Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

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

Based on post-marketing data forty-four patients described as immunosuppressed or with a condition relevant to potential immunosuppression were cumulatively reported with adverse reactions associated with the treatment of methylaminolevulinate. As there is limited experience from post-authorisation exposure in treating actinic keratoses and Bowen's disease in transplant patients on immunosuppressive therapy, the PRAC considered necessary to update the product information with the current experience in the treatment of immunocompromised patients. In addition, the revised warning highlights the importance of close follow-up of immunocompromised patients exposed to photodynamic therapy treatment, taking into account the generally increased risk of squamous cell carcinoma development in this patient group.

The CMDh 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 methylaminolevulinate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing methylaminolevulinate is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing methylaminolevulinate are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that such marketing authorisations are varied accordingly.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.4

~~"There is no experience of treating Bowen´s disease in transplant patients on immunosuppressive therapy or in patients with a history of arsenic exposure."~~

There is limited experience from post-authorisation exposure in treating actinic keratoses and Bowen´s disease in transplant patients on immunosuppressive therapy. A close monitoring of these patients, with re-treatment if necessary is recommended in this population. There is no experience of treating Bowen´s disease in patients with a history of arsenic exposure.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	5 May 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	4 July 2018