Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Infanrix Suspension for Injection in a pre-filled syringe.
Dephtheria-tetanus-and-pertussis (acellular component) vaccine (absorbed).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

'Infanrix' contains diphtheria toxoid, tetanus toxoid and three purified pertussis antigens [pertussis toxoid (TP), filamentous haemagglutinin (FHA) and pertactin (69 kilo Dalton outer membrane protein)] adsorbed on to an aluminium salt.

Each 0.5 ml dose contains:

Diphtheria toxoid	not less than 30 IU
Tetanus toxoid	not less than 40 IU
Pertussis toxoid	25 micrograms
Filamentous haemagglutinin	25 micrograms
Pertactin	8 micrograms
Aluminium (as Aluminium Hydroxide)	0.5 mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Suspension for Injection in a pre-filled syringe.
Turbid suspension for deep intramuscular injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

'Infanrix' is indicated for active primary immunisation against diphtheria, tetanus and pertussis from the age of 2 months onwards and as a booster dose for children who have previously been immunised with 3 doses of either DTPa or DTPw vaccine according to the national policy in effect at the time.

4.2 Posology and method of administration

Posology
Adults and elderly: Not recommended.

Children (up to and including 6 years of age): 0.5 ml of the vaccine by deep intramuscular injection.

The primary immunisation course consists of 3 doses with an interval of at least one month between each dose. The first dose should normally be given when the child is two months old.

A booster dose should be given after the completion of a primary course of DTP according to the national policy in effect at the time.

Method of administration
Shake well before use and administer by deep intramuscular injection

4.3 Contraindications

As with other vaccines, the administration of ‘Infanrix’ should be postponed in subjects suffering from acute sever febrile illness. The presence of a minor infection, however, is not a contraindication.

‘Infanrix’ should not be administered to subjects with known hypersensitivity to any component of the vaccine or to subjects having shown signs of hypersensitivity after previous administration of ‘Infanrix’ diphtheria and tetanus vaccine or DTPw.

Infanrix is contraindicated if the child has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances the vaccination course should be continued with diphtheria and tetanus vaccine.

4.4 Special warnings and precautions for use

It is good clinical practice that immunisation should be preceded by a review of the medical history (especially with regard to previous immunisation and possible occurrence of undesirable events) and a clinical examination.

If any of the following events occur in temporal relation to receipt of DTPa or DTPw, the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered. There may be circumstances, such as a high incidence of pertussis, when the potential benefits outweigh possible risks, particularly since these events are not associated with permanent sequelae.

The following events were previously considered contra-indications for DTPw and can now be considered to be general precautions:
Temperature of $\geq$ 40.5°C within 48 hours of vaccination, not due to another identifiable cause.
Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination.
Persistent, inconsolable crying lasting $\geq$ 3 hours, occurring within 48 hours of vaccination.
Convulsions with or without fever, occurring within 3 days of vaccination.

A history of febrile convulsions and a family history of convulsive fits do not constitute contra-indications.

HIV infection is not considered as a contra-indication.

As with all vaccinations, a solution of 1:1000 adrenaline should be available for injection should an anaphylactic reaction occur. Recipients of the vaccine should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction. It is not possible to specify an exact length of time.

The vaccine should be given by deep intramuscular injection.

'Infanrix' should be administered with caution to subjects with thrombocytopenia or bleeding disorders since bleeding may occur following an intramuscular administration to these subjects.

'Infanrix' should under no circumstances be administered intravenously.

4.5 Interaction with other medicinal products and other forms of interaction

'Infanrix' can be administered in any temporal relationship with other childhood vaccines.

Different injectable vaccines should always be administered at different injection sites.
In patients receiving immunosuppressive therapy or patients with immunodeficiency an adequate immunologic response may not be achieved.

4.6 Fertility, pregnancy and lactation

As 'Infanrix' is not intended for use in adults, information on the safety of the vaccine when used during pregnancy or lactation is not available.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

These are usually mild and confined to the first 48 hours after vaccination.

The commonest local symptoms are likely to be soreness, erythema, swelling and induration at the injection site. Redness and swelling of more than 10 cm have been reported after the booster dose and these resolved spontaneously. Some children will experience a mild fever. Uncommonly, fever > 39.5ºC may be observed.

Less common symptoms that may be observed are: unusual crying, vomiting, diarrhoea, eating or drinking less than usual, sleeping less than usual/restlessness and sleeping more than usual/drowsiness.

Very rare allergic reactions, including anaphylactoid reactions, have been reported.

Extremely rare cases of collapse or shock-like state (hypotonic-hyporesponsiveness episode) and convulsions within 2 to 3 days of vaccination have been reported. All the subjects recovered totally and spontaneously without sequelae.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Evaluation of pharmacodynamic properties is not required for vaccines.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

Appropriate safety tests are performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-phenoxyethanol
sodium chloride
Water for Injection.

For adjuvant details see section 2.

6.2 Incompatibilities

In the absence of compatibility studies, the vaccine must not be mixed with other medicinal products.

6.3 Shelf life

36 months.

After reconstitutions, the vaccine should be injected immediately. If not used immediately, in-use storage times and condition prior to use are the responsibility of the user and should normally not be longer than 8 hours at +2°C to +8°C (in a rerigerator).

6.4 Special precautions for storage

Store at 2^{o}C to 8^{o}C and keep the container in the outer carton to protect from light.

Do not freeze the vaccine. Vaccine which has been frozen should be discarded.

When using the vial presentation, the product should be used immediately after broaching the seal.

6.5 Nature and contents of container

'Infanrix' is presented as 0.5 ml single dose presentation in 1 ml glass prefilled syringes.

Each pack contains one pre-filled syringe.

The prefilled syringes are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements. Syringes are presented with or without needles. Syringes fitted without needles are fitted with grey butyl rubber tip caps. Syringes with needles are fitted with grey butyl rubber shields. Plunger stoppers are grey butyl rubber.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Upon storage a white deposit and clear supernatant can be observed in the syringe. This is not asign of deterioration. The syringe should be well shaken in order to obtain a homogenous turbid suspension and inspected visually for any foreign particulate matter and/or abnormalphysical appearance prior to administration. In the event of either being observed, the vaccine should be discarded.

Any unused product or waste material should be disposed of safely in accordance with local regulations.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 1077/030/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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