Simultaneous national scientific advice (SNSA) pilot project: launch of phase 2

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The EU Innovation Network (EU IN) has launched phase 2 of the simultaneous national scientific advice (SNSA) pilot project. SNSA is intended to be used in situations where an applicant wishes to obtain national scientific advice from more than one national competent authority (NCA) at the same time. The format is designed to enhance the quality and consistency of such advice. Following endorsement by the Heads of Medicines Agencies (HMA), phase 2 of the SNSA pilot project will run for a two-year period until the end of 2024. Phase 2 incorporates an optimised procedure to maximise the benefits for both applicants and competent authorities.

In conjunction with the Accelerating Clinical Trials in the EU initiative (ACT EU), this phase of the SNSA pilot project will have a specific focus on scientific advice to facilitate clinical trials (CT) within Europe. It will facilitate sponsors/developers to obtain clinical trial-related national scientific advice from NCAs in member states (MS) where they intend to perform clinical trials. The experience gained during the SNSA pilot project will be used to further develop the process and advice on clinical trials under the ACT EU Priority Action 7 (ACT EU PA7). The following are examples of scenarios for which developers can apply for SNSA.

- To prepare for clinical trial (CT) applications to be performed in more than one MS. If the involved NCAs agree during the SNSA that the questions raised would benefit from discussions at the Clinical Trial Coordination Group (CTCG) level, it is also possible to obtain feedback from CTCG-coordinated clinical trial experts as part of the SNSA procedure.
- Prior to applying for funding grants to support non-commercial clinical trials (academic researchers).
- To inform the early-stage development of innovative products for which clinical trials are planned (e.g. phase I/II clinical trials) especially where there is limited existing regulatory guidance. EMA scientific advice should continue to be used for scientific advice related to the suitability of the proposed clinical development to support a centralized marketing authorisation application.
- Prior to clinical trials intended to facilitate repurposing of authorised medicinal products, e.g. to support new innovative therapeutic indications.

Phase 2 of the SNSA pilot project builds on the success of the first phase of the pilot, it optimises the procedure, while maintaining the key principles associated with SNSA. The pilot project is open to applicants from different backgrounds including large pharmaceutical companies, while strongly encouraging small and medium enterprises (SMEs) and particularly inviting academic research centres and hospitals to join. Within each SNSA procedure, each participating NCA will prepare and discuss their positions on the questions raised by the applicant in order to maximise alignment prior to a joint advice meeting with the applicant. If divergent positions remain, they will be explained to the applicant in the joint advice meeting and will subsequently be summarised in consolidated meeting minutes in order to facilitate further consideration and appropriate follow-up upon agreement of the applicant.

The optimised SNSA pilot project process will continue to complement and provide a bridge between purely national scientific advice and centralised European scientific advice procedures from the European Medicines Agency (EMA) as well as support the aims of the ACT-EU initiative and the CTCG.

How to apply for SNSA?
Guidance on how to prepare and submit a formal SNSA application and relevant templates are listed below.

- Guidance for applicants
- Guidance on SNSA briefing book format and content
- List of participating NCAs and contact information
- Application form

For any further information, please contact sta-wta@fagg-afmps.be or SNSA@pei.de.

Additional Information

The key features of the optimised SNSA procedure include the following:

- An increased number of NCAs willing to participate in SNSA procedures.
- A common application form, briefing book template and a single point of contact (email to SNSA@pei.de) to reduce the administrative burden on applicants.
- The Paul-Ehrlich-Institut (PEI) will liaise with the leading MS who will act as the main contact point for the applicant during the procedure.
- A predictable timetable will be agreed prior to the start of each procedure.
- Each SNSA will involve two participating NCAs with the possibility of a third NCA joining as an observer. If sufficiently justified by the applicant, participation of a CTCG representative as observer in the SNSA meeting can also be requested. In justified cases, e.g. where the request relates to a clinical trial to be performed in more than two MS's, the involvement of additional MS's in a single SNSA procedure will be considered subject to the agreement of the NCAs.

The following principles will continue to apply.

- All types of applicants can apply for an SNSA pilot project. Pre-application guidance can be requested via the single point of contact for academia and SMEs to assist them in preparing their scientific advice request.
- Participation of an NCA in any individual SNSA procedure is on a voluntary opt-in basis.
- The scope of SNSA includes regulatory or scientific questions related to quality, safety and efficacy of medicinal products. Questions can relate to products under development as well as authorised products.
- The advice given will be limited to the scope of the questions raised by the applicant in the briefing document.
- SNSA is an opportunity for the applicants to discuss their queries with each of the NCAs involved in the procedure in a joint meeting with the possibility for the NCAs to raise questions related to clinical trials with the CTCG if considered appropriate.
- The outcome of each SNSA procedure is clearly documented and reflects the position of each of the involved NCAs.
- The fees for SNSA are based on the national scientific advice fees in each of the participating NCAs and should be paid directly to each participating NCA in the normal manner. There is no fee for the involvement of an NCA as an observer.
- Queries related to Health Technology Assessment (HTA) and reimbursement are currently excluded.

Practical information on how to submit an SNSA application is also available on the following websites:

- Guidance documents and other information on the FAMHP website.
- Other NCA's participating in the SNSA pilot project.
- HMA website.
- EMA website.