4 March 2019

EMA/72240/2008

Request for confirmation of the applicability of the Agency’s decision on class waivers

## <Request number> – EMA to add

Background information on the product

|  |  |
| --- | --- |
|  | **Applicant to complete all information into this column:** |
| Name (or corporate name) of applicant |  |
| Address of applicant |  |
| Name of contact person authorised by the applicant to communicate with EMA regarding this request |  |
| Email address of contact person |  |
| Telephone number of contact person |  |
| Name of active substance / INN | Applicant <agrees>/<disagrees> that the name of the active substance as shown above will be included in the published documents and treated as non-confidential. |
| Proposed non-confidential name *(mandatory if the applicant considers the name of active substance as confidential)* |  |
| Product name *(if available)* |  |
| Type of product |  |
| Class (condition) waiver you are referring to |  |
| Date of the Agency’s decision on class waiver | <CW/1/2011 of 19 December 2011> *only applicable until 27 July 2018*  OR  <CW/0001/2015 of 23 July 2015> |
| Proposed or authorised indication(s) in adults  *(For authorised products, please provide the exact authorised indication(s) as stated in the latest SmPC.)* |  |
| Therapeutic area |  |

Mechanism of action / target:

(Please provide a brief summary on the mechanism of action and the target.)

<Text>

<Text>

<Text>

Applicability of the published class waiver(s) to your indication(s):

(Please provide a short justification. This could include references to literature and/or disease classifications if available.)

<Text>

<Text>

<Text>

Potential use of the product in areas other than the proposed condition:

(If available, please provide a short summary on any potential or experimental use of your product in other therapeutic areas (paediatric or not) you are aware of, or are planning to investigate.)

<Text>

<Text>

<Text>

Annexes

Please annex any documents that may be relevant to your request, such as investigator brochure, etc.

**Review** *– PDCO/EMA use*

**Paediatric Co-ordinator:**

<The indication <text> *is considered to be covered by the EMA decision (Decision number), therefore discussion and an outcome adoption during upcoming PDCO plenary it is recommended.> Select this option if no doubt; there will be no PDCO Rapp appointed.*

*<<It is uncertain if the indication <* text *> is covered by the EMA decision (Decision number) > or <It is considered that the indication <* text *> is* ***not*** *covered by the EMA decision (Decision number)> therefore appointment of PDCO Rapporteur needed. Select this option if doubt or negative outcome is anticipated; there will be PDCO Rapp appointed prior to the PDCO discussion and outcome adoption.*

<Identified disease(s) in which there could be a therapeutic benefit from this medicine in the paediatric population is/are (when applicable): <text>.>

*If Rapp is needed, otherwise delete*

**Rapporteur:**

<text>

Paediatric Committee discussion and conclusion

|  |
| --- |
| **PDCO discussion and outcome**:  Medicinal product  Condition/indication  *<The applicability of the class waiver as referred to in the EMA decision <Decision number> to the planned therapeutic indication(s) <was/was not> confirmed.*  *Other potential paediatric interests of this medicine suggested by PDCO: <text>.*  *<Note, only applicable until 27 July 2018: in case of removal from the list of class waivers listed in the Agency’s Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency’s Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.>* |