Application for a Drug-Device Consultation

This application form is to be used for an application for a **scientific opinion** on an ancillary medicinal substance used in a medical devicesubmitted to the HPRA in accordance with Directive 93/42/EEC, as amended.

**A combined form is acceptable for a range of strengths or concentrations of the ancillary medicinal substance and for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance from the same manufacturer (give information successively, where appropriate)**.

**DECLARATION and SIGNATURE**

**Name of device:**

**Ancillary medicinal substance(s):**

**Strength/Concentration of medicinal substance(s):**

**Presentation of medicinal substance(s) as part of the device:**

*(e.g. is it coated on device etc.)*

**Notified body:**

**Person authorised for communication,**

**on behalf of the notified body\*:**

**Applicant for device approval:**

I hereby request a consultation with the HPRA concerning the medicinal substance(s) integrated in the above mentioned device. I declare that, for this product no application for consultation has been submitted to any other medicines authority and no consultation procedure is ongoing.

It is hereby confirmed that all existing data which are relevant to the quality, safety and usefulness of the ancillary medicinal substance(s) have been supplied in the dossier and that all required headings have been addressed.

I declare that fees have been paid according to the details provided in the HPRA *Guide to Fees* (*attach fee application form and proof of payment*).

On behalf of the notified body:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature(s)

Name      Function      Place and date (dd-mm-yy)

*\* Note: please attach letter of authorisation for communication/signing on behalf of the notified body in annex 5.1.*

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1. TYPE OF APPLICATION
   1. This application concerns

Initial consultation on an authorised ancillary medicinal substance being used for an established purpose, where the medicinal substance from the specified manufacturer has not been evaluated by any member state of the EEA (or the EMA) in connection with a previous marketing authorisation and/or a previous successful notified body consultation

**OR**

Initial consultation on an authorised ancillary medicinal substance being used for an established purpose from a known source (i.e. where the medicinal substance from the specified manufacturer has been evaluated by an EEA member state (or the EMA) or in connection with a previous marketing authorisation and/or a previous successful medicines authority consultation)

Previous authorisation/consultation:

Authorised medicinal product (complete section 4.1)

Medical device incorporating the medicinal substance (complete section 4.1)

1. APPLICATION PARTICULARS
   1. Description of the ancillary medicinal substance(s)
      1. Name of the ancillary medicinal substance(s)

*Note: Only one name should be given in the following order of priority: INN, Ph. Eur., National Pharmacopoeia, common name, scientific name; the active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant*

* + 1. Intended purpose of the ancillary medicinal substance(s) in the device (usefulness /reason for addition to device)

* + 1. Strength and concentration and presentation(s) of the ancillary medicinal substance(s)

Strength/Concentration:

Presentation(s):

* 1. Description of the medical device
     1. Proposed (invented) name of the medical device incorporating the ancillary medicinal substance(s)

* + 1. Short description of device and its intended purpose

* + 1. Route of administration(use current list of standard terms - European Pharmacopoeia where applicable)

* + 1. Packaging components, including description of material fromwhich it is constructed (Use currentlist of standard terms - European Pharmacopoeia where applicable)

**For each type of pack give:**

* + - 1. Package size(s):

* + - 1. Proposed shelf life (unopened):

* + - 1. Proposed device lifetime (once opened/in use):

* + - 1. Proposed storage conditions:

* + 1. Claims made in drug-device product information (Please state claims as made in product information, including any additional claims relating to the ancillary medicinal substance(s))

* 1. Notified body, Contact person, Applicant for device approval
     1. Notified body:

Name:

Address:

Country:

Identification number:

Telephone:

Telefax:

E-mail:

* + 1. Person/company authorised for communication on behalf of the notified body during the procedure:

Name of contact\*:

Address:

Country:

Telephone:

Telefax:

E-mail:

\*If different to 2.3.1 above, attach letter of authorisation (Annex 5.1)

* + 1. Applicant for device approval:

Name:

Address:

Country:

Telephone:

Telefax:

E-mail:

* 1. Manufacturers
     1. Manufacturer(s) of the ancillary medicinal product(s) or ancillary medicinal substance(s)

*For medicinal products (pre-obtained mixture of active ingredient(s) plus excipients) used as ancillary substance, complete all sections.*

*For active substances used as ancillary substances, Sections 2.4.1.1 and 2.4.1.2 do NOT need to be completed.*

* + - 1. Authorised manufacturer(s) (or importer) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC as amended

Name of company:

Address:

Country:

Telephone:

Telefax:

E-mail:

Manufacturing Authorisation number:

Attach copy of manufacturing authorisation(s) (Annex 5.2)

Attach justification if more than one manufacturer responsible for batch release is proposed (Annex 5.3)

* + - * 1. Contact person in the EEA for product defects and recalls, as defined in Article 79 of Directive 2001/83/EC as amended: *(for previously authorised medicinal products only)*

Name:

Address:

Country:

24H contact telephone number:

Telefax:

E-mail:

2.4.1.1.2 Batch control/Testing arrangements

Site(s) in EEA or in countries where an MRA or other Community arrangements apply where batch control/testing of medicinal product takes place (if different from 2.4.1.1) as required by Article 51 of Directive 2001/83/EC as amended:

Name of the company:

Address:

Country:

Telephone:

Telefax:

E-mail:

Brief description of control test(s) carried out by the laboratories concerned:

* + - 1. Manufacturer(s) of the ancillary medicinal product and site(s) of manufacture:

(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the ancillary medicinal product)

Name:

Company name:

Address:

Country:

Telephone:

Telefax:

E-mail:

Brief description of functions performed by manufacturer of dosage form/assembler, etc.:

Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 5.4).

**If the manufacturing site is in the EEA**

- Manufacturing authorisation number:

Attach manufacturing authorisations required under Article 40 of Directive 2001/83/EC as amended (Annex 5.2).

- Name of qualified person:

(if not mentioned in manufacturing authorisation)

**If the manufacturing site is outside the EEA**

Where Mutual Recognition Agreement or other Community arrangements apply, attach equivalent of manufacturing authorisation (Annex 5.2).

Has the site been inspected for GMP Compliance by an EEA medicines authority or by a medicines authority of countries where MRA or other Community arrangements apply within the terms of the agreement?

no  yes

If yes, please provide in Annex 5.5 for each site a statement from the

medicines authority which carried out the inspection, including:

* last GMP inspection date
* name of medicines authority which carried out the inspection
* category of products and activities inspected
* outcome: GMP compliant:  no  yes

Has the site been inspected for GMP Compliance by any other medicines authority including those of countries where MRA or other Community arrangements apply but not within the respective territory?

no  yes

If yes, please provide in Annex 5.5 for each site a statement from the

medicines authority which carried out the inspection, including:

* last GMP inspection date
* name of the medicines authority which carried out the inspection
* category of products and activities inspected
* outcome: GMP compliant:  no  yes
  + - 1. Manufacturer(s) of the ancillary active substance(s) and site(s) of manufacture.

*Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Brokers or supplier details alone are not acceptable.*

Substance:

Name:

Address:

Country:

Telephone:

Telefax:

E-mail:

Brief description of manufacturing steps performed by manufacturing site:

Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 5.4).

For each active substance, attach a declaration stating that the active substance manufacturer(s) referred to in Section 2.4.1.3 operates in compliance with the detailed guidelines on good manufacturing practice for starting materials. In addition, where applicable, attach a declaration from the Qualified Person of the manufacturer in Section 2.4.1.1 and from the Qualified Person of the manufacturing authorisation holder(s) listed in Section 2.4.1.2 where the active substance is used as a starting material (Annex 5.10).

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

no  yes

If yes,

substance:

name of the manufacturer:

reference number:

date of last update (*yyyy-mm-dd*):

Provide copy in Annex 5.6.

Is an Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?

no  yes

If yes,

substance:

name of the manufacturer:

reference number for EMA / medicines authority:

date of submission (*yyyy-mm-dd*):

date of last update (*yyyy-mm-dd*):

Attach letter of access for the HPRA (Annex 5.6) (See ‘Guideline on Active Substance Master File Procedure’ (CPMP/QWP/227/02)).

Attach copy of written confirmation from the manufacturer of the ancillary active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC as amended (Annex 5.7).

**Where an active substance manufacturer has been inspected by an EEA medicines authority:**

The following information should be provided in Annex 5.5 for each site:

last inspection date by an EEA medicines authority (yyyy-mm-dd)

name of medicines authority which carried out the inspection

type of inspection (pre/post-authorisation/special/re-inspection)

categories of ingredient and activities inspected

outcome:  positive  negative

* + - 1. If applicable, contract companies used for bioavailability or bioequivalence trials or used for the validation of medicinal substance manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:

Name:

Address:

Country:

Telephone:

Telefax:

E-mail:

Duty performed according to contract:

* + 1. Manufacturer of medical device:

Name of company:

Contact name:

Address:

Country:

Telephone number:

E-mail:

* 1. Qualitative and quantitative composition
     1. Qualitative and quantitative composition of the medical device in terms of the ancillary medicinal substance(s) or medicinal product:

Each device contains:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name(s) of medicinal substance(s)\* | Quantity | Unit | Reference/Monograph standard |
| **1** |  |  |  |  |
| **2** |  |  |  |  |
| **3** |  |  |  |  |
| **4** |  |  |  |  |
| **5** |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name(s) of other ingredient(s)\* | Quantity | Unit | Reference/Monograph standard |
| **1** |  |  |  |  |
| **2** |  |  |  |  |
| **3** |  |  |  |  |
| **4** |  |  |  |  |
| **5** |  |  |  |  |

*Note:* *\* only one name for each substance should be given in the following order of priority:   
 INN\*\*, Ph.Eur., National Pharmacopoeia, common name, scientific name*

*\*\* the medicinal substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant*

Details of any overages should not be included in the columns but stated below:

medicinal substance(s)

other ingredient(s)

* + 1. List of materials of animal and/or human origin contained or used in the manufacturing process of the ancillary medicinal substance or as other ingredients

**NONE**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Name | Function\*  AS OI R | Animal origin susceptible to TSE\*\* | Other animal origin | Human origin | Certificate of suitability for TSE (state number) |
| **1** |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |

\* AS= active substance, OI= other ingredients (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/culture medium (incl. those used in the preparation of master and working cell banks).

\*\* as defined in section 2 (scope) of the CHMP Note for Guidance.

If a Ph. Eur. Certificate of Suitability for TSE is available according to Resolution AP/CSP (99)4 of the Council of Europe attach it in Annex 5.8.

1. SCIENTIFIC ADVICE
   1. Was there formal scientific advice given by the CHMP for this ancillary medicinal substance/ product?

no  yes

If yes,

Date (*yyyy-mm-dd*):

Reference of the scientific letter:

Attach copy of the scientific letter (Annex 5.11)

* 1. Was there scientific recommendation(s) given by Member State(s) for this ancillary medicinal substance/ product?

no  yes

If yes,

Member State(s):       Date(s) (*yyyy-mm-dd*):

1. OTHER APPLICATIONS FOR THE SAME MEDICINAL SUBSTANCE

*Note: “same medicinal substance” means a Marketing Authorisation for a medicinal product or a medical device approval using the same medicinal substance* ***from the same manufacturer.***

* 1. Details of applications for the same medicinal substance in the EEA (including any application to the EMA)

Approval for a device containing the same medicinal substance

Marketing authorisation for the same active substance in a medicinal product

Authorised\*

Country:

Date of authorisation:

Trade name:

Authorisation number:

\*Attach marketing authorisation or device approval (Annex 5.9)

Pending

Country:

Date of submission:

Trade name:

Refused

Country:

Date of refusal:

Trade name:

Reason for refusal:

Withdrawn (by applicant before authorisation)

Country:

Date of withdrawal:

Trade name:

Reason for withdrawal:

Withdrawn (by applicant after authorisation)

Country:

Date of withdrawal:

Trade name:

Authorisation number:

Reason for withdrawal:

Suspended/revoked (by medicines authority)

Country:

Date of suspension/revocation:

Trade name:

Authorisation number:

Reason for suspension/revocation:

* 1. Details of applications for the same medicinal substance outside the EEA

Approval for a medical device containing the same medicinal substance

Marketing authorisation for the same medicinal substance in a medicinal product

Authorised

Country:

Date of authorisation:

Trade name:

Pending

Country:

Date of submission:

Trade name:

Refused

Country:

Date of refusal:

Trade name:

Reason for refusal:

Withdrawn (by applicant before authorisation)

Country:

Date of withdrawal:

Trade name:

Reason for withdrawal:

Withdrawn (by applicant after authorisation)

Country:

Date of withdrawal:

Trade name:

Authorisation number:

Reason for withdrawal:

Suspended/revoked (by medicines authority)

Country:

Date of suspension/revocation:

Trade name:

Authorisation number:

Reason for withdrawal/revocation:

1. ANNEXED DOCUMENTS (where appropriate)

**5.1** Letter of authorisation for communication/signing on behalf of the notified body.

**5.2** Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC as amended (or equivalent, outside of the EEA where MRA or other Community arrangements apply).

**5.3** Justification for more than one manufacturer responsible for batch release in the EEA.

**5.4** Flow-chart indicating the different sites involved in the manufacturing process of the ancillary medicinal substance / product.

**5.5** Statement from the medicines authority which carried out the inspection of the manufacturing site(s) or where applicable a summary of other GMP inspections performed in the last 3 years.

**5.6** Letter(s) of access to Drug Master File(s) or copy of Ph. Eur. Certificate(s) of suitability.

**5.7** Copy of written confirmation from the manufacturer of the ancillary active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC as amended.

**5.8** Ph. Eur. Certificate(s) of suitability for TSE.

**5.9** Marketing Authorisation(s) or device approval(s) in the EEA (a copy of the pages which give the authorisation/approval number, the date of authorisation/approval and the page which has been signed by the medicines authority/notified body will suffice) [c.f. Section 4.1].

**5.10** Declarations - For each active substance, attach a declaration stating that the active substance manufacturer(s) referred to in Section 2.4.1.3 operates in compliance with the detailed guidelines on good manufacturing practice for starting materials. In addition, where applicable, attach a declaration from the Qualified Person of the manufacturer in Section 2.4.1.1 and from the Qualified Person of the manufacturing authorisation holder(s) listed in Section 2.4.1.2 where the active substance is used as a starting material.

**5.11** Letter of scientific advice from CHMP.

**5.12** Proof of payment.

1. DOCUMENTATION CHECKLIST

One copy of each volume, securely bound but readily separable, with the documents in the order given below, clearly identified and separated from each other is required (Refer to HPRA Guide to Drug Device Consultations). In addition, a single electronic copy of the documentation should be provided.

**Volume 1 (Quality) Tick box**

Cover letter

Comprehensive table of content

Application form

Good manufacturing practice documentation

Product information and labelling

Quality summary (or expert report)

Quality overall summary (relevant parts)

Module 3: Quality

**Volume 2 (Non-clinical):**

Cover letter

Comprehensive table of content

Application form

Product information and labelling

Non-clinical overview (or expert report)

Tabular summaries for non-clinical studies

Non-clinical documentation following the headings

and data requirements of Section B.3 of the guideline

MEDDEV 2.1/3 rev. 2 [(a), (b), (h) – (o)].

**Volume 3 (Clinical):**

Cover letter

Comprehensive table of content

Application form

Product information and labelling

Explanation for classification

Verification of the usefulness of the medicinal substance

in the medical device

Clinical overview (or expert report)

Tabular summaries for clinical studies

Clinical documentation following the headings

and data requirements of Section B.3 of the guideline

MEDDEV 2.1/3 rev. 2 [(a), (b), (m) – (p)].