20 April 2022

EMA/579578/2022

European Medicines Agency

Application form

For initial consultation by a notified body on a companion diagnostic

Application form

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

A single application form should be used if the companion diagnostic concerns several medicinal products falling under the concerned EMA consultation.

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/579578/2022).

**Declaration and signature**

Name of companion diagnostic: <Name>

Concerned medicinal product(s): See section 2.1.4.

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 confirmed that the notified body submits this application in the context of an assessment of conformity of the above referred companion diagnostic upon request of the companion diagnostic manufacturer.

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.

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

**Initial consultation on a companion diagnostic**

For this application:

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

1. Application particulars
   1. Description of the companion diagnostic
      1. Proposed (trade) name of the companion diagnostic/range of companion diagnostic in the EU/EEA

<Name>

If different (trade) names are proposed, these should be listed below (*please add row to the table as needed*):

| Member State | Name | Serial number *(if available)* |
| --- | --- | --- |
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* + 1. Short description of the companion diagnostic

<Text>

* + 1. Intended purpose of the companion diagnostic

<Text>

According to the information given above is the companion diagnostic used for the identification, before and/or during treatment, of patients who are:

a) most likely to benefit from the corresponding medicinal product?

Yes

No

b) likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product?

Yes

No

### 2.1.4. Information on the 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. Type of development for the companion diagnostic (CDx)

**Co-developed device** (to be the (certified) CDx):

[*A device that is co-developed with a medicinal product in the framework of a pivotal clinical trial with the concerned medicinal product or in a bridging study assessing the concordance of the CDx and the device used in the pivotal clinical trial of the corresponding medicinal product.*]

**Follow-on device** (to be the (certified) CDx):

[*Where a medicinal product was authorised for use with a CDx, a follow-on CDx is a device that seeks the same therapeutic indication in its intended use as the original CDx. The follow-on CDx targets the same biomarker but is not developed in parallel with the clinical development programme of the medicinal product and it is not necessarily based on the same technology as the original CDx.*]

***Details of the other medical device(s) used in the concordance study(ies)***

Name of the medical device:

Is it a certified companion diagnostic (in accordance with IVDR)?

Yes

Competent authority with whom the consultation took place: <Text>

No

Short description of the medical device: <Text>

**Device already marketed under Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD)**

*[A device marketed under Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) that transitions to the IVDR as a CDx. In addition, tick which of the two scenarios above apply to this CDx]*

* 1. Notified body, contact person, companion diagnostic manufacturer
     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>

* + 1. 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 2.2.1 above, attach letter of authorisation (Annex 3.1)

* + 1. 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)

1. 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)