



7th February 2025

Simultaneous National Scientific Advice (SNSA) -Continuation and further development during 2025

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). SNSA specifically targets scenarios where applicants may wish to seek national scientific advice from more than one national competent authority at the same time. Examples of scenarios where SNSA could be used include preparation for planned clinical trials to be performed in more than one member state (MS) or planned marketing authorization applications using the decentralised or mutual recognition procedures.

Following a positive evaluation of the results of the SNSA pilot project at the 119th HMA meeting in January 2025, the HMA has supported the continuation of the SNSA concept.

Over the coming months, the SNSA Working Group of the EU-IN will continue to work on an optimised SNSA procedure taking into account the learnings from the pilot. In the meantime, applicants can continue submitting new SNSA requests via <u>snsa@fagg-afmps.be</u> according to the currently available SNSA scope, procedure and timelines until further notice. Further details on the optimised SNSA procedure including associated guidance will be published later in 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 : <u>https://www.ema.europa.eu/en/committees/working-parties-other-groups/eu-innovation-network-</u> <u>network-</u> <u>eu#:~:text=The%20European%20Medicines%20Agency%20(EMA,emerging%20therapies%20and%20as</u> <u>sociated%20technologies</u>.

• 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: <u>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</u> <u>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</u>

• For all advice offerings with EU regulators please see ACT EU PA7 and mapping: <u>https://accelerating-clinical-trials.europa.eu/document/download/d0b4538a-3936-49a2-a43e-e7bcf09f9aea_en?filename=science-advice-medicines-human-use-eu-medicines-regulatory-network_en.pdf</u>