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<Doc ref.> [only at the time of CHMP adoption]

Committee for Medicinal Products for Human Use (CHMP) [only at the time of CHMP adoption]

<<Co->Rapporteur’s><Joint Rapporteurs’><CHMP> assessment report on the significance of pre-clinical tests or clinical trials in support of a change in the classification of a medicinal product from prescription to non-prescription in accordance with Article 74a of Directive 2001/83/EC

Invented name:

<International non-proprietary name:>or<Common name>

Procedure No. EMEA/H/C/0000/00/00/00

<Applicant><Marketing authorisation holder (MAH)>:

1. Introduction

In accordance with the provisions of Article 74a of Directive 2001/83/EC, the <Marketing Authorisation Holder (MAH)><Applicant> has applied for a one year of data exclusivity in the framework of the <product name> procedure (<procedure number>).

The request was based on the <MAH’s><Applicant’s> position that significant pre-clinical tests or clinical trials were carried out in relation to the change in the classification of <product name> from prescription to non-prescription.

1. Justification of significance of pre-clinical tests or clinical trials as presented by the <MAH><Applicant>
   1. Pre-clinical tests and/or clinical trials carried out in relation to the change of classification
   2. <Significance of pre-clinical tests>
   3. <Significance of clinical trials>
2. Assessment of the <MAH’s><Applicant’s> justification of significance of pre-clinical tests or clinical trials[[1]](#footnote-3)
   1. Significance of pre-clinical tests>
   2. <Significance of clinical trials>
3. Conclusion

Summarise position on the assessment of justifications under 3., i.e. grounds for acceptance/refusal of significance of pre-clinical tests and/or clinical trials.

In order to consider pre-clinical tests or clinical trials significant, they must be relevant and necessary to the change in classification.

1. Recommendation

The CHMP reviewed the data submitted by the <MAH><Applicant>, taking into account the provisions of Article 74a of Directive 2001/83/EC and the [Guideline on changing the classification for the supply of a medicinal product for human use](http://ec.europa.eu/health/files/eudralex/vol-2/c/switchguide_160106_en.pdf), and <does not> consider<s> <by consensus/ by a majority of x votes out of x> that significant <preclinical tests><and><clinical trials> have been carried out in relation to the change in the classification of <product name> from prescription to non-prescription.

1. In accordance with the [Guideline on changing the classification for the supply of a medicinal product for human use](http://ec.europa.eu/health/files/eudralex/vol-2/c/switchguide_160106_en.pdf), part 3. [↑](#footnote-ref-3)