15 July 2019

EMA/624103/2019

Patient Health Protection

Consultation for a medicinal product for human use containing or consisting of a GMO

<Product name> <INN> <emea number>

In accordance with Article 6 of Council Regulation (EEC) No. 726/2004, necessary consultations will be held with the Competent Authorities (CAs) established under Council Directive 2001/18/EC with respect to the evaluation of environmental aspects.

The <committee for the evaluation of medicinal products (CHMP) / committee for advanced therapies (CAT)>, has appointed the following Rapporteurs responsible for the evaluation of the application:

<CHMP/CAT> Rapporteur: <name>

The evaluation will proceed in accordance with the following timetable:

Evaluation timetable (first phase)

|  |  |  |
| --- | --- | --- |
| **Date** | **Day** | **Activities** |
| ../../.. | Day 1 | EMA informs the CAs of the procedure start and provides the consultation timetable for planning purposes. |
| ../../.. | Day 80 | EMA sends to the CAs the section of the Day 80 assessment report on module 1.6.2, the module 1.6.2 and a consultation form. |
| ../../.. | Day 110 | The consulted CAs provides their comments to the Rapporteur and EMA. |
| ../../.. | Day 114 for CAT/ Day 120 for CHMP | Rapporteur and Committee take due account of the comments from the CAs for the List of Questions (LoQ)  The LoQ is adopted and sent to the Applicant.  The Agency sends the overview of comments received to the consulted CAs. |
|  | Clock stop | The evaluation is suspended for up to 6 months |

Second phase evaluation

In exceptional cases, it may be possible that the responsible committee requires additional input from the CAs after the day 120.

Should that be the case, the CAs will be sent the specific questions of the responsible committee after day 150, together with the deadline for the response.

Following the Commission Decision with respect to the granting of a marketing authorisation for the medicinal product, EMA publishes the European Public Assessment Report (EPAR) and EMA send a link to the final EPAR, SmPC and PL to the consulted CAs.