

# **Extension of the EU pilot project on simultaneous national scientific advice (SNSA)**

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The Head of Medicines Agencies has approved the extension of the European pilot project for simultaneous national scientific advice at its 107th meeting in February 2022. The approval followed a positive evaluation of the first results of the project since its launch in February 2020.

Since February 2020, the EU Innovation Network has been running a pilot project for simultaneous national scientific advice (SNSA) from national competent authorities (NCAs) to further strengthen early regulatory support for innovation. The concept of SNSA is to offer national scientific advice from different NCAs at an early stage of development at the same time, optimising the quality and consistency of such advice while saving time and resources for the applicant. The NCAs will initially independently review the questions raised and then interact to ensure the maximum possible alignment of their positions prior to a joint advice meeting with the applicant.

The key objectives of this pilot project (Phase 1: 2020 - 2021) are:

- to explore the needs/demands from the pharmaceutical sector (including large companies as well as local small and medium enterprises (SMEs) and academic research centres/hospitals),
- to subsequently demonstrate the potential added value of the SNSA concept to enhance the development of innovative medicinal products and therapies,
- to identify the key elements for developing a best practices model for future SNSA requests.

As a member of the EU-Innovation Network (EU-IN) and co-chair of the EU-IN's SNSA Working Group, the FAMHP has been actively involved in the pilot project handling twenty SNSA requests in pilot project phase 1 with other NCAs (such as Spain - AEMPS, The Netherlands - MEB, Germany - PEI), covering different therapeutic areas and products including COVID-19-vaccines.

Following a positive evaluation of the outcomes of pilot project phase 1 by the HMA in February 2022, the SNSA pilot project has been formally extended for two and a half years. The HMA also approved the SNSA working group's proposal to proceed to project phase 2 consisting of the following phases.

- **Phase 2a** (six months, from February till end of July 2022) will focus on the development of an optimised, common SNSA procedure between the participating NCAs as a best-practices model that could serve the future needs of different European initiatives and regulatory platforms. For this purpose, enhanced concertation and collaboration with potentially relevant working groups and scientific committees at the European Medicines Agency (EMA) is envisaged, for instance:
  - the clinical trials facilitation group (CTFG),
  - the clinical trials coordination group (CTCG),
  - the working group on accelerating clinical trials in the European Union (ACT-EU),
  - the Scientific Advice Working Party (SAWP),
  - the Coordination Group for Mutual recognition and Decentralised procedures – human (CMDh)

in order to future-proof the optimised SNSA procedure, requests submitted by applicants during this phase will still be handled according to the pilot project procedure that has been applied in pilot project phase I.

However, applicants may be allowed (if justified) to propose a third NCA as observer, to join the SNSA meeting together with the coordinating and participating NCA, following submission of a valid SNSA request and with the agreement of the three NCAs involved.

- **Phase 2b** (two years running from August 2022 until August 2024) is intended to implement and pilot the optimised, common SNSA pilot process developed in Pilot project phase 2a and which will be subject to reporting back and evaluation at HMA level.

Further information will be disseminated to all relevant FAMHP stakeholders in due time when entering this second part of pilot phase 2.

**More information**

- All practical information on [how to submit an SNSA request to the FAMHP](#) is available on the website
- HMA – [extension of SNSA Pilot Project](#)
- EMA – [more information on the SNSA pilot project](#)

