PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ODEFSEY (EMTRICITABINE/RILPIVIRINE/TENOFOVIR ALAFENAMIDE)

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

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

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

I. The Medicine and What is it Used for

Odefsey is authorized for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus-1 (HIV-1) (see SmPC for the full indication). It contains emtricitabine (FTC; F), rilpivirine (RPV) and tenofovir alafenamide (TAF) as the active substance and it is given orally.

Further information about the evaluation of Odefsey's benefits can be found in Odefsey's EPAR, including its plain-language summary, available on the EMA website, under the medicine's webpage*: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/004156/WC500209992.pdf.*

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of Odefsey, together with measures to minimize such risks and the proposed studies for learning more about Odefsey's risks, 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 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 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 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 Odefsey is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Odefsey are risks that need special risk management activities to further investigate or minimize 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 Odefsey. 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).

Table Part VI.1. List of Important Risks and Missing Information

Important Identified Risks	None
Important Potential Risks	None
Missing Information	Long-term safety information in adolescents
	Safety in pregnancy and lactation

II.B. Summary of Important Risks

Table Part VII.2. Summary of Important Risk(s) and Missing Information

Important Identified Risk	
None	
Important Potential Risk	
None	
Missing information	**Long-term safety information in adolescents**
Risk Minimization Measure(s)	No routine risk minimization measures are considered necessary for this population
Missing information	**Safety in Pregnancy and Lactation**
Risk Minimization Measure(s)	Routine risk communication: SmPC section 4.6 PL section 2
Additional Pharmacovigilance activities	Antiretroviral Pregnancy Registry See Section II.C of this summary for an overview of the post-authorization development plan.

II.C. Post-authorization Development Plan

II.C.1. Studies which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Odefsey.

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

Table Part VI.3. Other Studies in Post-Authorization Development Plan

Short Study Name	Purpose of the Study
Antiretroviral Pregnancy Registry (APR)	To collect information on the risk of birth defects in patients exposed to antiretroviral drugs (ARVs), including ODE, during pregnancy