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 dexlansoprazole, lansoprazole, the scientific conclusions are as follows:

During the reporting period, spontaneous cases and literature reports of visual hallucinations have been described in patients treated with lansoprazole, an event that is expected to have a very low incidence in the general population. Cumulatively, 20 cases of serious visual hallucinations have been identified including 5 cases with a clear positive dechallenge. In addition 15 non-serious cases of visual hallucinations have been received in patients treated with lansoprazole. With regards to dexlansoprazole, there have been 2 non-serious cases of visual hallucinations in patients reported cumulatively. Furthermore, a plausible mechanism has been postulated by Hanneken et al. 2013[1].

Based on the above information, the PRAC considers that an update of the product information to include the adverse reaction visual hallucinations with a frequency not known was necessary.

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 dexlansoprazole, lansoprazole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexlansoprazole, lansoprazole 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 dexlansoprazole, lansoprazole 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.

[1] Hanneken, A.M., N. Babai, and W.B. Thoreson, Oral proton pump inhibitors disrupt horizontal cell-cone feedback and enhance visual hallucinations in maculardegeneration patients. Invest Ophthalmol Vis Sci, 2013. 54(2): p. 1485-9.

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 adverse reaction should be added under the SOC Psychiatric disorders with a frequency not known (cannot be estimated from the available data):

Visual hallucinations

Package Leaflet

- Section 4

Not known: frequency cannot be estimated from the available data

Visual hallucinations

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	29 October 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	28 December 2017