PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for *rhesonativ* (human anti-D immunoglobulin)

This is a summary of the risk management plan (RMP) for *rhesonativ*. The purpose of an RMP is to detail important risks of a medicinal product, how these risks can be minimised, and how more information will be obtained about its risks and uncertainties (missing information).

rhesonativ´s summary of product characteristics (SmPC) and package leaflet give essential information to healthcare professionals and patients on how the *rhesonativ* should be used.

I. The medicine and what it is used for

rhesonativ is authorised for the prevention of Rh(D)-immunisation in Rh(D)-negative women and for the treatment of Rh(D)-negative persons after incompatible transfusions of Rh(D)-positive blood or other products containing red blood cells, e.g., platelet concentrate. It contains human anti-D immunoglobulin as the active substance and it is given by intramuscular injection.

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

Anti-D immunoglobulins such as *rhesonativ* have been in clinical use since the 1970s, and the risks associated with their use are well known to health professionals. As a result, *rhesonativ* is considered to not require any special pharmacovigilance activities or risk minimization measures other than those routinely performed.

Measures to minimise the risks usually 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessments, 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 associated with the use of a medicinal product 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 the product. Potential risks are concerns for which an association with the use of the 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 still 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	None
Missing information	None

II.B Summary of important risks

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

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 specific obligation of *rhesonativ*.

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

There are no studies required for *rhesonativ*.