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Transition of Simultaneous National Scientific Advice (SNSA) to 2025 following the end of SNSA pilot phase 2

Author: EU-IN Simultaneous National Scientific Advice Working Group

Since February 2020, the EU Innovation Network (EU IN) has been running a pilot project for simultaneous national scientific advice (SNSA) from national competent authorities (NCAs) to further strengthen early regulatory support for (pre)-clinical research and innovation. The concept of SNSA is to offer national scientific-regulatory advice from different NCAs at the same time and from an early stage of development onwards, thereby optimising the quality and consistency of such advice while saving time and resources for the applicant. The EU pilot on SNSA ended in Dec 2024 and the key results and learnings from the pilot were presented at the 119th Heads of Agencies (HMA) meeting along with a proposal to continue with the SNSA concept as a standardized, multi-national (consolidated) scientific-regulatory advice format offered from the European Medicines Agencies Network (EMRN) from 2025 onwards. Such standardized, consolidated advice format should meet the current and future needs from all types of innovators across Europe and would include further process optimisations in order to make the procedure more predictive, lean and efficient while safeguarding it's complementary nature to other existing advice offerings at national and EU level.

Following a positive evaluation of the results of the SNSA pilot project at the 119th HMA meeting on January 23rd 2025, the HMA has formally approved the continuation of the SNSA concept as a standardized, multi-national (consolidated) scientific-regulatory advice format from 2025 onwards, to address the gap between purely (mono)national scientific-regulatory advice procedures and the EU centralised scientific advice services offered by EMA.

In this context, the SNSA Working Group of the EU IN will continue to work in coming months on an optimised SNSA procedure and a more central coordination amongst all participating NCAs that would make the procedural timelines more predictive and the overall procedure more lean and efficient.

While awaiting the development and subsequent endorsement from HMA of the future, optimised SNSA procedure, Applicants can continue submitting new SNSA requests via snsa@fagg-afmps.be according to the currently available SNSA procedure and timelines until further notice. More news on the optimised SNSA procedure and it's new features, will be publically communicated as soon as possible in the course of 2025.

More information

- All practical information on how to submit an SNSA request is available on the following websites:
- **HMA** : https://www.hma.eu/about-hma/working-groups/eu-innovation-network-eu-in.html
- **EMA** : https://www.ema.europa.eu/en/committees/working-parties-other-groups/eu-innovation-network-eu#:~:text=The%20European%20Medicines%20Agency%20(EMA,emerging%20therapies%20and%20associated%20technologies.
- More information on SNSA can also be found at the **websites of the NCAs** participating in the SNSA procedures or via their respective innovation offices / scientific advice units:
  https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/EU-IN/2022_12_EU-IN_National_Scientific_Advice_Contacts.pdf
  https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/EU-IN/2022_12_EU-IN_National_Innovation_Offices_Contacts.pdf