13 October 2020
EMA/571057/2010

Marketing Authorisation Application (MAA) Pre-submission meeting request form

This pre-submission meeting request form provides an overview of the most relevant topics that an applicant is advised to consider when preparing their upcoming application for initial marketing authorisation, and which can be discussed at a MAA pre-submission meeting. For each topic, a reference is included to the corresponding 'question and answer' in the EMA Pre-authorisation Procedural Advice for Users of the Centralised Procedure, which is available on the EMA website. It should be noted that the pre-submission meeting is not intended to be used to provide pre-assessment of any of the (draft) documents submitted.

The EMA's pre-authorisation guidance addresses a number of questions together with hyperlinks to relevant legislative documents and procedural guidelines which complement the advice given. Applicants are asked to refer to this guidance first before completing this pre-submission meeting request form.

There should not be a need to check or confirm answers provided in the pre-authorisation guidance document at a pre-submission meeting. EMA commits to keeping the pre-authorisation guidance document updated. A topic should only be proposed for discussion, when the applicant's questions are not fully answered by the pre-authorisation or other available guidance documents, due to certain particularities of the upcoming application and/or nature of the product. In that case, applicants are advised to clearly describe the issues in the 'comments' box under the topic concerned, and to provide relevant background information. Other topics not listed in the form may be added.

The EMA would furthermore like to refer to the EC-EMA notice to marketing authorisation holders (MAHs) published in May 2017 on the European Commission and Agency websites. This notice reminds MAHs to check whether they have to adapt processes and to consider changes to the terms of their marketing authorisations in advance of UK's withdrawal from the EU. Required changes will need to be in place not later than 30 March 2019, in order to ensure processes and marketing authorisations continuous validity once the UK becomes a third country.

In case your application includes legal requirements and/or activities currently based in the UK, you are advised to consider the relevant changes in advance of the submission of your application.

Guidance can be found on the EMA website including in the form of Q&As.

For any questions that you may have further to the Q&As publication, you are advised to liaise with your EMA contact point.

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Send a question via our website www.ema.europa.eu/contact

EMA PRE-SUBMISSION MEETING -

- Date of request:
- Proposed date(s)*):

  *) *For the time being, pre-submission meetings will be held remotely at certain pre-defined dates and times. You may indicate a timeframe (day or week) when you would like the meeting to take place, which will be taken into account for the allocation of the date/time of your meeting, depending on availability.*

- Names of participants and function:

SUBMISSION OF THE APPLICATION

- Proposed submission date of application:

BACKGROUND INFORMATION

- Annex 1: Overview of the product and its development programme covering quality, non-clinical and clinical aspects (i.e. Draft Quality overview (Module 2, section 2.3) + non-clinical (Module 2, section 2.4) + clinical (Module 2, section 2.5) overviews, if available)
  - With regards to quality aspects: Please clearly highlight key pharmaceutical aspects in relation to the product such as for example: API synthetic scheme with starting materials labelled, cell line development and cell banking strategy, novel/non-standard processes/ novel expression system/ testing methodology, purification methods, viral removal steps, bioassay, novel/innovative formulation, QbD elements/Design Space, Real Time Release Testing, bridging data (different manufacturing sites, formulations, etc.), comparability data, deviation from guidelines, rationale for New Active substance (NAS) claim, etc.
- Annex 2: Draft RMP elements: safety specification, pharmacovigilance plan and risk minimisation measures, if available. Please specify the data sources that are expected to be used to support post-authorisation monitoring [e.g. randomised clinical trial/s, 'real world' data, patient/ disease registries, health / pharmacy claims, electronic medical records, prescription event monitoring, other (specify)].
- Annex 3: Copy of any scientific advice given by the CHMP and National Competent Authorities (NCAs) related to the application (if applicable), copy of any ATMP classification, ATMP certification (when applicable)
- Annex 4: Protocol and Statistical Analysis Plan for the pivotal studies (if module 2.5 is not available)
  - Biostatistics: indicate any statistical issues or complexities related to aspects of trial design or analysis in section 2.2. Ensure inclusion of the relevant documentation (e.g., protocol, statistical analysis plan, data monitoring committee charter) in Annex 1 or 4 as applicable.
- Annex 5: Draft Module 2.7.2 - Overview of clinical pharmacology studies (if module 2.5 is not available or if specific issues are foreseen to be important for the application – see below)
  - Clinical Pharmacology: highlight PK or PD issues related to clinical development in section 2.2. (e.g. bioanalytics, bioequivalence of formulations used in CTs and for marketing, biowaivers, ADME and studies in special populations, use of modeling and simulation).

- Annex 6: Overview of paediatric studies and overview of indications in relation to the conditions in the PIP
- Annex 7: Draft SmPC, labelling text and package leaflet (1 relevant example)
- Annex 8: Draft Application Form (CTD Module 1.2 – with annex 5.23 (justification for new active substance only)
- Annex 9: Module 1 indents, as applicable;
  - 1.5 Draft justification related to any specific requirements for different types of application (e.g. bibliographical, abridged, generic, hybrid or biosimilar applications, exceptional circumstances, conditional marketing authorisation)
  - 1.6 Draft ERA (GMO/non-GMO)
  - 1.7 Draft information related to orphan market exclusivity
- Annex 10: Draft Table of Content of the Application, listing studies performed for each CTD heading
- Annex 11: Copy of any other early EMA contacts such as SME RA advices, ITF minutes, Orphan and/or paediatric advices etc. (if applicable)
- Annex 12: Draft justification of accelerated assessment (if applicable)
- Any other information in relation to the issues to be discussed with the EMA (see form)
- Applicant's presentation (in Power Point format) in accordance with Q&A 'How is a marketing authorisation application pre-submission meeting conducted at EMA?' of the pre-authorisation guidance document
- Any additional background information needed related to the questions.

EMA CONTACT

Please send the completed form at least 6 weeks in advance of the proposed meeting date, by raising a ticket via EMA Service Desk, using the Question option "Pre-Submission Phase Request" followed by sub-option "Pre-Submission Meeting".

If you do not have an EMA Account, please create it via the EMA Account Management portal.

Subsequently, all of the above-mentioned meeting background information including the presentation, together with the remote set-up details should be provided to the EMA **at the latest 2 weeks** before the agreed meeting date. Late receipt of the complete background information and the presentation may require re-scheduling of the meeting.

All documents should be provided in an electronic format only via EMA Service Desk

INFORMATION ON THE APPLICANT

Please fill in all of the requested data.

Applicant:

Company Name:

Address

Line 1:

Line 2:

Line 3:

City:

Post Code:

Country:

SME Status: ☐ Yes ☐ No

Expiry Date of SME Status:

SME Number:

CONTACT PERSON

Please fill in all of the requested data.

Title:

Last Name:

First Name:

Company Name:

Address

Line 1:

Line 2:

Line 3:

City:

Post Code:

Country:

Telephone:

Fax:

Email:

ELIGIBILITY (For Eligibility to the Centralised Procedure Request (according to Regulation (EC) No 726/2004))

Eligibility basis*:

Date of CHMP confirmation:

*For example: Mandatory Scope (Article 3(1) of Regulation (EC) No 726/2004, Optional Scope (Article 3 (2) of Regulation (EC) No 726/2004), Automatic access-For substances already authorised via the Centralised Procedures)

INFORMATION ON THE PRODUCT

Product Name:

Product Number (assigned at Eligibility): H00

Additional Information on strength(s) with units, Pharmaceutical form(s) and route of administration(s):

Non-prescription product (OTC): ☐ Yes ☐ No

Application for ancillary medicinal substance in medical devices: ☐ Yes ☐ No

ACTIVE SUBSTANCES

Active Substance name:

INN, if available:

Or Common Name:

Chemical Name:

Company Code:

Substance Type:

Method of manufacture:

Biological Source:

Orphan: ☐ Yes ☐ No

Radiopharmaceutical: ☐ Yes ☐ No

Nanotechnology: ☐ Yes ☐ No

ATMP classification (provide ATMP classification in Annex 3, if applicable):

Contains GMO: ☐ Yes ☐ No

Description of ATMP finished product (precise):

ATC Classification:

Therapeutic indication:

Has the product been granted eligibility to PRIME? ☐ Yes ☐ No

Other relevant information on the product:

Medical Device(s) (integral or as delivery device or ("companion") diagnostic device):
☐ Yes ☐ No

If 'Yes, complete all sections. If more than one medical device, repeat the whole section per medical device

Name of Medical Device:

Description device:

The device has CE Mark: ☐ Yes ☐ No

The device has been assessed by a Notified Body (NB): ☐ Yes ☐ No

If device has a CE Mark, complete this section:

Notified Body (NB) name:

Address (Line 1):

Line 2:

Line 3:

Line 4:

City:

Post Code:

Country:

NB Contact Person:

Title:

Last Name:

First Name:

Address (Line 1):

Line 2:

Line 3:

Line 4:

City:

Post Code:

Country:

Telephone:

Fax:

Email:

Is there an Orphan designation for this product? ☐ Yes ☐ No

*If **'Yes',** complete this section. If more than one, provide all community register numbers.*

Number in the community register of Orphan Medicinal Products **:**

Scientific Advice provided (please provide copy in Annex 3): ☐ Yes ☐ No

Information on the Paediatric Investigation Plan

PIP Submitted:

If 'Yes', PIP procedure number (please also provide Annex 5 as mentioned above):

If 'No', Date of planned PIP submission:

Waiver:

TOPICS FOR POSSIBLE DISCUSSION AT PRE-SUBMISION MEETING

You only need to complete sections below if you have specific questions to ask.

Therefore, please delete each section (e.g. 1.1, 1.2) that you do not wish to discuss during the meeting.

When submitting your questions, please also provide the related information requested in italics or make reference to the background information (see pages 2-3 of this document).

1. QUALITY + GMP

1.1. Quality Development

Please provide details as part of Annex 1 to this form.

Please highlight key pharmaceutical aspects in relation to the product such as for example: ASMF, API synthetic scheme with starting materials labelled, cell line development and cell banking strategy, novel/non-standard processes/ novel expression system/ testing methodology, purification methods, viral removal steps, bioassay, novel/innovative formulation or technology (e.g. digital/devices), QbD elements/Design Space, Real Time Release Testing, continuous manufacturing, modeling (e.g. PBPK), bridging data (different manufacturing sites, formulations etc.), comparability data, statistical methods for the comparison of quality attributes, PMF aspects, deviation from guidelines, rationale for the New Active Substance claim if applicable, etc. (see also background information on pages 2-3).

Summary/listing of issues to be discussed:

1.2. GMP Inspections + Batch release in the EEA

See Q&A 'When can I expect a pre-authorisation GMP inspection and how are they conducted?' of the pre-authorisation guidance document

Regarding Mutual Recognition Agreements (MRA) with the EU, please see related information published on the EMA website.

Please provide a flow-chart indicating the sequence and activities of the different manufacturing sites involved in the manufacture of the drug product and drug substance, including batch release testing sites, and specify whether the production steps are synthetic, semi-synthetic or using biotechnology.

Summary/listing of issues to be discussed:

1.3. Active Substance Master File (ASMF) + Vaccine Antigen Master File (VAMF)

See Q&As 'How should I submit an active substance master file (ASMF)?' and 'What is the Community Vaccine Antigen Master File (VAMF) certification system?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

1.4. Plasma Master File (PMF)

See Q&A 'What is the Community Plasma Master File certification system?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

1.5. Genetically Modified Organisms (GMO)

See Q&A 'What should I submit if my medicinal product contains or consists of genetically modified organisms (GMOs)?' of the pre-authorisation guidance document

Please confirm understanding of consultation process with environmental competent authorities.

Summary/listing of issues to be discussed:

1.6. Materials of animal and/or human origin (TSE)

See Q&A 'What information should I provide if my medicinal product contains materials of animal and/or human origin or uses them in the manufacturing process?' of the pre-authorisation guidance document

Please provide the relevant completed TSE table.

Summary/listing of issues to be discussed:

1.7. Medical Devices

See Q&A 'Medical devices' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

1.8. Process Analytical Technology (PAT) + Design Space

See Q&A 'Can I apply for design space or process analytical technology (PAT) in my application?' of the pre-authorisation guidance document

Please provide a brief description of the proposed PAT or Design Space.

Summary/listing of issues to be discussed:

1.9. ATMPs

When applicable, please provide copy of the ATMP classification and ATMP certification (Annex 3).

Summary/listing of issues to be discussed:

2. NON-CLINICAL + CLINICAL + GLP + GCP

2.1. Non-Clinical Development

Please provide details as part of Annex 1 to this form.

Highlight specific non-clinical aspects relevant for human risk assessment/SmPC (e.g. conclusions from reproductive toxicity studies, genotoxicity, carcinogenicity).

Summary/listing of issues to be discussed:

2.1.1. Environmental risk assessment

See Q&A 'When do I have to submit an environmental risk assessment (ERA)?' of the pre-authorisation guidance document

Specify if the submitted ERA will include studies or a justification for not performing these, and related scientific basis.

Please provide details as part of Annex 1 to this form.

Summary/listing of issues to be discussed:

2.2. Clinical Development

Please provide details as part of Annexes 1, 4 and 5 to this form. **Summary/listing of issues to be discussed:**

2.3. GLP + GCP Inspections

See Q&As 'Which information do I need to provide in my marketing authorisation application regarding GCP inspections and GLP compliance?' and 'When can I expect a pre-approval GCP inspection and how are they conducted?' of the pre-authorisation guidance document

Please provide details:

- *GCP: a listing of the pivotal clinical trials + countries involved and most important clinical trial sites, which GCP standard used, details of inspections by regulatory authorities (who, where, when, outcome)*
- *GLP: A listing of the pivotal non-clinical study sites, details of inspections by regulatory authorities (who, where, when, outcome).*

Summary/listing of issues to be discussed:

3. PHARMACOVIGILANCE

3.1. Pharmacovigilance System

See Q&A 'What are the requirements for my pharmacovigilance system?' of the pre-submission authorisation document

Summary/listing of issues to be discussed:

3.2. Pharmacovigilance Inspections

Summary/listing of issues to be discussed:

3.3. EudraVigilance

See Q&A 'What is EudraVigilance? How will it apply to my marketing authorisation?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

3.4. Risk Management Plan

See Q&As 'Risk management plan (RMP)' of the pre-authorisation guidance document

Please provide the draft RMP elements: safety specification, pharmacovigilance plan and risk minimisation measures.

Summary/listing of issues to be discussed:

4. REGULATORY + PROCEDURAL

4.1. Eligibility for the Centralised Procedure

See Q&As 'Is my medicinal product eligible for evaluation under the centralised procedure?' and 'How and when should the eligibility request be sent to EMA?' of the pre-authorisation guidance document

Please provide a draft eligibility request. [For generic/hybrid applications of a national/MRP authorised product, the draft eligibility request should relate to Article 3(2) of the Regulation.]

Summary/listing of issues to be discussed:

4.2. Legal Basis of the Application

See Q&A 'What will be the legal basis for my application?' of the pre-authorisation guidance document and the European Commission Notice to Applicants, Volume 2A, Chapter 1 (http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2013-06_en.pdf)

In addition to the general requirements for applications submitted under Article 8(3) of the Regulation, for the applications listed below please provide:

- For **generic, hybrid and similar biological** medicinal products ("bio-similar") applications:
  - *Full details on the reference product(s) should be provided under section 1.4.2/1.4.3/ 1.4.4 of the Module 1.2 Application Form.*
  - *Expiry date of the data exclusivity period of the reference medicinal product:<insert date>*
  - *Please attach a comparative table of the SmPC of the reference product and the proposed SmPC for the generic/hybrid/biosimilar product.*
  - *Please complete the Appendix to this form, addressing specific issues to be discussed for generic/hybrid/biosimilar applications.*
  - *Please complete the "overview of the chosen reference product for comparability" table (see the Appendix to this form) – for biosimilar applications only.*
- *For **informed consent** applications:*
  - *Full details on the authorised product should be provided under section 1.4.7 of the Module 1.2 Application Form.*
- *For **fixed combination** applications:*
  - *Full details on the authorisation status of the individual components should be provided.*
- *For **well-established use** applications:*
  - *Details on the first date of authorisation of the substance in EU should be provided.*
  - *Please attach a draft WEU justification.*

Summary/listing of issues to be discussed:

4.3. Paediatric Development

See Q&As 'What is an application for a paediatric use marketing authorisation (PUMA)?' and 'Do I need to address any paediatric requirements in my application? of the pre-authorisation guidance document

Please provide the draft PIP compliance document and Annex 6 (see pages 2-3 of this document).

Summary/listing of issues to be discussed:

4.4. Orphan medicinal product(s) information

See Q&As 'What aspects should I consider if my medicinal product has been designated as an orphan medicinal product at the time of submission of my application?', 'What aspects should I consider if the designation for my orphan medicinal product is still pending at the time of submission of my application for marketing authorisation?', 'What aspects should I consider if there are other orphan medicinal products for a condition related to my proposed therapeutic indication?', 'What aspects should I consider if my medicinal product is considered similar to an orphan medicinal product?' and 'What is the procedure for assessment similarity and, where applicable, derogation report vis-à-vis authorised orphan medicinal products?' of the pre-authorisation guidance document

4.4.1. Orphan designated substances

Please specify if orphan designation has been applied for this medicinal product and if it is based on 'significant benefit' criteria.

Summary/listing of issues to be discussed:

4.4.2. Information relating to orphan market exclusivity

Please specify if any medicinal product has been designated and authorised as an orphan medicinal product for a condition relating to the proposed therapeutic indication.

Summary/listing of issues to be discussed:

4.5. Legal Status

See Q&A 'What legal status can I obtain for my medicinal product?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

4.6. Accelerated review

See Q&A 'Is my product eligible for an accelerated assessment?' of the pre-authorisation guidance document

Please provide a draft justification for the accelerated review request.

For applications for which accelerated assessment is to be proposed, please provide the following information required for early identification of a need for pre-authorisation inspections:

- *For all manufacturers to be included in the planned dossier:*
  - *name and address of the manufacturer*
  - *short description of activities performed by the manufacturer*
  - *compliance history of the manufacturing site*
  - *confirmation of inspections readiness of the manufacturer*
- *The list of all the pivotal clinical studies (protocol number and title) and for each pivotal study:*
  - *the study synopsis (or a mature draft with information at least on the design and conduct of the study)*
  - *a short discussion of the GCP compliance status (listing any GCP non-compliance identified, any breach of GCP, providing information on any site excluded including the reasons etc.)*
  - *list of investigators and their addresses*
  - *number of subjects enrolled at each site*
  - *list of GCP inspections conducted/planned by any regulatory authority (indicating the site inspected/to be inspected, the date of inspection and the regulatory authority involved). Alternatively, a confirmation that no inspections had been requested nor taken place and that no inspections are planned*

Summary/listing of issues to be discussed:

4.7. Multiple applications for the same medicinal product

See Q&A 'What should I do if I want to submit multiple applications for the same medicinal product?' of the pre-authorisation guidance document

Please provide a draft justification for the multiple applications.

Summary/listing of issues to be discussed:

4.8. Conditional MA + Exceptional Circumstances

See Q&As 'Could my application qualify for a conditional marketing authorisation?' and 'Is my medicinal product eligible for approval under exceptional circumstances?' of the pre-authorisation guidance document

Please provide a draft justification for the conditional approval or approval under exceptional circumstances.

Summary/listing of issues to be discussed:

4.9. Data Exclusivity/Market protection

See Q&A 'What is the period of protection for my medicinal product?' of the pre-authorisation guidance document

Please provide a draft justification for requesting a '+1' for a new indication or for a legal status switch.

Summary/listing of issues to be discussed:

4.10. Small and Medium-Sized Enterprises

See Q&A 'What special support is available for micro, small and medium-sized enterprises (SMEs)?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

5. PRODUCT INFORMATION

5.1. SmPC guideline + QRD Templates

See SmPC guideline and annotated QRD template, and further detailed guidance provided on the Agency webpage on Product information requirements

Summary/listing of issues to be discussed:

5.2. Expression of strength

See QRD recommendations on the expression of strength

Summary/listing of issues to be discussed:

5.3. Labelling exemptions

See Exemptions to labelling and package-leaflet obligations

Summary/listing of issues to be discussed:

5.4. Mock-ups and Specimens

See Q&A 'When should I submit mock-ups and/or specimens?' of the pre-authorisation guidance document

Please provide details and include a draft mock-up (if relevant for the discussion and if available).

Summary/listing of issues to be discussed:

5.5. Consultation with target patient groups

See Q&A 'When and how should I submit information on user consultation?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

5.6. Linguistic review

See Q&A 'What is the QRD review of the product information?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

5.7. ATC + INN

See Q&A 'How are ATC codes and international non-proprietary names (INN) applied within the centralised procedure?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

5.8. Braille on outer packaging

See Q&A 'Do I need to include Braille on the packaging of my medicinal product?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

5.9. (Invented) Name

See Q&A 'How will I know if the proposed (invented) name of my medicinal product is acceptable from a public health point of view?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

6. TRANSPARENCY

See related information on the EMA website.

6.1. Publication of information on the application and procedure outcome

See Guide to information on human medicines evaluated by EMA available on the EMA website

Summary/listing of issues to be discussed:

6.2. Publication of Clinical Data – Policy 070

See related information on the EMA website including guidance to industry.

Summary/listing of issues to be discussed:

7. ADMINISTRATIVE

7.1. Application fees

See Q&As 'What fee do I have to pay?', 'What definition of strength is used for the calculation of fees?' and 'When could a fee waiver/fee reduction be granted?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

7.2. Dossier submission requirements

See Q&As 'When should I submit my marketing authorisation application?' and 'How and to whom should I submit my dossier?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

7.3. Dossier format (incl. electronic submission)

See Q&As 'How and to whom should I submit my dossier?' and 'How are initial marketing authorisation applications validated at EMA?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

7.4. Application assessment timetable

See Q&A 'How long does it take for my application to be evaluated?' of the pre-authorisation guidance document

Summary/listing of issues to be discussed:

8. OTHER

In case you wish to obtain guidance on any other topic, please include your question(s) in the relevant sections 1-7 or below with relevant background information in the appropriate annex.

Summary/listing of issues to be discussed:

ADDITIONAL TOPICS TO BE ADDRESSED IN CASE OF GENERIC, HYBRID OR BIO-SIMILAR APPLICATIONS

9. Special issues for Generic applications under Article 10 (1) (if applicable)

- Is the **active substance** the **same in terms** of salt, esters, ethers, isomers, mixtures of isomers, complexes or derivatives than the reference medicinal product?

If not, please provide details:

- If **excipients** are different from the reference medicinal product, are there any **excipients** included that require **special safety warnings** in the product information compared to the reference medicinal product?

If yes, please provide details:

- Are there any **impurities** above the qualification threshold?

If yes, please provide details:

- Please provide an **overview table**, listing all studies/trials (incl. BE studies) indicating the product name, strength, pharmaceutical form, MA number, country of manufacturing of the finished product, country of batch release site, batch number, expiry date of the product used.

Summary/listing of issues to be discussed:

10. Special issues for hybrid applications under Article 10(3) (if applicable)

- Difference(s) compared to the reference medicinal product:

☐ Changes in the active substance(s)

☐ Change in therapeutic indication(s)

☐ Change in strength (quantitative change to the active substance(s))

☐ Change in pharmaceutical form

☐ Change in route of administration

☐ Where BE cannot be demonstrated through BA studies

Please indicate which of the above applies and provide background information/details in the relevant Annexes.

Summary/listing of issues to be discussed:

11. Special issues for bio-similar applications under Article 10(4) (if applicable)

- Please provide an **overview table of the chosen reference medicinal product** used throughout the comparability programme for quality, safety and efficacy studies during the development of the similar biological medicinal product (using template below)

Summary/listing of issues to be discussed:

- Are there **any difference(s)** compared to the reference medicinal product?

If yes, please identify change

☐ change(s) in the raw material(s)

☐ change(s) in the manufacturing process(es)

☐ change in therapeutic indication(s)

☐ change in pharmaceutical form(s)

☐ change in strength (quantitative change to the active substance(s))

☐ change in route of administration(s)

☐ other

Summary/listing of issues to be discussed:

OVERVIEW OF THE CHOSEN REFERENCE PRODUCT FOR COMPARABILITY

Applicant's product details

Name of applicant:	
Product Name, Strength, Pharmaceutical Form:	

Overview of the chosen EU reference medicinal product used in the quality comparability exercise

Reference Product Name **Strength, Pharmaceutical Form**	**Marketing Authorisation number in EU (Specify country)**	**Country of Manufacture of the finished medicinal product**	**Country of Batch Release Site in EEA**	**Comment**

Overview of the chosen reference medicinal product used in the non-clinical comparability exercise

Reference Product Name Strength, Pharmaceutical Form	**Marketing Authorisation number in EU (Specify country)**	**Country of Manufacture of the finished medicinal product**	**Country of Batch Release Site in EEA**	**Study No[1]**	**Comment**

Overview of the chosen reference medicinal product used in the clinical comparability exercise

Reference Product Name Strength, Pharmaceutical Form	**Marketing Authorisation number in EU (Specify country)**	**Country of Manufacture of the finished medicinal product**	**Country of Batch Release Site in EEA**	**Study No[2]**	**Comment**

[1] Short mention of the nature of the study, e.g. PK, PD, toxicology
[2] Short mention of the nature of the study, e.g. PK, PD, toxicology