatment of myasthenia gravis

7. To release the final Guideline on clinical investigation of medicinal products for the treatment of retinopathies

8. Tactical goals

8.1. Guidance activities

Guideline activities will be performed by one Rapporteur supported by the Drafting Groups that report back to the CNS WP on a regular basis.

(A) Activities ongoing/to be finalised in 2025/26

Revision of existing EU Guidelines:

Action: Lead

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

Target date

- Final guideline to be released 1Q2026

Action: Lead

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

Target date • Final guideline to be released Q4 2025

Action: Lead

Guideline on clinical investigation of medicinal products for the treatment of Parkinson's Disease

Target date • Concept paper to be released Q2 2025

(B) Activities to be started in 2025

Revision of existing EU Guidelines:

Action: Lead

Guideline on clinical investigation of medicinal products for the treatment of ALS; EMA/531686/2015 Corr. 1

Target date • Concept paper to be released Q4 2025

New EU Guidelines:

Action: Lead

Guideline on clinical investigation of medicinal products for the treatment of retinopathies

Target date • Concept paper to be released Q4 2025

Action: Lead

Guideline on clinical investigation of medicinal products for the treatment of myasthenia gravis

Target date • Concept paper to be released Q4 2025

8.2. Training and workshop activities

- Contribute to assessor trainings organised by EU Network Training Centre (EU NTC): provide training on newly released guidelines
- Maintain awareness of issues arising in the CNS field (via for example discussion with stakeholders and/or review of scientific advices provided by the EMA) in order to identify the need for review and update of guidelines and development of additional guidance documents.
- Contribution to the establishment and leadership for activities of CNS European Specialised Expert Community (ESEC) in line with the mandate adopted by the CHMP.

8.3. Communication and Stakeholder activities

8.3.1. European level

- 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 CNS WP 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.

8.3.2. International level

- 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.

8.4. Multidisciplinary collaboration

NA

9. Operational goals

9.1. Pre-submission activities

- The CNS WP will provide product-related support in the CNS field upon request from the SAWP during pre-submission phase.

9.2. Evaluation and supervision activities

- The CNS WP will provide product-related support in the CNS field upon request from Committees during evaluation of medicinal products.

10. List of Abbreviations

CP – Concept Paper

CNS – Central Nervous System

CNS ESEC – Central Nervous System European Specialized Expert Community

EU NTC - EU Network Training Centre

FDA- Food and Drug Administration

IMI – Innovative Medicines Initiative

SAWP – Scientific Advice Working Party