Summary of Risk Management Plan for VERZENIOS (abemaciclib)

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

Important new concerns or changes to the current ones will be included in updates to this RMP.

I - The Medicine and What It is Used for

VERZENIOS is authorised for locally advanced or metastatic breast cancer (see SmPC for the full indication). It contains abemaciclib as the active substance and it is given orally as immediate release film-coated tablets: 50, 100, and 150 mg.

Further information about the evaluation of VERZENIOS's benefits can be found in VERZENIOS's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

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

II.A List of Important Risks and Missing Information

Important risks of VERZENIOS 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 VERZENIOS. 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).

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	Reproductive and developmental toxicity
Missing information	Exposure and safety in patients with severe renal impairment

II.B Summary of Important Risks

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

Important Potential Risk: Reproductive and Developmental Toxicity	
Evidence for linking the risk to the medicine	Abemaciclib works by interfering with a certain step in cell division. Because foetal development requires cell division, it is likely that abemaciclib inhibits foetal development. In rats, lower foetal weight and other effects were observed, which is consistent with the classification of this risk as a potential risk.
Risk factors and risk groups	Chemotherapy exposure during pregnancy carries a higher risk of spontaneous abortion and major birth defects. Older patients (>40 years) are more likely to develop early menopause after chemotherapy. Additional risk factors include smoking, drinking alcohol, diabetes, and obesity.
Risk minimisation measures	Abemaciclib is not recommended during pregnancy or in women of childbearing potential who are not using contraception. Women of childbearing potential should use a highly effective birth control method during treatment and for 3 weeks following treatment.
Missing Information: Exposure and Safety in Patients with Severe Renal Impairment	
Risk minimisation measures	Use of abemaciclib in patients with severe renal impairment is not contraindicated. Abemaciclib should be administered with caution in patients with severe renal impairment. Complete blood counts should be monitored before starting abemaciclib therapy and every 2 weeks for the first 2 months of therapy. [Routine risk minimisation measures]

II.C Post-Authorisation Development Plan

II.C.1 Studies that are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of VERZENIOS.

II.C.2 Other Studies in Post-Authorisation Development Plan

Not applicable.