Guidance for applicants on a pilot for Simultaneous National Scientific Advice (SNSA)

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

The focus of the SNSA is on innovative developments to identify the needs of the applicants to enhance innovation and avoid gaps in early regulatory support. The pilot aims at exploring the opportunities and interest in providing such coordinated national scientific advice particularly to developers of new medicines and therapies.

Strengths of the SNSA:

- two in one approach = get two NCA opinions within one application
- structured and guided process - easy to apply
- optimization of human and financial resources
- opportunity for the applicants to discuss *earlier* (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 harmonization 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

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Advantages:

- opportunity to reach alignment/clarification of NCAs on specific critical issues before an application for e.g. a clinical trial, marketing authorization or variation/line extention is submitted which is expected to be particularly helpful considering the challenging timelines
- chance to enhance translational research processes by providing structured early advice based on the applicants' needs
- support for preparation of Scientific Advice requests at EMA complementary to the support opportunities routinely provided by EMA

Perspectives:

- opportunity for discussion at level of the EU-Innovation Network (EU-IN) with participation of nearly all EU-Member States
- possibility to share knowledge and experience from completed SNSA procedures within the European regulatory network through early discussion at the EU-IN and potentially relevant working groups and scientific committees of EMA to enhance preparedness for incoming innovation and reflect regulatory challenges
- opportunity to discuss divergent opinions and to create awareness for possible steps towards gradual convergence of identified issues
- chance to get to know the position and opinion of different NCA-experts, improve the exchange of knowledge and experience among them, especially in relation to the expectations regarding scientific development and relevant regulatory framework for especially innovative products/therapeutic concepts
- practical tool to identify challenges in the development of innovative technologies
- encourage the demand for early regulatory support

Target groups, NCAs, scope and procedure:

<u>Target groups:</u>

- no restrictions are foreseen, all types of applicants can apply for an SNSA pilot
- special guidance provided for academia and SMEs, especially with requests for early advice

Participating NCAs at the start of the pilot:

AGES – Austria (scientificadvice@basg.at)

FAMHP – Belgium (innovationoffice@fagg-afmps.be)

SUKL – Czechia (innovation@sukl.cz)

FIMEA – Finland (innovation.office@fimea.fi)

PEI – Germany (innovation@pei.de)

OGYEI – Hungary (tanacsadas@ogyei.gov.hu)

AIFA – Italy (scientificadvice@aifa.gov.it)

NOMA – Norway (jan-petter.akselsen@legemiddelverket.no)

URPL – Poland (magdalena.pajewska@ema.europa.eu)

AEMPS – Spain (ascina@aemps.es)

The pilot will be kept open to participation of more NCAs to get as many NCAs involved as possible to create as many NCA-pairs for the pilot as possible

For more details please click on https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

Scope:

Identical to 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 drug-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 each SNSA request.
- Information of the NCAs volunteering the pilot will be available at the website of each participating NCA as well as at the EMA and HMA-website.

Procedure:

Application for each SNSA is possible by an informal LOI (letter of intent) to only one of the two selected NCAs or by using an existing application form for the national scientific or regulatory advice procedure at one of the two selected NCAs. Based on the list of volunteering NCAs, the applicant proposes in one step the two NCAs he prefers to apply for advice together with an alternative NCA if possible, to which he can be redirected in case one of the selected NCAs cannot participate in the SNSA. The NCAs proposed need to accept the 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, change the procedure to a standard national scientific advice request or withdraw the whole application.

- The procedure will be communicated to the applicant of the SNSA at the beginning of the meeting request.
- By mutual agreement of the participating NCAs, one NCA will take over the lead of the procedure as the coordinating agency and coordinate the advice procedure as the main contact point with the applicant and the joining NCA.
- The timeline of the SNSA will also be mutually agreed on by both NCAs, respecting the preferred dates of the applicant 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.
- The 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.
- The applicant is 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 the respective national experts equal to the national procedures.
- The meeting minutes will be drafted by the applicant based on the common template provided and sent to each NCA for review and comments. The final document will reflect the formal SNSA opinions from both NCAs based on mutual agreement between them.
- The payment of the fees will be based on the cost regulations of each NCA involved and be in accordance with the corresponding payment procedure established, both to be announced to the applicant when applying for the SNSA.
- After completion of the SNSA the applicants will be asked for their feedback based on a short questionnaire.

- Potential requests for clarification from the applicant (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 pilot project is starting on **February 1st, 2020**.

As the pilot is the basis for the development of the best practice approach and the establishment of this concept as a new advice format, a widespread demand would support the approach.

A first evaluation of the SNSA pilot project is foreseen at the level of the EU IN and EMA/HMA approximately at the end of 2020 in order analyze the outcome and experiences gained from the completed SNSA requests both from NCA's and Applicant's perspective.

If the pilot shows that 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 optimize the current SNSA pilot process and the SNSA will be widened in a next project phase to have more than two NCAs participating in the advice process.