Summary of risk management plan for Abiraterone Orion (abiraterone acetate) Orion Corporation

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

I. The medicine and what it is used for

Abiraterone Orion is authorised for treatment of:

- newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)
- 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
- mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

See SmPC for the full indication.

It contains abiraterone as the active substance and it is given by mouth.

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

Important risks of Abiraterone Orion, together with measures to minimise such risks and the proposed studies for learning more about Abiraterone Orion '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*.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

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

There are no studies required for Abiraterone Orion.