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 PSURs for spironolactone, the scientific conclusions are as follows:

In view of available data from the literature including cases with close temporal relationship and positive dechallenge, and in view of existing plausible mechanism of action, the Lead Member State considers that a causal relationship between spironolactone and prostate specific antigen (PSA) increase in abiraterone-treated prostate cancer is established. The Lead Member State concludes that the product information of products containing spironolactone should be amended 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 spironolactone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing spironolactone 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 spironolactone 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 4.5

The interactions should be added as follows:
Spironolactone binds to the androgen receptor and may increase prostate specific antigen (PSA) levels in abiraterone-treated prostate cancer patients. Use with abiraterone is not recommended.

Package Leaflet

- Section 2

The following information should be added under the heading "Other medicines and >product name<":
Tell your doctor, if you are using abiraterone for treatment of prostate cancer.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	26 December 2021
Implementation of the position: by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 February 2022