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 sumatriptan the scientific conclusions are as follows:

In view of available data on risks of "Pain trauma activated" and "Pain inflammation activated" from the literature and spontaneous reports including cases of both pain exacerbation in relation to trauma and cases of pain reactivation in relation to inflammatory diseases such as rheumatoid arthritis and colitis with a close temporal relationship, a positive de-challenge and re-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between sumatriptan and "Pain trauma activated" and "Pain inflammation activated" is possible.

In view of available data on the risk of "Dysphagia" from the literature and spontaneous reports including positive re-challenge cases with plausible time-to-onset, the PRAC concluded that there is sufficient evidence for a causal association between sumatriptan and dysphagia.

The PRAC concluded that the product information of products containing sumatriptan 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 sumatriptan the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing sumatriptan 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 sumatriptan 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 (Undesirable effects)

The following adverse reactions should be added under the SOC General disorders and administration site conditions with a frequency "not known":

"Pain trauma activated"
"Pain inflammation activated"

The following adverse reactions should be added under the SOC Gastrointestinal disorders with a frequency "not known":

"Dysphagia"

Package Leaflet

- Section 4 (Possible side effects)

The following adverse reactions should be added with frequency "Not known: frequency cannot be estimated from the available data":

"If you had a recent injury or if you have inflammation (like rheumatism or inflammation of the colon) you may experience pain or pain worsening at the site of injury or inflammation."

"Difficulty swallowing"

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	13 July 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 September 2020