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Committee for Medicinal Products for Human Use (CHMP)

Pradaxa

Dabigatran etexilate

Procedure no. EMEA/H/C/829/PSU/034

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Pradaxa, the scientific conclusions of PRAC are as follows:

The contraindication in lesion or condition at significant risk for major bleeding which is now in place for Pradaxa does not allow for medical judgement, especially with regard to the prevention of VTE in surgery indications where, for example, an AV malformation or an aneurysm should not necessarily exclude a patient from receiving one of the new anticoagulants. This concern was viewed in perspective of safety profile of Pradaxa during PSUR period and was acknowledged by PRAC (a decreasing trend of cumulative reporting rates for serious bleedings). Therefore, the contraindication about lesions and conditions is revised slightly allowing the prescribing physician some more room for clinical judgment on when to consider the listed lesions and conditions as absolute contraindications.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Pradaxa the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance dabigatran etexilate is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.