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): rotigotine

Procedure No. EMEA/H/C/PSUSA/00002667/201702

Period covered by the PSUR: 16 Feb 2014 to 15 Feb 2017

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Scientific conclusions

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

Analyses of cases of diarrhoea suggested a chronological relationship and, therefore, the MAH was requested to conduct a Safety signal assessment report considering 'Diarrhoea' as a potential safety observation in the next PSUR. Nevertheless, the MAH has already conducted the SSAR and the signal was confirmed. The review seems to support the existence of a possible causal association between the exposure to rotigotine and the occurrence of diarrhea, based on the data from the cases in the safety database. Saturation of a biological system versus an idiosyncratic process is the likely potential mechanism by which rotigotine could cause diarrhea. Therefore, the MAH submitted, within this procedure, an updated product information to include the adverse reaction "diarrhoea" under SmPC section 4.8 and Package Leaflet section 4, with a frequency "not known".

Based on the above information, the PRAC considers that an updated of the product information to include the adverse reaction "diarrhoea" with a frequency not known was necessary.

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