Launch of phase 2 of the Simultaneous National Scientific Advice pilot

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

In conjunction with the ACT-EU initiative, this phase of the SNSA pilot 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 National Competent Authorities (NCA) in Member States (MS) where they intend to perform clinical trials. The experience gained during the SNSA pilot will be used to further develop the process and the provision of clinical trial-related advice as part of ACT EU Priority Action 7 (ACT EU PA7). The following are examples of scenarios where developers may choose to seek SNSA:

- In preparation for clinical trials (CT) applications to be performed in more than one MS. Where during the SNSA the involved NCAs agree that the questions raised would benefit from discussions at the Clinical Trial Coordination Group (CTCG) level, it is also possible to obtain CTCG-coordinated clinical trial expert feedback 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 builds on the success of the first phase of the pilot, it optimizes the procedure, while maintaining the key principles associated with SNSA. The pilot is open to applicants from different backgrounds including large pharmaceutical companies, while strongly encouraging SMEs and especially 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 with a view to maximising alignment prior to a joint advice meeting with the applicant. Where divergent positions remain, these will be explained to the applicant in the joint advice meeting and subsequently be summarised in consolidated meeting minutes with a view to facilitating further consideration and appropriate follow-up upon agreement of the applicant.

The optimized pilot SNSA process will continue to complement and provide a bridge between purely national scientific advice and centralised European scientific advice procedures from EMA as well as supporting 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 request and relevant templates are listed below:

- Guidance to applicants
- Guidance on SNSA briefing book format and content
- List of participating NCA's and contact info
- Application form

For any further information, please contact SNSA@pei.de.

Additional Information

Key features of the optimized SNSA procedure include:

- An increased number of NCAs willing to participate in SNSA procedures
- A common application form, briefing book template and a single-entry point (email to SNSA@pei.de) to reduce the administrative burden for applicants.
  PEI will liaise with the leading MS who will act as the main contact point for the applicant during the procedure.
- A predictable timetable to 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. When 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 2 MSs, the involvement of additional MSs in a single SNSA procedure will be considered subject to the agreement of the NCAs.

The following principles continue to apply:

- All types of applicants can apply for an SNSA pilot. Pre-submission guidance can be requested via the single-entry point 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 relating to the involvement of an NCA as an observer.
- Queries related to HTA and reimbursement are currently excluded.

Practical information on how to submit an SNSA request is also available on the websites of the NCA's participating in the SNSA pilots (cfr. List of participating NCA's and contact info) and on the HMA and EMA websites:

- HMA: Heads of Medicines Agencies: EU-Innovation Network (EU-IN) (hma.eu)
- EMA: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/accelerating-clinical-trials-eu-act-eu