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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): romiplostim

Procedure No. EMEA/H/C/PSUSA/00002660/201507

Period covered by the PSUR: 1 August 2014 to 31 July 2015

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During the PSUR reporting period a signal originated from the Marketing Authorisation Holder's (MAH) Product Complaints database where 9 product complaints regarding reconstitution and administration guideline were identified, indicating that the potential for confusion over vial overfill for Nplate exists. In relation to this concern the MAH performed a review of all available sources (safety database, clinical trial database, nonclinical data review, literature review…) where a total of 13 cases from post-marketing sources were identified. In addition, one case from a literature report was identified regarding the potential for confusion when preparing the solution for injection. In view of the available data, the PRAC recommends an update of the product information in order to clarify the vial overfill and how to reconstitute the product safely.

Therefore, in view of available data regarding romiplostim, the PRAC considered that changes to the product information were warranted.