Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

The study eliminated a 1.5-fold risk of venous thromboembolism (VTE) for NOMAC-E2 (nomegestrol acetate/estradiol) compared to COCLNG (combined hormonal contraceptive containing levonorgestrel). The results of the study show that nomegestrol acetate/estradiol (Zoely) may have a risk of VTE in the same range as observed with COCLNG. Therefore, in view of available data regarding the PASS final study report, the PRAC considers that changes to the product information are warranted.

The CHMP 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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.