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 nadifloxacin, the scientific conclusions are as follows:

Based on data from a post-marketing surveillance study carried out during the reporting period, the frequency categories for the adverse reactions erythema, application site burning, rash and urticaria have been estimated as uncommon for erythema, application site burning and rash (47, 36 and 27 cases respectively) and rare for urticaria (20 cases). The study included a total of 19.918 patients.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing nadifloxacin, were warranted.

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

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 adverse reactions application site burning and rash should be added with uncommon frequency. The frequency of the adverse reaction erythema should be changed to uncommon.
The frequency of the adverse reaction urticaria should be changed to rare.]

[…]

System Organ Class	Frequency	Adverse reactions
Skin and subcutaneous tissue disorders	Common	…
	Uncommon	Papules, dry skin, contact dermatitis, skin irritation, skin warm, **erythema**, **rash**
	Rare	**Urticaria**
General disorders and application site conditions	**Uncommon**	**Application site burning**
….		

Post-Marketing Data:

Isolated reports: ~~erythema, urticaria and~~ hypopigmentation of the skin.

[…]

Package Leaflet

4. Possible side effect

[The adverse reactions burning at application site and skin rash should be added with uncommon frequency. The frequency of the adverse reaction redness should be changed to uncommon.
The frequency of the adverse reaction urticaria should be changed to rare.]

[…]

Uncommon side effects (may affect up to 1 in 100 people):

[…]

- Redness

- Skin rash

- Burning at application site

Rare side effects (may affect up to 1 in 1,000 people):

- Urticaria

Post-Marketing Data:
Isolated reports: ~~erythema, urticaria and~~ hypopigmentation of the skin.

[...]

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 March 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 May 2017