

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 dapoxetine, the scientific conclusions are as follows:

Based on literature data, grapefruit juice can be classified as a potent CYP3A4 inhibitor and changes to the product information to add it as an interaction with dapoxetine are considered warranted. It is also concluded that grapefruit juice should be avoided within 24 hours prior to taking dapoxetine.

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 dapoxetine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing dapoxetine 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 dapoxetine 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 **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

Information on grapefruit juice as a potent CYP3A4 inhibitor should be added as follows:

- Section 4.5

CYP3A4 inhibitors

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Therefore, concomitant use of Priligy and potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazodone, nelfinavir, atazanavir is contraindicated. **Grapefruit juice is also a potent CYP3A4 inhibitor and should be avoided within 24 hours prior to taking Priligy** (see section 4.3).

Package Leaflet

- Section 2

What you need to know before you take Priligy

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Priligy with food, drink and alcohol

- **Do not drink grapefruit juice within 24 hours prior to taking this medicine as this can increase the level of this medicine in your body**
- This medicine can be taken with or without food.
- You should take this medicine with at least one full glass of water.
- Avoid alcohol when taking this medicine.
- The effects of alcohol such as feeling dizzy, sleepy and having slow reactions, may be increased if taken with this medicine.
- Drinking alcohol while taking this medicine may increase your risk of injury from fainting or from other side effects.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	September 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	3 November 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 January 2019