Part VI: Summary of the risk management plan

Summary of the risk management plan for Orgovyx (relugolix)

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

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

This summary of the RMP for Orgovyx should be read in the context of all this 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 Orgovyx RMP.

I. The medicine and what it is used for

Orgovyx is authorized for treatment of adult patients with advanced prostate cancer who respond to hormone therapy. It contains relugolix and it is given by oral route.

Further information about the evaluation of Orgovyx's benefits can be found in Orgovyx EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website: https://www.ema.europa.eu/en/medicines/human/EPAR/orgovyx

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

Important risks of Orgovyx, together with measures to minimize such risks and the proposed studies for learning more about the risks associated with Orgovyx, are outlined below.

Measures to minimize 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 authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed 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 Orgovyx is not yet available, it is listed under missing information below.

II.A List of important risks and missing information

Important risks of Orgovyx are risks that need special risk management activities to further investigate or minimize 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 Orgovyx. 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 (eg, on the long-term use of the medicine).

Table 1 List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C Post-authorization development plan

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

There are no studies that are conditions of the marketing authorization or specific obligations of Orgovyx therapy.

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

There are no studies required for Orgovyx therapy.