EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): thyrotropin alfa

Procedure No. EMEA/H/C/PSUSA/00002940/201811

Period covered by the PSUR: 30 November 2015 To: 30 November 2018

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Scientific conclusions

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

Following review and characterisation of adverse event data acquired since 2011 regarding stroke, it is considered that the descriptive information included within section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Package Leaflet (PL) regarding this particular Adverse Drug Reaction (ADR), is no longer reflective of the clinical experience to date. For instance, this information specifies that cases have occurred in female patients. However, a number of cases (n=3, 21%) have been reported in male patients since the previous update in 2011. While it is acknowledged that a greater proportion of cases have occurred in female patients, this apparent disproportionality could be attributed to gender differences in the prevalence of thyroid cancer which would translate to a predominantly female patient population being treated with thyrotropin alfa and as such a higher reporting rate in this particular cohort. As specified by the MAH within the RMP for thyrotropin alfa (version 9.0), the age-standardised rate (ASR) of thyroid cancer is 6.1 per 100,000 females and 1.98 per 100,000 males. In addition, since the initial update regarding stroke in 2011, which was based on 2 serious cases, several serious cases (n=11), have been received, including three cases which are indicative of a causal association and two which are supportive. As a result, section 4.8 of the SmPC is updated to delete the information regarding stroke which is included within the description of selected adverse reactions. The package leaflet is updated accordingly.

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