Part VI: Summary of the risk management plan

Summary of risk management plan for [invented name] 500 mg film-coated tablets

This is a summary of the risk management plan (RMP) for [invented name]. The RMP details important risks of [invented name] and how more information will be obtained about [invented name]'s risks and uncertainties (missing information).

[invented name]'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [invented name] should be used.

Important new concerns or changes to the current ones will be included in updates of [invented name]'s RMP.

I. The medicine and what it is used for

Abiraterone 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) (see section 5.1)
- 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 (see section 5.1)
- 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 orally.

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

Important risks of [invented name], together with measures to minimise such risks and the proposed studies for learning more about [invented name]'s 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 patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 [invented name] is not yet available, it is listed under ‘missing information’ below

II.A List of important risks and missing information

Important risks of [invented name] are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 [invented name]. 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);

Summary of safety concerns	
Important identified risks	Hepatotoxicity Cardiac disorders Osteoporosis including osteoporosis-related fractures Rhabdomyolysis/Myopathy Allergic alveolitis Increased exposure with food
Important potential risks	Anaemia Cataract Drug-drug interaction (CYP2D6)
Missing information	Use in patients with active or symptomatic viral hepatitis Use in patients with moderate/severe hepatic impairment and chronic liver disease Use in patients with severe renal impairment 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 [invented name].

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

There are no studies required for [invented name].