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| --- | --- |
| Scientific Advice Office  European Medicines Agency  EUnetHTA ED Secretariat  Haute Autorité de Santé | Date: |

Letter of intent for Parallel Consultation EMA and EUnetHTA[[1]](#endnote-1)

Please fill all the predefined fields as accurately as possible

|  |  |
| --- | --- |
| **Unique Product Identifier** |  |
| **\*Substance** | |
| **INN** (if available) |  |
| **Trade name** (if available) |  |
| **Company product code** |  |
| **\*Description of the product & mechanism of action** |  |
| **\*Type of product** | Chemical:  Generic  Antisense  NCE  Others  Bio(techno)logical  Classical biological:  Blood derived  Enzyme  Vaccine  Other biologicals  Recombinant DNA derived product:  Cytokine  Hormone  Monoclonal antibody  Vaccine  Transgene-derived (animal/biopharm)  Other Recombinant  Similar biological  Nucleic acid-based:  DNA vaccine  Oncolytic virus  Advanced Therapy:**[[2]](#endnote-2)**  Gene Therapy  Autologous  Allogeneic  Xenogeneic  Somatic cell therapy:  Autologous  Allogeneic  Xenogeneic  Tissue-engineered product:  Autologous  Allogeneic  Xenogeneic  Therapeutic, Scientific or Technical innovation |

Comments:

|  |  |
| --- | --- |
| **\*Intended Indication for the current procedure** |  |
| **Therapeutic field** | Cancer HIV/AIDS Diabetes  Neurodegenerative disorder Viral disease  Autoimmune disease/dysfunction  Cardiovascular Other |
| **\*ATC code** (broad or detailed if known) | ; or detail here: |

Comments:

|  |  |
| --- | --- |
| **\*Applicant / Company** | [[3]](#endnote-3)Customer Account Number:  Company Name:       Address:  Country: |
| **\***Contact Person details | Title and Name:     Direct tel:    Fax:  Email: |
| **\***Alternate Contact Person details**[[4]](#endnote-4)** | Title and Name:          Direct tel:       Fax:  Email: |
| Financial contact person details (if applicable or different from procedure contact person)[[5]](#endnote-5) | Title and Name:            Direct tel:       Fax:  Email: |
| Customer Reference Number/ Purchase order number (if applicable)[[6]](#endnote-6) | Details: |

Comments:

|  |  |
| --- | --- |
| **\*Small and Medium Sized Enterprises (SME) status[[7]](#endnote-7)** | NO – N/A  YES (please fill additional rows)  - SME Number: |

|  |  |
| --- | --- |
| **Consultant on behalf of Applicant (if applicable)** | Title and Name:        Direct tel: Fax:  Email: |
| Contact Person details | Title and Name:        Direct tel: Fax:  Email: |
| Alternate Contact Person details (if applicable) | Title and Name:        Direct tel: Fax:  Email: |
| Letter of authorisation from applicant | NO (to be provided within 15 days)  YES (please attach) |

|  |  |
| --- | --- |
| **Non-EEA SME Client Company[[8]](#endnote-8)** | Is applicable: YES NO |
| **\***Company details | [[9]](#endnote-9)Customer Account Number:  Company Name:        Address:  Country: |
| **\***Contact Person details | Title and Name:        Direct tel: Fax:  Email: |
| Financial contact person details (if applicable or different from procedure contact person)[[10]](#endnote-10) | Title and Name:            Direct tel:       Fax:  Email: |
| \*Small and Medium Sized Enterprises (SME) status[[11]](#endnote-11) | NO – N/A  YES (please fill additional rows)  - SME Number: |
| \*Invoice to[[12]](#endnote-12) | Applicant Customer Account Number  Client company Customer Account Number |

|  |  |
| --- | --- |
| \***Requirement for EMA pre-submission meeting[[13]](#endnote-13)** | NO  YES (specify preferred week for meeting):  If yes please indicate if there are any NO YES  regulatory topics to be discussed: |
| **Aimed start of the procedure at SAWP meeting** | Click here to enter a date. |

Comments:

|  |  |
| --- | --- |
| **\*Type of request** |  |
| **Previous advices received** | This request is a follow-up to the advice given by the CHMP. Procedure number: EMEA/H/SA/  Other CHMP Scientific Advice (s) given to this product. Procedure number: EMEA/H/SA/  Previous Scientific Advice(s) received by relevant Competent Authorities, EU or non-EU (including exact dates):  Previous briefing meeting with EMA: |
| **Particular request** (choose if applicable) | Request relating to Conditional marketing authorisation  Advice relating to “Justification” criteria  Advice relating to development  WHO Art. 58  FDA Parallel advice  Request on general issues (broader advice)  Request relating to marketing authorisation under “Exceptional circumstances”  Advice relating to “Justification” criteria  Advice relating to development |
| **Request for includes** (choose if applicable) | Process Analytical Technology  Modelling and Simulation |

Comments:

|  |  |
| --- | --- |
| **Parallel Consultation EMA EUnetHTA** | |
| **Participating HTAs (preference)[[14]](#endnote-14)** |  |
| **Request for ED includes** | Economic analysis  YES  NO |
| **Involvement of Early Dialogue Working Party (EDWP) preferred[[15]](#endnote-15)** | YES  NO |
| **Exchange of documents between EMA and EUnetHTA** | Please tick if the Applicant consents to share Administrative information List of Issues Final Advice Letter |
| **Clinical trial phase(s) for which Parallel Consultation is requested:** |  |
| **Are the Trial(s) for which advice is requested ongoing?** | YES  NO |
| **Does this represent a new mechanism of action for in this indication?** | YES  NO |
| **Does the indication target a life-threatening or chronically debilitating disease?** | YES  NO |
| **Does the indication target an Unmet need?** | YES  NO |
| **Summary of safety and efficacy annexed[[16]](#endnote-16)** | YES  NO |
| **Comments** |  |

|  |  |
| --- | --- |
| **Post-Authorisation Studies (PAS)** | **Centrally Authorised Products (CAPs)**  **Nationally Authorised Products (NAPs)** |
| Post-Authorisation Safety Study (PASS) category | 1  2  3  4 |
| Is this a multi-company study? | YES  NO |
| Objective of study | Drug Utilisation Study  PASS  PAES  Assessment of risk minimisation program  Other  Other objective |

|  |  |
| --- | --- |
| **\*Paediatric Investigation Plan/Waiver** | Status: Submitted  YES  NO/NA  Planned  Date of PIP Submission:  PIP procedure number: |

Comments:

|  |  |
| --- | --- |
| **Orphan status[[17]](#endnote-17)** | NO – N/A  YES (please fill additional rows)  - Orphan Designation (OD) EU Number: EU/  - OD date:  - OD application number: EMEA/OD/  - Indication for which OD has been granted:  **-** Protocol Assistance Fee waiver requested:**[[18]](#endnote-18)**  YES NO |

Comments:

|  |  |
| --- | --- |
| **Status of the product/pipeline:** | MA granted  MA not yet granted  N/A |
| **Marketing Authorisation (MA) already granted** | Date of MA granting:  Route of MA:   * National procedure * MRP/Decentralised Procedure * Centralised Procedure   Specify in which indication: |
| **MA 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) |
| **Additional EMA Scientific Advice planned** | NO  YES; planned date: |

Comments:

|  |  |
| --- | --- |
| **Area Of Advice[[19]](#endnote-19)** | Quality (Paediatric only request: [[20]](#endnote-20)) Preclinical (Paediatric only request: xx) Clinical (Paediatric only request: xx) x) Pharmacokinetics Statistics Safety / Efficacy Risk management plans Significant benefit (related to Orphan Drug status) **Please briefly outline the scope/content of each question, for each area of advice:** |

Comments:

**Important: please send this form in Word format as it is to:** [**scientificadvice@ema.europa.eu**](mailto:scientificadvice@ema.europa.eu)

**and** [**EUnetHTA-has@has-sante.fr**](mailto:EUnetHTA-has@has-sante.fr)

**Do not convert it into PDF.**

1. At the time of submission the request should be provided in line with the current Parallel Consultation Guidance Document EMA/385780/2017

   [↑](#endnote-ref-1)
2. For type of products falling into this category, a pre-submission meeting is strongly recommended. [↑](#endnote-ref-2)
3. This field is mandatory. Please quote your customer account number with the Agency. To request a customer account number or for any account query please send an e-mail to [accountsreceivable@ema.europa.eu](mailto:accountsreceivable@ema.europa.eu). [↑](#endnote-ref-3)
4. An additional alternate contact person is requested in case the main contact point is unavailable. All official correspondence will be sent to both contact persons. If a Consultant is acting on behalf of the applicant, the alternate contact person details are not requested. [↑](#endnote-ref-4)
5. Please provide details of a contact person for matters related to settlement of invoices, statements of account, etc. The Agency will send an invoice to the billing address it has on file at the time of receipt of the present application. For queries on billing addresses please send an e-mail to [accountsreceivable@ema.europa.eu](mailto:accountsreceivable@ema.europa.eu). Please note that EMA fees are payable net of all bank charges, withholding taxes and any other deduction imposed on the customer by legislation of the country of residence. [↑](#endnote-ref-5)
6. Applicants requiring a purchase order number or similar references on the invoice are requested to clearly indicate it on the cover letter or application form accompanying the dossier. The Agency does not accept stand-alone notifications of purchase order numbers that are not associated with a dossier. Applicants not requiring a purchase order number on the invoice should also clearly state this in the cover letter. [↑](#endnote-ref-6)
7. To be eligible for an SME fee reduction the applicant must be a legal entity with registered office in the European Economic Area (EEA) and have SME status assigned by the EMA. Where the applicant is an EEA-based SME consultant, applying on behalf of a non-EEA based SME client company, the EEA-based consultant should be the “Applicant” and details of the non-EEA based client company should be entered in the section “Non-EEA SME Client Company” (see note ix). [↑](#endnote-ref-7)
8. This section must be filled in only when the applicant is an SME consultant applying on behalf of a non-EEA SME client company (see note vii). Please provide details of the client company. [↑](#endnote-ref-8)
9. This field is mandatory. Please quote your customer account number with the Agency. To request a customer account number or for any account query please send an e-mail to [accountsreceivable@ema.europa.eu](mailto:accountsreceivable@ema.europa.eu). [↑](#endnote-ref-9)
10. Please provide details of a contact person for matters related to settlement of invoices, statements of account, etc. [↑](#endnote-ref-10)
11. If the client company has an SME status, at the time of submission please provide the fee reduction confirmation document from the EMA SME office. Failure to do so will incur a validation of the request without SME fee reduction. [↑](#endnote-ref-11)
12. The Agency will send an invoice to the billing address it has on file at the time for receipt of the present application. For queries on billing addresses please send an e-mail to [accountsreceivable@ema.europa.eu](mailto:accountsreceivable@ema.europa.eu). Please note that EMA fees are payable net of all bank charges, withholding taxes and any other deduction imposed on the customer by legislation of the country of residence. [↑](#endnote-ref-12)
13. Please note that the meeting will not take place during CHMP & SAWP meeting dates. [↑](#endnote-ref-13)
14. Preferences for HTAs will be taken into account but are not guaranteed.

    For all EUnetHTA participants, please see EUnetHTA website <http://eunethta.eu/contactus/all/356/all>

    For EUnetHTA Work package 5 participants, please see: <http://www.eunethta.eu/activities/eunethta-joint-action-3-2016-20/work-package-5-life-cycle-approach-improve-evidence-gener> [↑](#endnote-ref-14)
15. Preference for the EDWP will be taken into account but is not guaranteed [↑](#endnote-ref-15)
16. A summary of available safety and efficacy data for the intended product and indication must be annexed when submitting the letter of intent. [↑](#endnote-ref-16)
17. If the applicant is applying for protocol assistance, but Orphan Drug designation EU number is pending and awaited, please choose "SCIENTIFIC ADVICE NEW REQUEST OR FOLLOW UP REQUEST" as Type of Request and submit details at a later stage within end of validation, together with your fee waiver request (see below). This is applicable also if a change of sponsor of the Orphan Drug Designation is on going/pending. [↑](#endnote-ref-17)
18. If the applicant is applying for protocol assistance, at the time of submission please provide the fee reduction and/or waiver confirmation document from the EMEA Orphan Drug office. Failure to do so will incur a validation of the request as Scientific Advice and an invoice of the full amount will be sent by our account department.

    [↑](#endnote-ref-18)
19. Regulatory topics may be addressed at pre-submission meetings or in writing separately from the Scientific Advice request. [↑](#endnote-ref-19)
20. Please tick if the questions only relate to Paediatric development. [↑](#endnote-ref-20)