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): measles / mumps / rubella vaccines (live, attenuated)

Procedure No. EMEA/H/C/PSUSA/00001937/201805

Period covered by the PSUR: 05 May 2015 to 04 May 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for measles / mumps / rubella vaccines (live, attenuated), the scientific conclusions of CHMP are as follows:

The MAH presented an analysis of reports with PT (preferred term) "Crying" From the data provided by the MAH "crying" was reported during clinical trials, post marketing source and literature report in paediatric population as an ADR.

In addition and as previously underlined from the first of June 2010 until the fifth of February 2016, the Dutch Pharmacovigilance Center (Lareb) received 327 reports of MedDRA® Preferred Term (PT) 'Crying' (preferred term) following immunization with the MMR vaccine. Exposure was estimated at 171,000 infants per year. In 297 reports a clear time to onset could be determined. 71% of the reports (212 of 297) concerned crying with a time to onset of more than 24 hours. The majority of the crying occurred 6 to 10 days after vaccination. This latency period appears to correspond with the time to onset of general malaise that often occurs after the MMR vaccination.

The MAH concluded that the review of both clinical trial and post-marketing data (including the EudraVigilance Data Analysis System (EVDAS)) for MMR, as well as a review of the literature, has not provided evidence to suggest a causal relationship for MMR and crying and therefore, a label update is not warranted at this time. The conclusion of the MAH is not endorsed by the PRAC. Therefore, based on the aforementioned information the PRAC recommends a variation in section 4.8 to add "Crying" with the frequency "uncommon".

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 measles / mumps / rubella vaccines (live, attenuated) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing measles / mumps / rubella vaccines (live, attenuated) 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.