4 June 2024
EMA/255386/2024

Application form to request Simultaneous National Scientific Advice (SNSA) or a pre-CTA Advice

Please fill out all the predefined data fields and sections of this form as accurately and completely as possible. When completing the form, it may be possible that for some sections multiple tick boxes need to be selected.

Please send you application for SNSA or Pre-CTA Advice to: SNSA@fagg-afmps.be.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Please indicate your advice request by ticking the box:

|  |  |
| --- | --- |
| [ ] [ ]  | **SNSA**: please proceed with the application form below |
| [ ] [ ]  | **Pre-CTA Advice**: please use the section at the end of this form. |

 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Applicant / Company |

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Applicant type: | [ ] Commercial (non-SME)[ ] SME[ ] Non-for profit organisation (non-academic)[ ] Academia |

 |
| Contact Person Detail |

|  |  |
| --- | --- |
| Name: |  |
| Direct tel: |  |
| Email: |  |

 |
| Alternate contact person details (if applicable)/ financial contact person (if applicable or different from procedure contact person) |

|  |  |
| --- | --- |
| Name: |  |
| Direct tel: |  |

[ ] Consultant on behalf of Applicant [ ]  Letter of authorisation from applicant[ ] Other |
| Comments |  |

|  |  |
| --- | --- |
| Drug substance name |  |
| Drug product name/trade name (if available)  |   |
| Description of the request (incl. dosage form, administration route) |  |
| Intended use | [ ] Human use [ ] Veterinary use [ ] Other, please specify:   |
| Type of drug product | [ ] Chemical[ ] Generic [ ] Antisense  [ ] NCE  [ ] Other[ ] Radiopharmaceutical[ ] Bio(techno)logical

|  |  |
| --- | --- |
| [ ] Blood derived  | [ ] Vaccine |
|  [ ] Enzyme  | [ ] Other biologicals |
|  [ ] Nucleic Acid-based DNA vaccine | [ ] Radiobio(techno)logical |
|  [ ] Nucleic Acid-based oncolytic virus | [ ] Recombinant Cytokine |
|  [ ] Recombinant hormone | [ ] Recombinant vaccine |
|  [ ] Recombinant monoclonal antibody | [ ] Similar Biological |

 |
|  | [ ] Biological ATMP [ ] Somatic-cell therapy medicinal product

|  |  |
| --- | --- |
|  [ ] Autologous | [ ] Allogeneic |
|  [ ] Xenogeneic | [ ] Transfected cells |

 |
|  |  [ ] Tissue-engineered medicinal product

|  |  |
| --- | --- |
|  [ ] Autologous | [ ] Allogeneic[ ] Xenogeneic |

 |
|  | [ ] Gene therapy medicinal product

|  |  |
| --- | --- |
|  [ ] ex vivo products | [ ] in vivo products |

 [ ] Combined ATMP |
|  | [ ] GMO |
|  | [ ] Herbal product |
|  | [ ] Homeopathic product[ ] Therapeutic, scientific, or technical innovation[ ] Borderline Qualification & Classification |
|  | [ ] Combination Product (e.g. Medicinal Product pursuant to pharmaceutical legislation + Medical Device or IVD) |
| Comments |  |

|  |  |
| --- | --- |
| Intended indication |  |
| Therapeutic field | Choose an item from the list (click here) |
| ATC code  |   |
| Comments |  |
| Type of request |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  | New SNSA request | [ ]  | Follow-up SNSA request |

 |

 |
| Timing of request |

|  |  |
| --- | --- |
| [ ]   | Pre-grant (prior to applying for funding grants)  |
| [ ]  | MP development / Manufacturing process |
| [ ] [ ]  | Non-clinical developmentExploratory Phase (phase 0) |
| [ ]  | Clinical development

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | phase 1 | [ ]  | phase 2 | [ ]  | phase 3 |

 |
| [ ]  | Pre (MA)submission ((pivotal) phase 3) |
| [ ]  | Post (MA) (phase 4) |
| [ ]  | Development Program |
| [ ]  | Other:  |

 |
| Area of advice |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  | Quality | (Paediatric only request: | [ ]  | ) |
| [ ]  | Non-clinical (3R) | (Paediatric only request: | [ ]  | ) |
| [ ]  | Clinical | (Paediatric only request: | [ ]  | ) |

 [ ] Pharmacokinetics [ ] Statistics [ ] Safety/Efficacy

|  |  |
| --- | --- |
| [ ]  | Significant benefit (Orphan Drug) |
| [ ]  | Pharmacovigilance plans (pre-/post marketing) or risk-management plans |
| [ ]  | Early market authorisation/access |
| [ ]  | Unmet medical need |
| [ ]  | Clinical Trial Design/Methodology |
| [ ]  | Regulatory aspects |
| [ ]  | Switch Rx to OTC status |
| [ ]  | Benefit-Risk |
| [ ]   | Real World Evidence (RWE) |
| [ ]  | Repurposing of authorised medicinal products |
| [ ]  | Other:  |

 |
| Requested NCAs | NCA 1 (Lead NCA[[1]](#footnote-3)): NCA 2 (participating NCA): NCA 3 (participating NCA):Additional NCA as observer[[2]](#footnote-4):Justification for observer request:Additional participating NCAs in justified cases[[3]](#footnote-5): Alternative NCA(s) to replace aforementioned NCAs:Alternatively:[ ]  Please follow the list of Member States (MSs) indicated in the clinical trials section below in the order given.Participation of a CTCG representative [[4]](#footnote-6)[ ]  yesJustification:Participation of an Ethics Committee (EC) representative4[ ]  yesJustification:Suggested Member State/RMS:  |
| Please briefly outline the scope of the request for SNSA |  |
| Preferred meeting dates (minimum 3 options, in different weeks) | Preferred dates for meetings should be indicated at least 2 months before the meeting, unless in justified cases:Justification: |
| Ethics committee(s)  |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ]  | PlannedMember State(s): |

 |
| Previous advices received\*/applied for/planned\*please provide copy of advice report |

|  |  |
| --- | --- |
| Please specify: | *Regulatory body, e.g. NCAs, EMA/FDA etc./EMA working groups or EU committees, e.g. SAWP, ITF, ETF, CTCG:*  |
| Date: |  |
| Please specify: | *Regulatory body, e.g. NCAs, EMA/ FDA etc./EMA working groups or EU committees, e.g. SAWP, ITF, ETF, CTCG:* |
| Date: |  |
| Please specify: | *Regulatory body, e.g. NCAs. EMA/FDA etc.)/EMA working groups or EU committees, e.g. SAWP, ITF, ETF, CTCG:* |
| Date: |  |

 |
| Comments |  |
| Clinical trials (/with the drug product; in which the applicant for this SNSA request acts as sponsor or applicant and which are related to this SNSA request |

|  |  |
| --- | --- |
| [ ]  | No |
| [ ]  | Yes (on-going or applied for) |
|  | CTA-procedure no. – if available |  |
| [ ]  | Planned |  |
|  | Member States: |  |
|  | Reference Member State (RMS): |  |

 |
| Comments |  |
| Manufacturing license  |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ]  | PlannedMember State(s): |

 |
| Comments |  |
| ATMP classification procedure |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ]  | PlannedDate: |

 |
| Comments |  |
| ATMP certification procedure |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ]  | PlannedDate:  |

 |
| Comments |  |
| Orphan status  |

|  |  |
| --- | --- |
| [ ]  | Rare disease |
| [ ]  | Orphan designation received/applied for/planned |
|  |

 |
| Comments |  |
| Paediatric statusDate: |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| [ ]  | PUMA |  |  |  |  |
| [ ]  | PIP | [ ]  | Submitted  | [ ]  | Planned  |
| [ ]  | Waiver | [ ]  Deferral |  |
| [ ]  | Submitted  | [ ]  | Planned  |

 |
| Comments |  |
| PRIME designation |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ]  | PlannedDate:  |

 |
| Marketing Authorisation not yet granted. | MA Application planned date: Route of MA planned.

|  |  |
| --- | --- |
| [ ]  | National Procedure |
| [ ]  | MRP/Decentralised Procedure |
| [ ]  | Centralised Procedure (according to Reg. (EC) No 726/2004) |

 |
| Marketing Authorisation (MA) already granted.Please provide copies of assessment reports | Date of MA granting: Route of MA

|  |  |
| --- | --- |
| [ ]  | National Procedure |
| [ ]  | MRP/Decentralised Procedure |
| [ ]  | Centralised Procedure (according to Reg. (EC) No 726/2004) |

Specify in which indication:  |
| Particular Marketing Authorisation request | Authorisation granted: [ ]  Yes – date:  [ ]  No – application planned date: Type: [ ]  Conditional MA [ ]  MA under exceptional circumstances [ ]  Accelerated assessment [ ]  WHO Art. 58 prequalification |
| Comments |  |
| Data sharing | In case of issues to be discussed at EMA/HMA working groups, e.g. CTCG [ ]  agree[[5]](#footnote-7) [ ]  disagree |

**NOTE**:

The application for the SNSA includes the declaration of consent to the involved NCA’s to store the data indicated for the evaluation of the SNSA pilot.

The application for the SNSA includes acceptance of fees to be paid directly to each participating NCA based on the national regulations for scientific advice fees or any applicable national fee reductions.

**IMPORTANT!**

Please enclose additional information on the scope of the advice requested and a draft list of questions to this application form.

**Please do not convert this form into PDF!**

**Pre-CTA advice application**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Applicant / Company |

|  |  |
| --- | --- |
| Name:  |  |
| Address: |  |
| Applicant type: | [ ] Commercial sponsors (large industry)[ ] Commercial sponsors (SMEs)[ ] Non-commercial sponsors (please specify) [ ]  Others (please specify) |

 |
| Contact Person Detail |

|  |  |
| --- | --- |
| Name: |  |
| Direct tel: |  |  |  |
| Email: |  |

 |
| Alternate contact person details (if applicable)/ financial contact person (if applicable or different from procedure contact person) |

|  |  |
| --- | --- |
| Name:  |  |
| Direct tel: |  |  |  |

[ ] Consultant on behalf of Applicant [ ] Letter of authorisation from applicant[ ] Other |

**Scope of the pre-CTA advice**

The following topics fall within the scope of the pre-CTA advice. The list is not exhaustive. Please select the option that applies to your request:

[ ]  CT within scope of the Clinical Trial Regulation (Y/N)?

[ ]  Low Intervention Clinical Trial;

[ ]  Combination products / combined CTs (MDR/IVDR);

[ ]  Operational aspects of the submission of the CTA in CTIS (Complex CT, transition of CT);

[ ]  Regulatory request on GLP GL;

[ ]  Regulatory request on AxMP GL;

[ ]  Decentralized elements in CTs;

[ ]  Risk based trial performance (e.g. reduced safety reporting);

[ ]  Open questions before re-submission of updated dossier;

[ ]  Other regulatory and technical aspects of the CTA, please specify Click or tap here to enter text.

**Out of scope of pre-CTA advice pilot**

* Requests on scientific aspects of clinical trials are out of scope and better suited for other advice procedures ([Scientific Advice on medicines for Human use in the EU medicines regulatory network (europa.eu)](https://www.ema.europa.eu/system/files/documents/other/scientific_advice_on_medicines_for_human_use_in_the_eu_medicines_regulatory_network_en.pdf).
* Preassessment of CTA is out of scope.

Please use this application ticking the box on the entry page above indicating that the request refers to a pre-CTA advice.

Please add the following information:

* The proposed reporting member state (RMS) for the clinical trial application.

 Choose an item.

* The proposed concerned member state (MSCs) for the clinical trial application

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

* Where applicable provide the Trial reference number: Click or tap here to enter text.
* List of relevant documents for the pre-CTA advice submitted with this pre-CTA advice request: Click or tap here to enter text.

Please also add the file with the list of questions for which you are requesting the pre-CTA advice (up to 5).

**NOTE**:

The application for the pre-CTA advice includes the declaration of consent to the involved NCA’s to store the data indicated for the evaluation of the pre-CTA advice pilot.

The application for the pre-CTA advice includes acceptance of fees based on the national regulations for scientific advice fees or any applicable national fee reductions.

**IMPORTANT!**

Please enclose additional information on the scope the advice requested and a draft list of questions to the application form.

**Please do not convert this form into PDF!**

1. Lead NCA = Coordinator of the procedure, i.e. central communication point between participating NCAs and Applicant. [↑](#footnote-ref-3)
2. NCAs participating as observer are involved in the preparation of the meeting, but do not provide comments or contribute to discussions during the advice meeting.

The Applicant should adequately justify why involvement of NCAs as observer is being proposed and considered to be of added value.

NCAs that can only participate as observer for formal reasons are exempt from this rule. [↑](#footnote-ref-4)
3. 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 and if adequately justified by the Applicant.

 [↑](#footnote-ref-5)
4. The Applicant should adequately justify why the involvement of a CTCG or EC representative is being proposed and considered to be of added value. [↑](#footnote-ref-6)
5. By participating in the SNSA pilot scheme, the Applicant hereby grants the NCA’s within the European Medicines Regulatory Network (EMRN) the right to share in a confidential manner the knowledge and experiences gained from completed SNSA procedures within the EMRN e.g. through early discussion at the EU-IN and potentially relevant working groups and scientific committees of EMA/HMA to enhance preparedness for incoming innovation and reflect on regulatory challenges. The Applicant hereby also gives his consent to allow the NCA’s to store and share the SNSA dossier in a confidential manner (e.g. by means of an IT datasharing platform used within the EMRN). [↑](#footnote-ref-7)