PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Abiraterone Apollo 250 mg and 500mg film-coated tablets

This is a summary of the risk management plan (RMP) Abiraterone Apollo 250 mg and 500 mg film-coated tablets.

The RMP details important risks of Abiraterone Apollo, how these risks can be minimised, and how more information will be obtained about Abiraterone Apollo risks and uncertainties (missing information).

Abiraterone Apollo Summary of Product Characteristics (SmPC) and its Patient leaflet (PIL) give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Abiraterone Apollo 250mg and 500mg film-coated tablet's RMP.

I. The medicine and what it is used for

Abiraterone Apollo 250mg and 500mg film-coated tablets are used to treat cancer of the prostate (a gland of the male reproductive system) in adult men when the cancer is metastatic (has spread to other parts of the body) (see SmPC for the full indication). It contains abiraterone acetate as the active substance and it is given by oral route of administration.

Abiraterone is used together with the medicines prednisone or prednisolone in the following situations:

- when the cancer is newly diagnosed, high risk and still sensitive to hormones; Abiraterone is then used in combination with a treatment called androgen deprivation therapy;
- when medical castration (using medicines to stop the production of male hormones) with an androgen deprivation therapy has not worked or no longer works in men who have either no symptoms or only mild symptoms of the disease, and who do not yet need chemotherapy (cancer medicines);

- when medical or surgical castration and chemotherapy containing docetaxel have not worked or no longer work.

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

Important risks of Abiraterone Apollo 250 mg and 500 mg film-coated tablets, 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 Apollo 250 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

In the case of Abiraterone Apollo 250 mg and 500 mg film-coated tablets, these routine measures are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

II.A List of important risks and missing information

Important risks of Abiraterone Apollo 250 mg and 500 mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Apollo 250 mg and 500 mg film-coated tablets. 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 are risk where patient population has not studied and clinical data are not available to mitigate risk.

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing Information	• None

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 for Abiraterone Apollo 250 mg and 500 mg film-coated tablets.

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

There are no studies required for Abiraterone Apollo 250 mg and 500 mg film-coated tablets.