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| Scientific Advice OfficeEuropean Medicines AgencyEUnetHTA ED SecretariatHaute 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:

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| **\*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:

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| **\*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:

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

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| **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)  |

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| **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   |

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| \***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 [ ] YESregulatory topics to be discussed: |
| **Aimed start of the procedure at SAWP meeting** | Click here to enter a date. |

Comments:

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| **\*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:

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| **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** |  |

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| **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       |

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| **\*Paediatric Investigation Plan/Waiver** | Status: Submitted [ ]  YES [ ]  NO/NA [ ]  PlannedDate of PIP Submission:PIP procedure number: |

Comments:

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| **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:

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| **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:

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| --- | --- |
| **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**

**and** **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. [↑](#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. 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. [↑](#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. 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)