31 July 2023

EMA/781233/2021

European Medicines Agency

Letter of intent for the submission of a consultation to the European Medicines Agency by a notified body on a companion diagnostic in accordance with Regulation (EU) 2017/746

Note: A single letter of intent should be used if the companion diagnostic concerns several medicinal products falling under the EMA consultation.

Please consult the ‘Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics’.

Application details

Name of companion diagnostic: <Name>

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

Contact person authorised for communication

on behalf of the notified body: <Name>

Companion diagnostic manufacturer: <Name>

Short description of the companion diagnostic

<Text>

Intended purpose of the companion diagnostic

<Text>

Information on the concerned medicinal product(s)

[ ]  The corresponding medicinal product (or one of them if multiple) was submitted and/or authorised through the centralised procedure.

Does this application involve more than one medicinal product?

[ ]  Yes Number of INN: <Text>

 Number of medicinal products for each INN: <Text>

[ ]  No

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

| **Active substance(s)**  | **Name of medicinal product** | **EMA number (*if available*)** |
| --- | --- | --- |
| <INN/common name> | <product/invented name> | <EMEA/H/C/XXXXXX> |
|  |  |  |
|  |  |  |

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

[ ]  Yes

[ ]  No

[ ]  **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 qualifies as a CDx under the IVDR.]*

[ ]  **Device first marketed under Regulation (EU) 2017/746 (IVDR)**

Notified body, contact person, companion diagnostic manufacturer

Notified body (Applicant)

Name: <Name>

Contact person: <Contact person>

Address: <Address>

 <Address 2>

Country: <Country>

Telephone: <+XX XX XXXX XXXX>

E-mail: <E-mail address>

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>

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 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>

|  |
| --- |
| <YYYY-MM-DD> |

**Intended submission date[[1]](#footnote-1):**

On behalf of the notified body:

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

Signature(s)

Contact person consultation procedure: <Name>

Function: <Title>

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

To submit your request, raise a ticket via [EMA Service Desk](https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=ed0cc4d81b4fe1508ad7edf2b24bcbd4), selecting the tab “Business Services”, category “Human Regulatory”. The subcategory to be selected is “Pre-Submission Phase - Human”, followed by the sub-option: “Companion Diagnostics Request”. This letter of intent should be attached to the request.

If you do not have an EMA Account, you may create one via the [EMA Account Management portal](https://register.ema.europa.eu/identityiq/login.jsf). For further information or guidance about how to create an EMA Account reference the guidance "[Create an EMA Account](https://register.ema.europa.eu/identityiq/help/selfregister.html)".

1. it is expected that the consultation will be started once the notified body has performed their review as part of the conformity assessment of the device and the draft SSP and IFU have been updated accordingly. [↑](#footnote-ref-1)