

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 roxithromycin, the scientific conclusions are as follows:

In a MAH's review of eye disorder events several cases presented a compatible chronology following the use of roxithromycin; positive dechallenge has also been observed. Considering that ocular events are known for other macrolides (azithromycin, erythromycin), the PRAC agreed that visual impairment and blurred vision should be listed in paragraph 4.8 of the SmPC with the frequency "unknown" and in the corresponding paragraph of the PL. Considering the impact of these eye disorders on the ability to drive, the PRAC also agreed that an update to section 4.7 of the SmPC and the related paragraph of the PL is 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 roxithromycin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing roxithromycin 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 roxithromycin are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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 4.7

(...) Visual impairment and vision blurred may have an effect on a patient's ability to drive or operate machinery (section 4.8)

- Section 4.8

The following adverse reactions should be added under the SOC "**Eye disorders**" with a frequency unknown:

Visual impairment, blurred vision

Package Leaflet

- Driving and using machines

(...) Visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery.

- Possible side effects

Other side effects include:

Impairment of vision

Problems with your eye sight (blurred vision)

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	September 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 October 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 December 2017