This is a summary of the risk management plan (RMP) for M-M-RVAXPRO®.

The RMP details important risks of M-M-RVAXPRO® that require additional pharmacovigilance (PV) activities and/or additional risk minimization activities, beyond routine PV and risk minimization activities, and how more information will be obtained about M-M-RVAXPRO®'s risks and uncertainties (missing information).

M-M-RVAXPRO®'s EU Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how M-M-RVAXPRO® should be used.

This summary of the RMP for M-M-RVAXPRO® should be read in the context of all of 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 safety concerns or changes to the current ones will be provided in updates of M-M-RVAXPRO®'s RMP.

I. The Medicine and What it is Used For

M-M-RVAXPRO® is authorised for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older (see SmPC for full indication). It contains live measles, mumps, and rubella vaccines as the active substances and it is given subcutaneously.

Further information about the evaluation of M-M-RVAXPRO® benefits can be found in M-M-RVAXPRO®'s EPAR, including its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/medicines/human/EPAR/m-m-rvaxpro.

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

Important risks of M-M-RVAXPRO®, together with measures to minimise such risks and the proposed studies for learning more about M-M-RVAXPRO®'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 EU SmPC and package leaflet 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of M-M-RVAXPRO® 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 M-M-RVAXPRO®. 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).

There are currently no important risks or missing information for M-M-RVAXPRO® that require additional, special risk management activities beyond routine PV and routine risk minimization activities.

Table II.A.1: List of Important Risks and Missing Information

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 EU SmPC is aligned to the reference medicinal product. There are no identified risks, potential risks, or missing information in this RMP.

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 a specific obligation of M-M-RVAXPRO®.

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

There are no studies required for M-M-RVAXPRO®.