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

How to submit an SNSA request

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Introduction

Developers of medicinal products or medical devices and other 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 from 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. Thus, 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, it wants to identify applicants' needs, enhance innovation and avoid gaps in early regulatory support. The pilot project aims at exploring the opportunities and interest in providing such coordinated national scientific advice to developers of new medicines and therapies.

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 optimising human and financial resources.
- SNSA offers an opportunity to applicants to discuss early on (including at the very beginning of the development process) and simultaneously in a broader context and a multi-national 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, i.e. 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 EU scientific advice from EMA.

Advantages

SNSA offers multiple advantages to both applicants and NCAs.

- An opportunity to reach alignment/clarification of NCAs on specific critical issues before an application for e.g. 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 EMA complementary to support opportunities routinely provided by EMA.

Perspectives

The concept of SNSA was thought up with following perspectives in mind:

- creating an opportunity for discussion at EU-Innovation Network (EU-IN) level with participation of nearly all EU member states,
- offering the possibility to share knowledge and lessons learned from completed SNSA procedures within the European regulatory network through discussion at the EU-IN and potentially relevant working groups and scientific committees at 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,

- giving a chance 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,
- putting in place 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 academia and small and medium-sized enterprises (SMEs), especially in regard to requests for advice early on in the innovation process.

NCAs participating in the voluntary SNSA pilot project

The participating NCAs at the start of the pilot are:

AEMPS - Spain

AGES - Austria

AIFA - Italy

FAMHP - Belgium

FIMEA - Finland

NOMA - Norway

OGYEI - Hungary

PEI - Germany

SUKL - Czechia

URPL - Poland

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

The pilot is open to more NCAs' participation. 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 defined for the SNSA procedure is identical to that of single national scientific 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 (e.g. questions on study design and statistical aspects),
  - excluding HTA and reimbursement aspects,
- scientific advice requests related to medicine-medical device-combination products 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 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

- Requesting SNSA is possible by 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 for supplying the advice (i.e. based on the list of NCAs volunteering for the SNSA pilot project). The proposed NCAs need to accept this request for advice. In case one NCA is not able to join the SNSA, the applicant can suggest an alternative 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 (e.g. 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 telephone or video conference. 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.
- 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.

Potential requests for clarification from applicants (e.g. 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 starts 1 February 2020. As the pilot is the basis for developing the best practice approach and establishing this concept as a new advice format, widespread demand would support the approach.

A first evaluation of the SNSA pilot project at EU-IN and EMA/HMA level is foreseen approximately at the end of 2020. This evaluation will analyse the outcome and experiences coming from completed SNSA requests both from NCA's and applicants' perspective.

If the pilot shows there is sufficient demand for the SNSA, the concept is manageable and proves to be effective, providing added value for both applicants and regulators, further efforts will be initiated to optimise the current SNSA pilot process and SNSA will be extended in a next project phase with more than two NCAs participating in the advice process.