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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): irbesartan

Procedure No. EMEA/H/C/PSUSA/00001782/201508

Period covered by the PSUR: 12 August 2012 to 11 August 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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 irbesartan, the scientific conclusions of CHMP are as follows:

76 cases of thrombocytopenia were detected. 2 of these cases presented positive re-challenge and a positive de-challenge was noted in 9 cases.

Time to onset was short (1 day to a few weeks) in 20 cases, long (from a few months to 8 years) in 11 cases and unknown in the rest of 45 cases.

4 cases were well documented and relevant. 32 cases were considered to have scarce information regarding underlying history and concomitant drugs, at least five of them have compatible chronology; but a causal association cannot be excluded in these cases.

Overall, the information coming from post-marketing experience, cases with short time to onset, compatible chronology, and information of de-challenge and re-challenge cases and the well documented reports, point towards a causal association.

It is noted that other Angiotensin Receptor Blockers has thrombocytopenia listed as Adverse Drug Reaction (ADR) in the Product Information, as well as irbesartan in the FDA product information.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing irbesartan are warranted.

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 irbesartan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing irbesartan 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.