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): asfotase alfa

Procedure No.: EMEA/H/C/PSUSA/00010421/201807

Period covered by the PSUR: 04 January 2018 to 03 July 2018

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## Scientific conclusions

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

The PRAC considers that based on a review of data available regarding immunogenicity wording in section 4.8 of the SmPC and the Package Leaflet concerning immunogenicity should be included to reflect that cases of antidrug antibodies in conjunction with reduced clinical efficacy of asfotase alfa have been reported. At present the data is limited in terms of the time to onset of such events and action which can be taken to mitigate against or resolve such events. In one case the patient restarted asfotase alfa following plasmapheresis and rituximab treatment, however there is insufficient data to support the inclusion of advice concerning a desensitisation regimen.

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