Summary of risk management plan for *Infanrix-IPV*

This is a summary of the risk management plan (RMP) for *Infanrix-IPV*. The RMP explains that there are no safety concerns (i.e., important identified or potential risks and missing information) for of *Infanrix-IPV*.

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

I. The medicine and what it is used for

Infanrix-IPV was developed as a vaccine for primary (i.e., children aged 2 months and older) and booster vaccination (i.e., individuals from 16 months to 13 years of age inclusive who have previously been immunised with diphtheria, tetanus and pertussis (DTP) and polio. In Europe, in countries where the product is authorized through national procedure (Belgium and Luxembourg), both indications are registered, but for the countries of the MRP (i.e., in the countries included in this procedure) only the booster vaccination is registered (see SmPC for the full indication).

The vaccine contains diphtheria toxoid, tetanus toxoid, *Bordetella pertussis* antigens (pertussis toxoid, filamentous haemagglutinin and pertactin), inactivated poliovirus types 1, 2 and 3 as active substances and is given by intramuscular injection, usually into the deltoid muscle. However, the anterolateral thigh may be used in very young subjects if preferred.

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

Important risks of *Infanrix-IPV*, together with measures to minimise such risks and the proposed studies for learning more about *Infanrix-IPV* 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 authorized 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 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 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 *Infanrix-IPV* 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 *Infanrix-IPV*. 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	None

II.B Summary of important risks

The safety information in the proposed Product Information (PI) is aligned to the reference safety information for the 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 *Infanrix-IPV*.

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

There are no studies required for *Infanrix-IPV*.