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 hydroxyzine chloride / hydroxyzine pamoate and all fixed combination, hydroxyzine, the scientific conclusions are as follows:

In view of available data on weight increased from spontaneous reports including in some cases a close temporal relationship and taking into account the already established association of this adverse event with the parent compound cetirizine (hydroxyzine is metabolised into cetirizine), the PRAC considers that a causal relationship between hydroxyzine containing products and *weight increased* is at least a reasonable possibility. The PRAC concluded that the product information of hydroxyzine containing products should be amended 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 hydroxyzine chloride / hydroxyzine pamoate and all fixed combination, hydroxyzine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydroxyzine chloride / hydroxyzine pamoate and all fixed combination, hydroxyzine 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 hydroxyzine chloride / hydroxyzine pamoate and all fixed combination, hydroxyzine 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 **<u>underlined and in bold</u>**, deleted text ~~strike through~~)>

Summary of Product Characteristics

Section 4.8

The following adverse reaction(s) should be added under the SOC Investigations with a frequency unknown:

- **<u>Weight increased</u>**

Package leaflet

Section 4

The following mention should be added under side effects with frequency Not known (frequency cannot be estimated from the available data):

- **<u>Weight increased</u>**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position :	08 August 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07 October 2021