Summary of risk management plan for Abiraterone Mylan (Abiraterone acetate)

This is a summary of the risk management plan (RMP) for Abiraterone Mylan. The RMP details important risks of abiraterone, how these risks can be minimised, and how more information will be obtained about abiraterone's risks and uncertainties (missing information).

Abiraterone Mylan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Abiraterone Mylan should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Abiraterone Mylan's RMP.

I. The medicine and what it is used for

Abiraterone Mylan is authorised 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; and the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. It contains abiraterone as the active substance and it is given by oral administration.

Further information about the evaluation of Abiraterone Mylan's benefits can be found in Abiraterone Mylan's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/abiraterone-mylan

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Abiraterone Mylan, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Abiraterone Mylan is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Abiraterone Mylan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Abiraterone Mylan. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine/use in special patient populations etc.).

Table 1: Summary of safety concerns

List of important risks and missing information	
Important identified risks	• Hepatotoxicity (Liver toxicity) • Cardiac disorders (Heart Problems) • Osteoporosis including osteoporosis-related fractures (A condition in which bones become weak and brittle and can lead to fractures)

	• Rhabdomyolysis/Myopathy (Breakdown of muscle tissue) • Allergic alveolitis (Inflammation of air sacs (alveoli)) • Increased exposure with food (Taking the tablets with food increases systemic exposure to abiraterone)
Important potential risks	• Anaemia (Decrease in the haemoglobin level) • Cataract (Clouding of the lens) • Drug-drug interaction (CYP2D6)
Missing information	• Use in patients with active or symptomatic viral hepatitis (Use in patients with viral liver infection or having symptoms of liver infection) • Use in patients with moderate/severe hepatic impairment and chronic liver disease (Use in patients with moderate or severe liver problems) • Use in patients with severe renal impairment (Use in patients with severe kidney problems) • Use in patients with heart disease as evidenced by myocardial infarction, or arterial thrombotic events in the past 6 months, severe or unstable angina, or New York Heart Association Class III or IV heart disease or cardiac ejection fraction measurement of <50%

II.B Summary of important risks.

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Abiraterone Mylan.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Abiraterone Mylan.