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 nafarelin, the scientific conclusions are as follows:

In view of the continued post-marketing cases of Ovarian hyperstimulation syndrome and considering the seriousness of the reported cases, the PRAC concluded that the product information of products containing nafarelin should be amended in order to better reflect the important identified risk of ovarian hyperstimulation syndrome.

Update of section 4.4 of the SmPC to add a warning on ovarian hyperstimulation syndrome. 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 nafarelin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nafarelin 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 nafarelin 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 4.4

A warning should be added as follows:

As with other GnRH agonists, there have been reports of ovarian hyperstimulation syndrome (OHSS), associated with the use of nafarelin in combination with gonadotropin. Patients being treated for controlled ovarian stimulation prior to in vitro fertilisation should be monitored carefully. If signs of OHSS develop, treatment should be discontinued (see section 4.8).

Package Leaflet

Section 2:

Use of <Invented name> in combination with gonadotropin to treat infertility can sometimes cause an overreaction in your ovaries (ovarian hyperstimulation syndrome, OHSS). You may notice stomach pain, swelling of your stomach, and feeling or being sick. If this happens, tell your doctor. See also section 4 Possible side effects.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	14 October 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 November 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 January 2022