

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 dexamfetamine, the scientific conclusions are as follows:

Based on review of safety data, the PRAC considered that a causal relationship between the use of dexamfetamine and the occurrence of Raynaud's phenomenon could not be excluded and therefore requests an update of the Summary of products characteristics of dexamfetamine containing products to insert this adverse drug reaction with the frequency not known. The Package Leaflet is updated accordingly.

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 dexamfetamine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexamfetamine 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 dexamfetamine are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

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 4.8

The following should be added under the SOC Vascular disorders with a frequency not known:

Raynaud's phenomenon

Package Leaflet

- Section 4

The following adverse reaction should be added under Side effects with frequency not known (frequency cannot be estimated from the available data):

Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon).

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	April 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	09 June 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	08 August 2018