Summary of risk management plan for Rotarix (Rotavirus vaccine)

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

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

This summary of the RMP for *Rotarix* 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 of *Rotarix*'s RMP.

I. The medicine and what it is used for

Rotarix is authorised for the active immunisation of infants aged 6 to 24 weeks for prevention of gastro-enteritis due to rotavirus infection (see SmPC for the full indication). It contains human rotavirus, live attenuated as the active substance and it is given by oral administration. Further information about the evaluation of *Rotarix*'s benefits can be found in *Rotarix*'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage Rotarix European Medicines Agency (europa.eu).

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

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

II.A List of important risks and missing information

Important risks of *Rotarix* 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 *Rotarix*. 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	None.
Missing information	Long term genetic stability of the vaccine virus strain (concern that genetic variations in the *Rotarix* vaccine strain could lead to clinical symptoms of Gastroenteritis - GE)

II.B Summary of important risks

Important identified risk: None

Important potential risk: None.

Missing information: Long term genetic stability of the vaccine virus strain (concern that genetic variations in the *Rotarix* vaccine strain could lead to clinical symptoms of Gastroenteritis - GE)	
Risk minimisation measures	None
Additional pharmacovigilance activities	Monitoring of strain prevalence through continued support of existing strain surveillance networks. The Company is currently supporting the Australian Rotavirus Surveillance Program.

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 *Rotarix*.

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

There are no studies required for *Rotarix*.