Guidance for applicants: pilot project for simultaneous national scientific advice (SNSA)

How to submit an SNSA request

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Version 2.1

Introduction

Developers of medicinal products or medical devices and other medical technologies often seek national scientific advice in order to prospectively optimise development programmes. Scientific advice can be received at a national level from national competent authorities (NCAs), or at a central level coordinated by the European Medicines Agency (EMA). Experience has shown that national advice is often requested from more than one NCA. In order to optimise resources on both sides and improve regulatory support, a new approach has been developed: in one single step national scientific and/or regulatory advice can be requested simultaneously at two NCAs. The objective of the concept is to establish a more efficient procedure based on the existing principles and structures for applicants seeking advice from different NCAs for the same questions and data package. So, the new approach is envisioned to be a complementary tool to the established regulatory/scientific national or European advice procedures without duplicating existing advice procedures.

Simultaneous national scientific advice (SNSA) focuses on innovative developments, aims to identify applicants' needs, enhance innovation and prevents gaps in early regulatory support. The pilot project aims to explore the possibilities and interest in providing such coordinated national scientific advice to developers of new medicines and therapies, including combination products of a medicine/medical device, if they have the regulatory status of a medicinal product.

Strengths of SNSA

- SNSA is a two-in-one approach: applicants get two NCA opinions within one application.
- SNSA is a structured and guided process, easy to apply.
- SNSA helps optimise human and financial resources.
- SNSA offers applicants the opportunity to discuss in an early stage (including at the very beginning of the development process) and simultaneously in a broader context and a multinational setting. This is expected to allow:
    - earlier exchange of opinions and interaction of experts from NCAs compared to sequential advice approaches;
    - early identification of divergent opinions of the NCAs;
    - potential alignment of NCAs on initially different regulatory positions and requirements, for instance NCAs will aim at providing consolidated views to the maximum extent possible even if complete harmonisation is not the main objective of this procedure;
    - early identification of critical scientific or regulatory issues that may require formal European scientific advice from the EMA.

Advantages

SNSA offers numerous advantages to both applicants and NCAs.

- An opportunity to reach alignment/clarification of NCAs on specific critical issues before an application for instance for a clinical trial, marketing authorisation or variation/line extension is submitted. This is expected to be particularly helpful considering the challenging timelines.
- A chance to enhance translational research processes in an early stage by providing structured advice based on the applicants' needs.
- Support in preparing scientific advice requests destined for the EMA complementary to support opportunities routinely provided by the EMA.

Perspectives

The concept of SNSA was conceived with the following perspectives in mind:

- creating an opportunity for discussion at EU-Innovation Network (EU-IN) level with participation of almost all European member states;
- providing the possibility to share knowledge and lessons learned from completed SNSA procedures within the European medicines regulatory network (EMRN) through discussion at the EU-IN and potentially relevant working groups and scientific committees at the EMA to enhance preparedness for upcoming innovation and to reflect on regulatory challenges;
- providing an opportunity to discuss divergent opinions and creating awareness for possible steps towards gradual convergence of identified issues;
- providing an opportunity to get to know the position and opinion of different NCA experts and to improve the exchange of knowledge and lessons learned between them, especially in relation to the expectations regarding scientific development and relevant regulatory frameworks for particularly innovative products/therapeutic concepts;
- introducing a practical tool for identifying challenges in the development of innovative technologies;
- encouraging requests for regulatory support early on in the innovation process.

Target groups

No restrictions are foreseen, all types of applicants can apply for an SNSA pilot. Special guidance will be provided for academic centres and small and medium-sized enterprises (SMEs), particularly for advice requests at an early stage of the innovation process.

NCAs participating in the voluntary SNSA pilot project

The participating NCAs at the start of the pilot are:

- AEMPS – Spain (ascina@aemps.es)
- AGES – Austria (scientificadvice@basg.at)
- AIFA – Italy (scientificadvice@aifa.gov.it)
- FAMHP – Belgium (innovationoffice@fagg-afmps.be)
- FIMEA – Finland (innovation.office@fimea.fi)
- NOMA – Norway (jan-petter.akselsen@legemiddelverket.no)
- OGYEI – Hungary (tanacsadas@ogyei.gov.hu)
- PEI – Germany (innovation@pei.de)
- SUKL – Czech Republic (innovation@sukl.cz)
- URPL – Poland (magdalena.pajewska@ema.europa.eu)

More details on the participating NCAs can be found on EMA's website.

The pilot is open to participation of other NCAs. In doing so, we hope to get as many NCAs as possible involved in order to create the highest possible amount of NCA pairs for the pilot.

Scope of the SNSA procedure

The scope of the SNSA procedure is identical to the scope of single national scientific, technical and regulatory advice procedures currently offered by NCAs.

- Questions on quality, safety and efficacy:
  - of medicinal products for human use,
  - at any stage of product development without restrictions,
  - including, but not restricted to clinical trial applications/concepts (for instance questions on trial design and statistical aspects),
  - excluding health technology assessment (HTA) and reimbursement aspects.
- Scientific advice requests related to combination products of medicine/medical device for human use may be included in the scope of the SNSA pilot if this type of products falls within the remit of the participating NCAs.
- Each SNSA will be limited to the scope and questions raised in the briefing documents.
- The pilot project will start with two voluntary NCAs for every SNSA request.
- Information on the NCAs volunteering in the pilot project will be available on the website of every participating NCA as well as on the EMA and Heads of Medicines Agencies (HMA) website.

SNSA procedure

- Applying for SNSA is possible via an informal letter of intent (LOI) to one of two selected NCAs or by an existing application form for the national scientific or regulatory advice procedure at one of two selected NCAs. The applicant indicates the two desired NCAs to provide the advice (for instance based on the list of NCAs volunteering for the SNSA pilot project) together with an alternative NCA, if possible, to which the applicant can be redirected in case one of the selected NCAs cannot participate in the SNSA. The proposed NCAs need to accept this request for advice. In case one NCA is not able to join the SNSA, the applicant can continue the SNSA procedure with the alternative second NCA, turn the request into a standard national scientific advice request (for just one NCA) or withdraw the request.
- The procedure will be communicated to the SNSA applicant at the beginning of the meeting request.
- By mutual agreement of the participating NCAs, one NCA will take the lead in the procedure as coordinating NCA and will coordinate the advice procedure as the main contact point for the applicant as well as the second NCA involved in the procedure.
- The timeline of the SNSA will also be mutually agreed on by both NCAs. This timeline will be in line with the applicant's preferred dates as far as possible.
- The briefing documents and list of questions need to be sent to both NCAs separately, considering special requirements with regard to submission timelines, template, scope, content and extent of the documents of each NCA. Assistance is provided by the coordinating NCA.
- Formal validation of the briefing documents with regard to for example, scope and focus of questions and rationales (positions) will also be within the remit of each NCA. In case of any queries (for instance validation questions raised by one of the NCAs towards the applicant), the coordinating NCA will get in touch with the applicant.
- Applicants are not allowed to add new questions or change questions or data in the course of the SNSA procedure.
- The SNSA will be arranged as a face-to-face meeting providing room for open discussion between the coordinating NCA – taking the lead in the set up and management of the formal SA meeting – and the applicant, with the other NCA joining in via tele- or videoconference. Both NCAs will be represented by their respective national experts, just as is customary in national procedures.
- Meeting minutes will be drafted by the applicant, using the common template provided, and will be sent to each NCA for review and comments. The final document will reflect the formal SNSA opinions from both NCAs based on their mutual agreement.
- The payment of the fees will be based on the cost regulations of each NCA involved and will be in accordance with the established corresponding payment procedure, both to be announced to the applicant when applying for the SNSA.

- After completion of the SNSA, applicants will be asked for their feedback in a short questionnaire.

Any requests for clarification from applicants (for instance on the scientific regulatory opinions provided in the context of the formal SNSA) might be accepted and handled in agreement between both NCAs and in compliance with their respective procedures whereas new questions from the applicant would be dealt with in a follow-up advice request.

Implementation and participation

Implementation of the SNSA pilot project started on 1 February 2020 and was initially extended till end of 2021 (= project phase 1). As the pilot is the basis for the development of the best practices approach and the introduction of this concept as a new advice format, the approach has so far been supported by a broad demand.

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

- **Phase 2a** (six months, from February until 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, especially in view of the new Clinical Trial regulation (CTR) and enhanced clinical trial support that needs to be established in the European Union following the COVID-19-pandemic. SNSA 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.