**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 mifepristone, the scientific conclusions are as follows:

In view of available data on the cardiovascular risk in association with misoprostol from the literature, the PRAC Lead Member State considers that the product information of products containing mifepristone should be amended.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

**Grounds for the variation to the terms of the marketing authorisation(s)**

On the basis of the scientific conclusions for mifepristone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing mifepristone is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

**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 amended as follows:

*Mifepristone (MAH Exelgyn)*

Rare but serious cardiovascular accidents (myocardial infarction and/or spasm of the coronary arteries and severe hypotension) have been reported following the **use** ~~intra vaginal and intra muscular administration of a high dose~~ of prostaglandin analogue. ~~Misoprostol administered orally could also constitute a potential risk factor of acute cardiovascular events.~~ For this reason, women with risk factors for cardiovascular disease (e.g. age over 35 years with chronic smoking, hyperlipidemia, diabetes) or established cardiovascular disease should be treated with caution.

*Mifepristone (MAH Linepharma)*

Rare but serious cardiovascular accidents have been reported following the **use** ~~intra muscular administration~~ of prostaglandin analogue. For this reason, women with risk factors for cardiovascular disease or established cardiovascular disease should be treated with caution.

**Annex III**

**Timetable for the implementation of this position**

**Timetable for the implementation of this position**

| | |
|---|---|
| Adoption of CMDh position: | January CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 10 March 2024 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 9 May 2024 |