

22 November 2022

Application form to request a Simultaneous National Scientific Advice (SNSA)

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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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: |       |  |  |
| Email: |       |

[ ] 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 |

 |
|  | [ ] Combination Product (e.g. Medicinal Product pursuant to pharmaceutical legislation + Medical Device or IVD)[ ] 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 |
| 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 (phase 3) |
| [ ]  | Post(MA) (phase4) |
| [ ]  | 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:  |

 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ethics committee(s)  |

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

 |
| 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 (on-going or applied for) 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 |
|  | EudraCT nr(s) – if available |       |
| [ ]  | planned |  |
|  | Member States: |  |

 |
| Comments |       |
| Manufacturing license  |

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

 |
| Comments |       |
| ATMP classification procedure |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ] Date: | Planned |

 |
| Comments |       |
| ATMP certification procedure |

|  |  |
| --- | --- |
| [ ]  | Received  |
| [ ]  | Applied for  |
| [ ] Date: | Planned  |

 |
| 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  |
| [ ] Date: | Planned  |

 |
| 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 grantedPlease 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 |  |
| Please briefly outline the scope of the request for SNSA |       |
| Preferred meeting dates (minimum 3 options, in different weeks) |  |
| Requested NCAs | NCA 1 : NCA 2 : NCA 3 (as observer) :Alternative NCA to replace NCA 1 or NCA 2:Additional NCAs in justified cases (1): Participation of a CTCG representative as observer (2)[ ]  yesJustification: |
| Data sharing | In case of issues to be discussed at EMA/HMA working groups, e.g. CTCG [ ]  agree (3) [ ]  disagree |

(1) 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.

(2) The applicant should adequately justify why the involvement of a CTCG representative as observer is being proposed and considered to be of added value.

(3) By agreeing, the applicant hereby grants the involved NCA’s the right to share in a confidential manner the knowledge and experiences gained from completed SNSA procedures within the European regulatory network 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 regulatory challenges.

**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 send this form in Word format as it is to SNSA@pei.de.

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