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 flubendazole, the scientific conclusions are as follows:

In view of the reviewed data on the use of flubendazole use on pregnancy and lactation, and also taking into account that abnormalities or foetal malformation cases have also been reported for other benzimidazole antihelmintic products such as alebendazole, which is contraindicated in pregnancy, and mebendazole, the PRAC considered that the risk of abnormalities or foetal malformations cannot be excluded and concluded that this information should be included in section 4.6 of the Summary of Product Characteristics (SmPC) of flubendazole containing products. In addition, the PRAC considered that the statement “experience in humans has not shown any increase in the risk of malformations” included in section 4.6 of the SmPC is not justified and should be therefore revised in order to reflect that limited data on the use of flubendazole in pregnant women is available. The package leaflet is updated 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 flubendazole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing flubendazole 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 flubendazole 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

- Section 4.6

[The following text should be revised as follows]

Flubendazole has been associated with embryotoxic and teratogenic activity in some rat studies. No such findings have been reported in teratology studies in the rabbit or mice.

~~Experience in humans has not shown any increase in the risk of malformations.~~ **There are limited data on use of flubendazole in pregnant women.** ~~Nonetheless~~, ~~it is better to avoid using the product in pregnant women or in those liable to become pregnant.~~ **Flubendazole is not recommended during pregnancy or in women of childbearing potential not using contraception.**

Package Leaflet

- Section 4

[The following text should be revised as follows]

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, if you think you are pregnant or plan to become pregnant **or if you are a woman of childbearing potential,** you should consult your doctor or pharmacist before taking this medicine. Flubendazole should only be given to pregnant or breast-feeding women if prescribed by doctor.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 November 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 January 2018