22 February 2018
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): botulinum toxin b

Procedure No. EMEA/H/C/PSUSA/00000428/201706

Period covered by the PSUR: 1 July 2014 – 30 June 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for botulinum toxin b, the scientific conclusions of CHMP are as follows:

At the time of the granting of the initial Marketing Authorisation, an additional risk minimisation measure (Health Care Professionals and Patient educational materials) was imposed for the important identified risks off-label use and toxin spread.

Having into consideration the poor response rate (1%) to the questionnaires, that the product is on the market for several years, the decrease in sales and patient exposure, as well as the low number of ADR reported, the PRAC recognises that, at this stage, routine risk minimisation measures and routine pharmacovigilance activities would be sufficient. Therefore, the educational materials are consequently discontinued and should be removed as a condition to the marketing authorisation.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for botulinum toxin b the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing botulinum toxin b is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.