20 April 2022

EMA/579577/2022

European Medicines Agency

Application form

For a follow-up consultation procedure by a notified body on a companion diagnostic

Application form

This application form is to be used for a follow-up consultation for a **scientific opinion** on a companion diagnostic submitted to the European Medicines Agency (EMA), in the context of a procedure for a supplement to the EU technical documentation assessment certificate or a supplement to the initial EU type-examination certificate, in accordance with Regulation (EU) 2017/746 (IVDR).

Note: Please consult the ‘[Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-procedural-aspects-consultation-european-medicines-agency-notified-body-companion_en.pdf)’ (EMA/579577/2022).

**Declaration and signature**

Name of companion diagnostic: <Name>

Concerned medicinal products(s): See section 1.1.4.

Applicant (notified body) for companion diagnostic: <Name>

Person authorised for communication

on behalf of the notified body: <Name>

Companion diagnostic manufacturer: <Name>

It is hereby confirmed that the notified body (NB) has submitted the draft Summary of Safety and Performance (SSP) and the draft Instructions For Use (IFU), further to their latest review.

It is hereby declared that (*please tick the appropriate declarations*):

[ ]  There are no other changes than those identified in this application.

[ ]  The changes do not adversely affect the suitability of the companion diagnostic to the concerned medicinal product(s) as initially assessed by the notified body.

[ ]  Where applicable, all conditions as set for the follow-up consultation are fulfilled.

It is hereby confirmed that a written declaration from the companion diagnostic manufacturer confirming that they will pay to EMA the corresponding fees for this application according to the Union rules is attached herein.

It is hereby confirmed that the notified body has not charged the companion diagnostic manufacturer for the present application before EMA and that there is no double-charging in view of Article 46 of Regulation (EU) 2017/746.

Changes will be implemented from: Date: <DD Month YYYY>

On behalf of the notified body:

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

Signature(s)

Name: <Name>

Function: <Function>

Place and date <Place> <DD-MM-YYYY>

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1. Type of application

**Follow-up consultation on a companion diagnostic**

For this application:

| **(Lead[[1]](#footnote-1)) Rapporteur:**  | **<Name of CHMP/CAT member>[[2]](#footnote-2)**  |
| --- | --- |

1. Application particulars

2.1. Description of the companion diagnostic

2.1.1. Name of the companion diagnostic

| EMA number for this procedure | Name |
| --- | --- |
| <EMA product number {EMEA/H/D/0000/00/00/00}> | <Name> |

2.1.2. Short description of the companion diagnostic

<Text>

2.1.3. Current intended purpose of the companion diagnostics

<Text>

### 2.1.4. Information on the current concerned medicinal product(s)

Does this application involve more than one medicinal product?

[ ]  Yes Number of INN: <Text>

 Number of medicinal products for each INN: <Text>

[ ]  No

Is one or more of the concerned medicinal products an Advanced Therapy Medicinal product (ATMP)?

[ ]  Yes

[ ]  No

Name(s) of the medicinal product(s)/INN and authorisation number/EMA procedure number (if available):

| INN | Name of medicinal product | EMA number (*if available*) |
| --- | --- | --- |
|       |       |       |
|       |       |       |

2.1.5. Description of the changes to the companion diagnostic

[ ]  Changes concern (tick all changes applicable)

[ ]  Performance

[ ]  Intended use

[ ]  Suitability of the device in relation to the concerned medicinal product(s)

[ ]  Other

Precise scope and background of the changes[[3]](#footnote-3):

<Text>

| Present[[4]](#footnote-4)  | Proposed |
| --- | --- |
| <Text> | <Text> |

*If the change concerns suitability of the device with a new medicinal product, please provide below information on this concerned medicinal product:*

Is the concerned medicinal product an Advanced Therapy Medicinal product (ATMP)?

[ ]  Yes

[ ]  No

Name(s) of the medicinal product(s)/INN and authorisation number/EMA procedure number (*if available*):

| INN | Name of medicinal product | EMA number (*if available*) |
| --- | --- | --- |
|       |       |       |
|       |       |       |

2.2. Notified body, contact person, companion diagnostic manufacturer

2.2.1. Notified body

Name of notified body: <Name>

Contact person: <Contact person>

Address: <Address>

Address 2: <Address 2>

Country: <Country>

Telephone: <+XX XX XXXX XXXX>

E-mail: <E-mail address>

2.2.2. Person/company authorised for communication on behalf of the notified body during the EMA consultation procedure

Name of contact\*: <Contact person>

Address: <Address>

Address 2: <Address 2>

Country: <Country>

Telephone: <+XX XX XXXX XXXX>

E-mail: <E-mail address>

\*[ ]  If different to 1.3.1 above, attach letter of authorisation (Annex 2.1)

2.2.3. Companion diagnostic manufacturer

Name: <Name>

Address: <Address>

Address 2: <Address 2>

Country: <Country>

Telephone: <+XX XX XXXX XXXX>

E-mail: <E-mail address>

Has SME status been assigned to the companion diagnostic manufacturer by the EMA?

*Registering as an SME will qualify for a reduced consultation fee.*

 No

 Yes

 EMA-SME number: <Number>

 Date of expiry: <YYYY-MM-DD>

 [ ]  Attach copy of the ‘Qualification of SME status’ (Annex 3.2)

3. Annexed documents (where appropriate)

3.1 [ ]  Letter of authorisation for communication on behalf of the notified body.

3.2 [ ]  Copy of the ‘qualification of SME Status’.

3.3 [ ]  Instructions For Use (IFU)

3.4 [ ]  Summary of Safety and Performance (SSP)

3.5 [ ]  Written declaration from the companion diagnostic manufacturer confirming that they will pay to EMA the corresponding fees for the present application according to the Union rules.

1. In case of several medicinal products concerned by that companion diagnostic, a lead rapporteur will be appointed amongst Rapporteur of these medicinal products. [↑](#footnote-ref-1)
2. CHMP = Committee for Medicinal Products for Human Use; CAT = Committee for Advanced Therapies [↑](#footnote-ref-2)
3. Include a description and background of all proposed changes. [↑](#footnote-ref-3)
4. Specify the precise present and proposed wording or specification in the draft Instructions For Use (IFU) and the draft Summary of Safety and Performance (SSP). [↑](#footnote-ref-4)