EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/CHMP/313865/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abiraterone Mylan

abiraterone acetate

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Abiraterone Mylan, intended for the treatment of metastatic prostate cancer.

The applicant for this medicinal product is Mylan Ireland Limited.

Abiraterone Mylan will be available as 500 mg and 1000 mg film-coated tablets. The active substance of Abiraterone Mylan is abiraterone acetate, a hormone antagonist (ATC code: L02BX03) that inhibits the production of androgens in the testes, adrenal glands and prostatic tumour tissues.

Abiraterone Mylan is a generic of Zytiga, which has been authorised in the EU since 5 September 2011. Studies have demonstrated the satisfactory quality of Abiraterone Mylan and its bioequivalence to the reference product Zytiga. A question and answer document on generic medicines can be found here.

The full indication is:

Abiraterone Mylan is indicated with prednisone or prednisolone for:

- the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)
- the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated
- the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

Abiraterone Mylan should be prescribed by an appropriate healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.