PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for XEPLION (Paliperidone Palmitate 1-Monthly Injection)

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

XEPLION's Summary of Product Characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how XEPLION should be used.

This summary of the RMP for XEPLION 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 XEPLION's RMP.

I. The Medicine and What it is Used For

XEPLION is authorised for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone and in selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone.

XEPLION may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed (see SmPC for the full indication).

It contains paliperidone as the active substance and it is administered by intramuscular (IM) injection as a prolonged-release suspension in prefilled syringes containing 39, 78, 117, 156, or 234 mg of XEPLION; which is equivalent to 25, 50, 75, 100, or 150 mg, respectively, of paliperidone. XEPLION is administered by a health care professional.

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

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

Important risks of XEPLION, together with measures to minimise such risks and the proposed studies for learning more about XEPLION'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 PL 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 (eg, 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 including Periodic Safety Update Report (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 XEPLION is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

Important risks of XEPLION 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 XEPLION. 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.

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	Exposure during pregnancy

II.B. Summary of Important Risks

Missing Information: Exposure during pregnancy	
Risk minimisation measures	**Routine risk minimisation measures:** INVEGA, XEPLION, and TREVICTA SmPCs Section 4.6, Fertility, pregnancy and lactation Section 5.3, Preclinical safety data **Additional risk minimisation measures:** None

II.C. Post-authorisation Development Plan

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

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

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

There are no studies required for XEPLION.