**Letter of Expression of Interest**

**EUnetHTA multi-HTA Early Dialogues**

**EUnetHTA EMA multi-stakeholder Early Dialogues**

Last updated: 24-Mar- 2017

This Letter of Expression of Interest template is to be used for both EUnetHTA multi-HTA Early Dialogues and EUnetHTA EMA multi-stakeholder Early Dialogues.

Colour coding:

Sections shaded in light blue should be inserted only for EUnetHTA EMA multi-stakeholder Early Dialogues.

Please follow the submission instructions at the end of the form.

Should you have any questions regarding the completion of this form, please contact:

[eunethta-has@has-sante.fr](mailto:eunethta-has@has-sante.fr) if applying for EUnetHTA multi-HTA Early Dialogues

[eunethta-has@has-sante.fr](mailto:eunethta-has@has-sante.fr) and [scientificadvice@ema.europa.eu](mailto:scientificadvice@ema.europa.eu) if applying for EUnetHTA EMA multi-stakeholder Early Dialogues.

Thank you in advance for your interest.

Please note: no applications will be accepted if the trial(s) for which you are requesting advice are currently on-going.

|  |  |
| --- | --- |
| **EUnetHTA Early Dialogues Secretariat** [**eunethta-has@has-sante.fr**](mailto:eunethta-has@has-sante.fr) | **Date:** Click to select date |

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| **Request for:** Please Select the Type of Early Dialogue Scientific Advice Requesting |

**Please fill in 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 the 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[[1]](#endnote-1) |
|  | Gene therapy |
|  | Autologous |
|  | Allogenic |
|  | Xenogenic |
|  | Somatic cell therapy |
|  | Autologous |
|  | Allogenic |
|  | Xenogenic |
|  | Tissue-engineered product |
|  | Autologous |
|  | Allogenic |
|  | Xenogenic |
|  | Therapeutic, Scientific, or Technical Innovation |

Comments:

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| --- | --- |
| **Intended indication for the scope of the current ED** |  |
| **Therapeutic field** | Cancer  HIV/AIDS  Diabetes  Neurodegenerative disorder  Viral disease  Autoimmune disease/dysfunction  Cardiovascular  Other |
| **ATC code (broad or detailed if known)** | Click to select. or detail here: |

Comments:

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| --- | --- |
| **Applicant / Company** | Company Name:  Address:  Country: |
| **For EUnetHTA EMA multi-stakeholder Early Dialogues only:** [[2]](#endnote-2)EMA Customer Account Number: |
| Contact Person details | Title and Name:  Direct Tel: Fax:  Email: |
| Alternate Contact Person details[[3]](#endnote-3) | Title and Name:  Direct Tel: Fax:  Email: |
| Financial Contact Person details[[4]](#endnote-4) | Title and Name:  Direct Tel: Fax:  Email: |
| Customer Reference Number/ Purchase order number (if applicable)[[5]](#endnote-5) | **For EUnetHTA EMA multi-stakeholder Early Dialogues only:**  Details: |

Comments:

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| **Small and Medium Sized Enterprises (SME)[[6]](#endnote-6)** | NO – N/A |
| YES |
| **(For EUnetHTA EMA multi-stakeholder Early Dialogues only):** 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 30 days)  YES (please attach) |

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| **Section to be completed for EUnetHTA EMA multi-stakeholder Early Dialogues only** | |
| **Non-EEA SME Client Company[[7]](#endnote-7)** | Is applicable: YES NO |
| Company details | [[8]](#endnote-8) EMA 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)[[9]](#endnote-9) | Title and Name:  Direct Tel: Fax:  Email: |
| Small and Medium Sized Enterprises (SME) status[[10]](#endnote-10) | NO – N/A  YES (please fill additional rows) - SME Number: |
| Invoice to[[11]](#endnote-11) | Applicant Customer Account Number:   Client company Customer Account Number: |

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| **EUnetHTA EMA multi-stakeholder Early Dialogues: Aimed start of the procedure at SAWP meeting; See EMA website for dates.** |  |
| **EUnetHTA multi-HTA Early Dialogues : Aimed date of the face-to-face meeting (*please refer to the EUnetHTA Early Dialogues procedure for the full timeline*)** |  |

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| **Targeted HTABs *(please indicate your preference)*** |  |

Comments:

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| **Section to be completed for EUnetHTA multi-HTA Early Dialogues only** | |
| **Type of request** | **Early Dialogue New Request** |
| **Other scientific advice or early dialogue (received or planned)** | EMA Scientific Advice: NO / Not planned    YES Date:   Previous EUnetHTA or SEED Early Dialogue (ED)  Date of the ED:  Other Early Dialogues with individual HTA bodies: NO / Not planned    YES Which countries: |

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| **Section to be completed for EUnetHTA EMA multi-stakeholder Early Dialogues only** | |
| **Type of request** |  |
| **Previous advices received** | This request is a follow-up to the advice given by the CHMP  Procedure number: EMA/H/SA/   Other CHMP Scientific Advice(s) given to this product.  Procedure number: EMA/H/SA/   Previous Scientific Advice(s) received by relevant Competent Authorities, EU or non-EU (including exact dates):   Previous briefing meeting with EMA. Date: |
| **Particular request** (choose if applicable) | Request relating to conditional marketing authorisation   Advice relating to “Justification” criteria   Advice relating to development  WHO Art. 58  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 SA/PA includes (choose if applicable)** | Process Analytical Technology  Modelling and Simulation |

Comments:

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| --- | --- |
| **Post-Authorisation Studies (PAS) in another indication** | **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  Planned  Date of PIP Submission:  PIP procedure number: |

Comments:

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| **Orphan status [[12]](#endnote-12)** | NO – N/A   YES (please fill in additional rows)  - Orphan Designation (OD) EU Number: EU/   - OD date: |
| - OD application number: EMA/OD/ |
| - Indication for which OD has been granted: |

Comments:

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| **Status of the product / pipeline** | MA Granted in another indication MA not yet granted N/A |
| **Marketing Authorisation (MA) already granted in another indication** | 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[[13]](#endnote-13)** | **Quality (Paediatric only request: [[14]](#endnote-14))  Preclinical (Paediatric only request: [[15]](#endnote-15))** |
| **Clinical (Paediatric only request: [[16]](#endnote-16))** |
| Pharmacokinetics |
| Statistics  Safety / Efficacy |
| Risk Management plans |
| **Economic** |
| **Significant benefit** (related to Orphan Drug status) |
| **Please briefly outline the scope/content of each question, for each area of advice:** |

Comments:

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| **Exchange of documents between participating HTA bodies and the EMA** | Please check if the Applicant consents to share:  List of Issues   Final Advice Letter  Sharing the above documents is highly recommended for the purposes of the parallel procedure |

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| **Important: please send this form in Word format as it is to:** | |
| **EUnetHTA multi-HTA Early Dialogue**  [eunethta-has@has-sante.fr](mailto:eunethta-has@has-sante.fr?subject=Request%20for%20EUnetHTA%20multi-HTA%20Early%20Dialogue) | **EUnetHTA EMA multi-stakeholder Early Dialogue**  Simultaneously to:  [eunethta-has@has-sante.fr;](mailto:scientificadvice@ema.europa.eu;%20eunethta-has@has-sante.fr?subject=Request%20for%20EUnetHTA-EMA%20Parallel%20Scientific%20Advice)  [scientificadvice@ema.europa.eu](mailto:scientificadvice@ema.europa.eu;%20eunethta-has@has-sante.fr?subject=Request%20for%20EUnetHTA-EMA%20Parallel%20Scientific%20Advice) |

1. For type of products falling into this category, a pre-submissions meeting is strongly recommended [↑](#endnote-ref-1)
2. 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-2)
3. 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-3)
4. 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 tile of the present application. For queries on billing addresses please send an email 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-4)
5. 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 notification 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-5)
6. 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 EEQ-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-6)
7. 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 ix). Please provide details of the client company. [↑](#endnote-ref-7)
8. 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-8)
9. Please provide details of a contact person for matters related to settlement of invoices, statements of account, etc. [↑](#endnote-ref-9)
10. If the applicant 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-10)
11. The Agency will send an invoice to the billing address it has on file at the tile of the present application. For queries on billing addresses please send an email 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-11)
12. 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-12)
13. Regulatory topics may be addressed at pre-submission meetings or in writing separately from the Scientific Advice request. [↑](#endnote-ref-13)
14. Please check if the questions relate only to Paediatric development. [↑](#endnote-ref-14)
15. Please check if the questions relate only to Paediatric development. [↑](#endnote-ref-15)
16. Please check if the questions relate only to Paediatric development. [↑](#endnote-ref-16)