4 June 2024
EMA/255759/2024

Feedback Questionnaire for Applicants on the Simultaneous National Scientific Advice (SNSA) pilot procedure

|  |
| --- |
| **INTRODUCTION****This questionnaire aims to capture the Applicant’s view on the qualitative aspects of the SNSA pilots handled by the National Competent Authorities (NCAs) involved in this project promoted by the EU Innovation Network (EU-IN). The qualitative feedback from the Applicants should allow the NCAs and the EU-IN to improve and optimize the SNSA concept to respond effectively to the Applicants’ specific needs.****The questionnaire includes general and specific questions to gather the Applicant’s experience from the SNSA pilot procedure offered by the NCAs participating voluntarily in this pilot project.****Please fill out one questionnaire per SNSA request and send it back to the lead NCA who coordinated your SNSA procedure as well as to the SNSA coordination unit via :** **snsa@fagg-afmps.be****Data from feedback questionnaires will be subject to confidential treatment.****Please send the completed document by e-mail within maximum one month after receipt.** |

**USER INSTRUCTIONS**

**Please answer each question electronically:**

**- by clicking in the appropriate box,**

**and/or**

**- by filling the empty boxes with free text answers**

**and/or**

**- by selecting in the continuous scale attached to each question/statement your level of agreement within the range from 1 “strongly disagree” to 5 “strongly agree”**

**1 strongly disagree**

**2 disagree**

**3 neither agree nor disagree**

**4 agree**

**5 strongly agree**

**For those questions/statements that would NOT apply to your SNSA request , please leave the answer boxes open.**

**PART A: DETAILS OF THE SNSA REQUEST**

**Procedure no: SNSA/H/M/xxxx/NRorFU/n/date submission:**

Please tick the corresponding box(es) and add any other participating or observer NCAs (i.e. in case more than 3 NCA’s were involved in your SNSA procedure.

**Type of Scientific Advice request**

 NCA1 (= lead NCA)

 Name of NCA1: \_\_\_\_\_\_\_\_\_\_\_

 Member state: \_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Initial SNSA request  [ ]  Follow-up SA or SNSA request

 Procedure no. previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 NCA of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 Meeting date of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 NCA2 (= participating NCA)

 Name of NCA2: \_\_\_\_\_\_\_\_\_\_

 Member state: \_\_\_\_\_\_\_\_\_\_\_

 [ ]  Initial SA request [ ]  Follow-up SA or SNSA request

 Procedure no. previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 NCA of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 Meeting date of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

NCA3 (= observer NCA)

 Name of NCA3: \_\_\_\_\_\_\_\_\_\_

 Member state: \_\_\_\_\_\_\_\_\_\_\_

 [ ]  Initial SA request [ ]  Follow-up SA or SNSA request

 Procedure no. previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 NCA of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 Meeting date of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

**If Applicable:**

1. NCA replaced by NCA 1, 2 or 3 (= NCA initially proposed by the Applicant, who declined the participation to the pilot SNSA procedure).

 Name of NCA replaced: \_\_\_\_\_\_\_\_\_\_\_

 Member state: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Initial SA request [ ]  Follow-up SA or SNSA request

 Procedure no. previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 NCA of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

 Meeting date of previous (SN)SA : \_\_\_\_\_\_\_\_\_\_\_

1. Reason for re-scheduling:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Applicant**

 [ ]  Academic research centre / academic hospital

 [ ]  Other non-profit / non-commercial organisation

 (please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 [ ]  SME (based on EC definition)

 [ ]  Pharmaceutical company (non-SME)

 [ ]  Other (please specify in the “additional comments” section below)

Additional comments

**Product**

 [ ]  Chemical

 [ ]  Bio(techno)logical

 [ ]  ATMP

 [ ]  Combined Medical Device Products (including drug-device combinations)

 [ ]  Digital health

 [ ]  Platform technology (please specify in the “additional comments” section below)

 [ ]  Other (please specify in the “additional comments” section below)

Additional comments

**Area of disease**

 [ ]  Cancer

 [ ]  HIV/AIDS

 [ ]  Diabetes

 [ ]  Neurodegenerative disorder

 [ ]  Viral disease

 [ ]  Autoimmune disease/dysfunction

 [ ]  Cardiovascular disease

 [ ]  COVID-19

 [ ]  Other (please specify in the “additional comments” section below)

Additional comments

**Development stage at which SNSA is requested**

 [ ]  Technology (e.g. 3D-(Bio)printing)

 [ ]  Quality development

 [ ]  Non-clinical stage

 [ ]  Starting clinical development: ≤ Phase 1

 [ ]  ≤ Phase 2

 [ ]  ≤ Phase 3 / MAA stage

 [ ]  Post-Marketing stage

 [ ]  Not applicable (e.g. in case of non-product related advice requests)

**Area(s) of advice (possible to tick more boxes)**

[ ]  Technology

[ ]  Quality [ ]  Non-clinical [ ]  Clinical

[ ]  Regulatory - Procedural [ ]  Other (please specify in the “additional comments”

 section below)

Additional comments

**PART B: GENERAL QUESTIONS WITH REGARD TO THE PRODUCT DEVELOPMENT**

1. **A. The current orientation/scientific advice will assist in the development of the product/technology.**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

**B. If yes, please summarise the positive impact of the SNSA on your product development, e.g. faster project timing, broader scope of regulatory requirements, improved planning consistency.**

1. **As a result of this orientation/scientific advice, a clearer understanding of the regulatory requirements relating to the present product/technology has been obtained.**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

1. **Subsequent to the SNSA there was need for a clarification request**

[ ]  Yes [ ]  No

Please specify the issue:

1. **A. The orientation/scientific advice is expected to result in changes to the development plan for the innovative product/technology.**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

**B. If yes, please summarise the likely changes (e.g. additional testing/studies to be performed).**

1. **A. Have you previously obtained orientation/scientific advice relating to this product/technology from any other competent authority? (e.g. innovation office meeting / formal scientific advice from NCAs or EMA)**

 [ ]  NO

 [ ]  YES, as a standard National Scientific Advice. Please state the name(s) of the

 NCAs and related procedure number(s)

[ ]  YES, as a Simultaneous National Scientific Advice. Please state the names of

 the NCAs and related SNSA procedure number(s).

 [ ]  YES, Innovation/Orientation Meeting or Pre-Advice. Please state the name of the
 NCAs

[ ]  YES, EMA - Innovation Task Force. If applicable, please state the NCA(s) and MS that participated

[ ]  YES, EMA – SAWP (please mention the related SAWP procedure number(s))

[ ]  YES, with any other authority(ies). Please state the name of the authority(ies)

**B. If answered yes in Question 5A, is the orientation/scientific advice received in the SNSA pilot considered to be consistent with orientation/advice previously received?**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

(please specify issues of (in)consistency in the “additional comments” section below)

Additional comments

Consistencies:

Inconsistencies:

1. **The SNSA is more appropriate to answer the questions raised in the advice than in separate standard national Scientific Advice procedures**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

Additional comments/further details:

1. **Do you plan to seek further formal advice(s)/informal interaction(s) with the EMA (SAWP, PRIME, ITF) or other EU regulatory group (CTFG, MDCG, EC)?**

 [ ]  NO

 [ ]  YES

If yes, please specify which: \_\_\_\_\_\_\_\_\_\_\_\_

If yes, please specify when: \_\_\_\_\_\_\_\_\_\_\_\_

1. **General remarks/comments**

**PART C: SPECIFIC QUESTIONS WITH REGARD TO THE SNSA CONCEPT**

1. **The SNSA has generally clear advantages compared to standard national Scientific Advice procedures**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

Additional comments/further details:

1. **The format of the SNSA procedure is more appropriate to address the specific questions you raised than standard national Scientific Advice procedures**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

Additional comments/further details:

1. **The exchange of expertise from the NCAs involved in the SNSA procedure is appropriate and provides efficient support to product development compared to the standard national Scientific Advice procedures**

[ ]  1 Strongly disagree [ ]  2 [ ]  3 [ ]  4 [ ]  5 Strongly agree

Additional comments/further details:

1. **What are the top 3 most important advantages / added value of the SNSA procedure compared to standard national Scientific Advice procedures?**

 [ ]  Quality of the formally issued advice

 [ ]  Possibility to achieve consolidated views from both NCAs

 [ ]  Early identification of potentially divergent opinions

 [ ]  Possibility to avoid significant differences in opinions

 [ ]  Early identification of major challenges / critical issues requiring follow-up discussions
 at EU level (e.g. SAWP advice)

Others: \_\_\_\_\_\_\_\_\_\_\_\_

1. **In which specific settings/context do you see the biggest potential added value of the SNSA concept in relation to your needs: e.g. in early development stage vs late stage development setting, for discussion of specific scientific/regulatory issues related to future MAA/variations that may only need discussion with e.g. (Co)Rapp/RMS, etc. ?**
2. **Do you see any potential disadvantages or potential risks related to the SNSA concept (vs the standard national Scientific Advice) that might have an impact on the formally issued advice or would discourage you from using the SNSA procedure in the future? Please elaborate on your top 3 perceived potential disadvantages:**
3. **To which extent more convergence in opinions could be observed between the two NCAs involved in the SNSA request or which critical issues could be identified that require further follow-up scientific advice/guidance and/or follow-up discussions at EU-IN / EMA level? In order to quantify the level of convergence in opinions, please fill out the table below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Opinion | Identified major challenges / critical issues | Identified major challenges / critical issues requiring follow-up discussions at EU level beyond the SNSA dossier. |
|  | Convergent | Harmonized1 | Divergent2 | No | Yes2  | No | Yes2 |
| Technology development |  |  |  |  |  |  |  |
| Quality development |  |  |  |  |  |  |  |
| Non-clinical development |  |  |  |  |  |  |  |
| Clinical development |  |  |  |  |  |  |  |
| Study design |  |  |  |  |  |  |  |
| Regulatory - Technical  |  |  |  |  |  |  |  |
| Other: |  |  |  |  |  |  |  |

1 (i.e. initial divergent opinion become harmonized after interaction between NCAs in the context of the SNSA procedure)

2 If yes,

Please indicate the specific issue(s), e.g. discussion of endpoint, OS or topics for new or modified guidance in the “additional comments” section below

Additional comments/further details:

1. **Any general comments or other suggestions to improve the pilot SNSA concept?**
2. **What are your next steps with regard to product development and within which estimated timeframe?**

**Would you agree to be contacted by the EU-IN to discuss whether/how the SNSA recommendations have been implemented in your development plan? Your feedback will contribute to advance regulatory science.**

 Agree ☐

 Disagree ☐

**Please indicate the details of your contact point for follow-up:**

**Name :**

**e-Mail address :**

**Telephone number :**