Parallel EMA/EUnetHTA 21
Joint Scientific Consultation (JSC)
Application Form

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 ☐ Vaccine ☐ Enzyme ☐ 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 Medicinal Product (ATMP): ☐ Gene therapy: ☐ Autologous ☐ Allogenic ☐ Xenogenic ☐ Somatic cell therapy: ☐ Autologous ☐ Allogenic ☐ Xenogenic ☐ Tissue-engineered product ☐ Autologous ☐ Allogenic ☐ Xenogenic ☐ Therapeutic, scientific, or technical Innovation
Is the product used together with a digital application?	☐ YES ☐ NO If yes, please describe:
Is the product used together with a medical device or an *in vitro* diagnostic medical device?	☐ YES ☐ NO If yes, please describe:

Comments:

Intended indication for the scope of the current JSC	
Products with market authorization in similar indication	
Products in development with similar indication	
Application type EMA (anticipated):	☐ Initial market application (IMA) ☐ Extension of Indication (EoI)

	☐ Line Extension (LE) ☐ First in class (FC) ☐ Priority Medicine (PRIME) ☐ Accelerated access (AC) ☐ Orphan designation (OD) if current OD, please provide: OD number: EU/ Date: YYYY-MM-DD Indication for which OD has been granted:
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:

Applicant	**Company Name:** **Address:** **Country:**
Contact Person details	**Title and Name:** **Direct Tel:** **Fax:** **Email:**
Alternate Contact Person details[i]	**Title and Name:** **Direct Tel:** **Fax:** **Email:**

Comments:

Small and Medium Sized Enterprises (SME)	☐ NO – N/A ☐ YES - 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)

Aimed date of the draft Briefing Package ready for submission *(Please refer to the EUnetHTA 21 Joint Scientific Consultation procedure for the full timeline.)*	[Please indicate the **earliest and the latest possible date for the submission of the Draft Briefing Package**. If the request for a Parallel EMA/HTA body (HTAb) Scientific Advice is accepted, the exact time slot for the consultation will be planned accordingly.]

Comments:

Clinical trial phase(s) for which JSC is requested	☐Phase I ☐Phase II ☐Phase III ☐Phase IV, PLEG (only in conjunction with request for discussion of pivotal trial design) If the clinical trial phase for which JSC is requested is not Phase III: Is a Phase III study planned: ☐ YES ☐ NO If no, please explain why not:
Are the trial(s) for which advice is requested on-going?	☐ YES ☐ NO If yes, please specify study registry/ID number: Study title | registry/ID-number | | | | | |
Does the product target an unmet need?	☐ YES ☐ NO If yes, please describe:
Is the product the first in its class?	☐ YES ☐ NO If yes, please describe:
Does the product have potential impact on patients, public health, or healthcare systems?	☐ YES ☐ NO If yes, please describe:
Will the product have significant cross-border dimension?	☐ YES ☐ NO If yes, please describe:
Will the product have a major Union-wide added value?	☐ YES ☐ NO If yes, please describe:
Does the product address Union clinical research priorities?	☐ YES ☐ NO If yes, please describe:

Summary of expected information (study phase, minimum information on PICO scheme) annexed[ii]	☐ YES ☐ NO

Comments:

Other scientific advice (received or planned)	EMA Scientific Advice: ☐ NO ☐ YES Date: Click to select date Previous EUnetHTA Early Dialogue (ED) or Joint Scientific Consultation (JSC): ☐ NO ☐ YES, ED or JSC Number: Date: Click to select date Other scientific advices with individual HTA bodies: ☐ NO / Not planned ☐ YES Which countries:

Comments:

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)

Comments:

Area of Advice	Please briefly outline the scope/content of <u>each</u> question, for <u>each area of advice following topic order proposed below</u>: ☐ Target Population: ☐ Intervention: ☐ Comparator choice: ☐ Outcomes choice: ☐ Study Design including statistical analysis method: ☐ Post-Launch Evidence Generation (only in conjunction with request for discussion of pivotal trial design) ☐ Health Economics:

Comments:

Important application submission instructions:

1. Please send this form in Word format. Do not convert it into PDF.
2. The Application Form for parallel EMA/EUnetHTA 21 JSC should be submitted to the EUnetHTA 21 JSC Secretariat via Eudralink (EUnetHTA21-JSC@g-ba.de).

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[i] 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.

[ii] As available, a summary of expected information (study phase, high level design with minimum information on Population, Intervention, Comparator, Outcomes (PICO)) for the intended product and indication must be annexed when submitting the Application Form.