ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PROCOMVAX suspension for injection
Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Polyribosylribitol phosphate (PRP) from *Haemophilus influenzae* type b as PRP-OMPC	7.5 µg
Neisseria meningitidis OMPC (outer membrane protein complex of the B11 strain of *Neisseria meningitidis subgroup B)*	125 µg
Adsorbed hepatitis B surface antigen produced in recombinant yeast cells (*Saccharomyces cerevisiae)*	5.0 µg

in 0.5 ml.

For excipent, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection in vial.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PROCOMVAX is indicated for vaccination against invasive disease caused by *Haemophilus influenzae* type b and against infection caused by all known subtypes of hepatitis B virus in infants 6 weeks to 15 months of age.

4.2 Posology and method of administration

Posology
Infants born of HBsAg negative mothers should be vaccinated with three 0.5ml doses of PROCOMVAX, ideally at 2, 4, and 12-15 months of age. If the recommended schedule cannot be followed exactly, the interval between the first two doses should be approximately two months and the interval between the second and third dose should be as close as possible to eight to eleven months. All three doses must be administered to complete the vaccination regimen.

Children who receive one dose of hepatitis B vaccine at or shortly after birth may be administered PROCOMVAX on the schedule of 2, 4, and 12 -15 months of age.

Children not vaccinated according to recommended schedule
Vaccination schedules for children not vaccinated according to the recommended schedule should be considered on an individual basis.

Method of administration
FOR INTRAMUSCULAR ADMINISTRATION
Do not inject intravenously, intradermally, or subcutaneously

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients. Individuals who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine.

Because of the potential for immune tolerance (impaired ability to respond to subsequent exposure to the PRP antigen) PROCOMVAX is not recommended for use in infants younger than 6 weeks of age.

It has been recommended that immunisation should be delayed during the course of an acute febrile illness. All vaccines can be administered to infants with minor illnesses such as diarrhoea or mild upper-respiratory infection. Infants with moderate or severe febrile illness should only be vaccinated as soon as they have recovered from the acute phase of the illness.

4.4 Special warnings and special precautions for use

As for any vaccine, adequate treatment provisions, including adrenaline, should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

PROCOMVAX must not be mixed with other vaccines in the same syringe.

Infants born of HBsAg-positive mothers should receive Hepatitis B Immune Globulin and Hepatitis B Vaccine (Recombinant) at birth and should complete the hepatitis B vaccination series. The subsequent administration of PROCOMVAX for completion of the hepatitis B vaccination series in infants who were born of HBsAg positive mothers and received HBIG or infants born of mothers of unknown status has not been studied.

In infants with bleeding disorders such as haemophilia or thrombocytopenia, special precautions should be taken against the risk of haematoma following the injection.

Since PROCOMVAX has not been studied in persons who have malignancies or are otherwise immunocompromised, the extent of the immune response in such persons is unknown.

PROCOMVAX will not protect against invasive disease caused by *Haemophilus influenzae* other than type b or against invasive disease (such as meningitis or sepsis) caused by other microorganisms.

PROCOMVAX will not prevent hepatitis caused by other viruses known to infect the liver. Because of a long incubation period for Hepatitis B, it is possible for unrecognised infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

PROCOMVAX may not induce protective antibody levels immediately following vaccination and may not result in a protective antibody response in all individuals given the vaccine.

As reported with Haemophilus b Polysaccharide Vaccine and another Haemophilus b Conjugate Vaccine, cases of Haemophilus b disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccines.

The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

4.5 Interaction with other medicinal products and other forms of interaction

Immunogenicity results from open-labeled studies indicate that PROCOMVAX can be administered concomitantly with DTP (Diphtheria, Tetanus and whole cell Pertussis vaccine), OPV (Oral Poliomyelitis vaccine), IPV (inactivated poliomyelitis vaccine) and Merck MMR (Measles, Mumps,

and Rubella Virus Vaccine Live) using separate sites and syringes for injectable vaccines. Additionally, limited immunogenicity results from an open-labeled, controlled study indicate that PROCOMVAX may be administered concomitantly with DTaP (Diphtheria, Tetanus, and acellular Pertussis vaccine), using separate sites and syringes for injectable vaccines.

Efficacy of whole cell or acellular pertussis vaccines when given concomitantly with PROCOMVAX has not been established in field trials.

4.6 Pregnancy and lactation

Not applicable. For paediatric use only.

4.7 Effects on ability to drive and use machines

Not applicable. For paediatric use only.

4.8 Undesirable effects

In clinical trials involving the administration of 7,350 doses of PROCOMVAX to 2,993 healthy infants 6 weeks to 15 months of age, PROCOMVAX was generally well tolerated. Of these infants, 1,177 were involved in clinical trials in which most received PROCOMVAX concomitantly with other licensed paediatric vaccines. Of these, 1,110 were monitored for both serious and non-serious adverse experiences. The remaining 1,816 infants were involved in trials where PROCOMVAX was administered concomitantly with either an investigational pneumococcal polysaccharide protein conjugate vaccine or an investigational preparation of diphtheria, tetanus, pertussis, and inactivated poliovirus vaccine and were under surveillance for serious adverse experiences.

Among the 2,993 children given PROCOMVAX, 33 had serious adverse experiences within 14 days of vaccination. None of the serious adverse experiences was judged by the study investigator to be related to this vaccine.

In one of these trials, a randomized, multicenter study, 882 infants were assigned in a 3:1 ratio to receive either PROCOMVAX or Merck Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) (Merck PRP-OMPC Vaccine) plus Merck Hepatitis B (Recombinant) Vaccine at 2, 4, and 12-15 months of age, with the children monitored daily for five days after each injection for local reactions and systemic complaints. Most children received DTP and OPV concomitantly with the first two doses of PROCOMVAX or Merck PRP-OMPC Vaccine or Merck Hepatitis B (Recombinant) Vaccine. Across all three doses of PROCOMVAX, there were no significant differences in the frequency of adverse experiences between PROCOMVAX and the monovalent vaccines Merck PRP-OMPC Vaccine and Merck Hepatitis B (Recombinant) Vaccine. However, the frequency of irritability was statistically higher after all three injections of PROCOMVAX combined and after the first injection of PROCOMVAX compared to the monovalent vaccines.
The following local reactions and systemic complaints were reported in ≥1.0 % of children within five days after any injection of PROCOMVAX: pain/soreness, erythema, swelling/induration at the injection site; fever (>38.3 °C, rectal equivalent); anorexia, vomiting, diarrhoea; irritability, somnolence, crying including unusual high-pitched crying, prolonged crying (>4hrs), and crying not otherwise specified; otitis media. No increase in the frequency or severity of adverse events was seen with subsequent doses.

Post marketing Experience

PROCOMVAX
Hypersensitivity
Rarely : anaphylaxis, angioedema, urticaria, erythema multiforme.

Nervous System
Seizure, febrile seizure

Respiratory, thoracic and mediastinal disorders
Apnoea in very premature infants (≤ 28 weeks of gestation) (see section 4.4)

Skin
Injection site nodule

Potential Adverse Effects

In addition, a variety of adverse effects have been reported with marketed use of either Merck PRP-OMPC Vaccine or Merck Hepatitis B (Recombinant) Vaccine in infants and children through 71 months of age. These adverse effects are listed below.

Liquid Merck PRP-OMPC Vaccine

Haematologic/Lymphatic
Lymphadenopathy

Skin
Pain at the injection site

Merck Hepatitis B (Recombinant) Vaccine
Common reactions

Local reactions at injection site: transient soreness, erythema, induration

Rare

- elevation of liver enzymes, fatigue, fever, malaise, influenza-like symptoms, bronchospasm-like symptoms, serum sickness, thrombocytopenia
- dizziness, headache, paresthesia
- nausea, vomiting, diarrhea, abdominal pain
- arthralgia, myalgia
- rash, pruritus,
- hypotension, syncope
- paralysis (Bell's palsy), neuropathy, neuritis (including Guillain Barre Syndrome, myelitis including transverse myelitis), encephalitis, optical neuritis.
- lymphadenopathy.

4.9 Overdose

There are no data with regard to overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group : anti infectious, ATC code : J07CA
PROCOMVAX is a sterile bivalent vaccine made of the antigenic components used in producing Merck PRP-OMPC Vaccine and Merck Hepatitis B (Recombinant) Vaccine. These components are the Haemophilus influenzae type b capsular polysaccharide (PRP) that is covalently bound to an outer membrane protein complex (OMPC) of Neisseria meningitidis and hepatitis B surface antigen (HBsAg) from recombinant yeast cultures.

The protective efficacy of the components of PROCOMVAX has been established in field trials performed with the monovalent vaccines.

Anti-HBs Responses to PROCOMVAX in Infants Not Previously Vaccinated with Hepatitis B Vaccine

In 4 clinical trials conducted between 1992 and 2000, PROCOMVAX was administered to 1809 infants, approximately 2 months of age, who had not previously received any hepatitis B vaccine. These infants nominally received PROCOMVAX at 2, 4, and 12-15 months of age.

In these studies, 1503 infants had anti-HBs results available following the first 2 doses of PROCOMVAX and 1309 had anti-HBs results available following the third dose of PROCOMVAX. Post-dose 2, 77% to 96% of infants developed a protective level of anti-HBs (≥ 10 mIU/ml) and the GMTs ranged from 30 mIU/ml to 190 mIU/ml. Post-dose 3, 96 % to 100 % of infants developed a protective level of anti-HBs and the GMTs ranged from 897 mIU/ml to 4467 mIU/ml.

Anti-HBs Responses to PROCOMVAX in Infants Previously Vaccinated with Hepatitis B Vaccine

In 4 clinical trials conducted between 1992 and 2000, PROCOMVAX was administered to 722 infants, approximately 2 months of age, who had previously received a single dose of hepatitis B vaccine at birth. These infants nominally received PROCOMVAX at 2-3, 4-5, and 12-15 months of age

In these studies, 618 infants had anti-HBs results available following the first 2 doses of PROCOMVAX and 461 had anti-HBs results available following the third dose of PROCOMVAX. Post-dose 2, 93 % to 100 % of infants developed a protective level of anti-HBs (≥ 10 mIU/ml) and the GMTs ranged from 125 mIU/ml to 417 mIU/ml. Post-dose 3, 98 % to 100 % of infants developed a protective level of anti-HBs and the GMTs ranged from 1509 mIU/ml to 3913 mIU/ml.

The duration of the protective effect for hepatitis B in healthy vaccinees is unknown at present and the need for a routine booster dose with hepatitis B-containing vaccines is not yet defined.

Anti-PRP Responses to PROCOMVAX in Infants

In 6 clinical trials conducted between 1992 and 2000, PROCOMVAX was administered to 2528 infants, approximately 2 months of age, who had not previously received any Hib vaccine. These infants nominally received PROCOMVAX at 2, 4, and 12-15 months of age.

In these studies, 2121 infants had anti-PRP results available following the first 2 doses of PROCOMVAX and 1768 had anti-PRP results available following the third dose of PROCOMVAX. Post-dose 2, 95 % to 99 % of infants developed > 0.15 µg/ml of anti-PRP, a level associated with short-term protection against invasive Hib disease, and the GMTs ranged from 2.5 µg/ml to 4.3 µg/ml. Post-dose 3, 92 % to 99 % of infants developed >1.0 µg/ml of anti-PRP, a level associated with long-term protection against invasive Hib disease, and the GMTs ranged from 7.7 µg/ml to 14.0 µg/ml.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formulation contains amorphous aluminium hydroxyphosphate sulphate and sodium borate in 0.9% sodium chloride.

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other vaccines or other medicinal products in the same syringe.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.

6.5 Nature and contents of container

0.5 ml suspension in vial (type I flint glass).

6.6 Instructions for use and handling

The vaccine should be used as supplied; no reconstitution is necessary.

After thorough agitation, PROCOMVAX is a slightly opaque, white suspension. Parenteral medicinal products should be inspected visually for extraneous particulate matter and discoloration prior to administration whenever solution and container permit.

Shake well before withdrawal and use. Thorough agitation is necessary to achieve suspension of the vaccine.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur MSD S.N.C.
8, rue Jonas Salk
F - 69007 LYON

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/99/104/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/05/1999
Date of latest renewal: 02/08/2004

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES

Name and address of the manufacturer of the biological active substances

For Haemophilus B conjugate and Hepatitis B surface antigen:

Merck & Co. Inc.
Sumneytown Pike
West Point
Pennsylvania 19486 USA

Name and address of the manufacturer responsible for batch release

Merck Sharp & Dohme B.V. (Merck Manufacturing Division)
Waarderweg 39,
2031 BN, P.O. Box 581,
2003 PC Haarlem
The Netherlands

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

Official batch release: in accordance with Article 114 Directive 2001/83/EEC, the official batch release will be undertaken by a state laboratory or a laboratory disignated for that purpose.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PROCOMVAX - single dose in vial - Pack of 1

1. NAME OF THE MEDICINAL PRODUCT

PROCOMVAX suspension for injection

Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (recombinant) Vaccine.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 dose (0.5 ml) contains :
7.5 µg of PRP from *Haemophilus influenzae* type b as PRP-OMPC
125 µg of *Neisseria meningitidis* OMPC
5.0 µg of hepatitis B surface antigen produced in recombinant yeast cells

3. LIST OF EXCIPIENTS

Excipients: Amorphous aluminium hydroxyphosphate sulphate and sodium borate in 0.9 % sodium chloride

4. PHARMACEUTICAL FORM AND CONTENTS

1 single dose 0.5 ml in vial.
Suspension for injection in vial.

5. METHOD AND , ROUTE(S) OF ADMINISTRATION

Shake well before use.
Intramuscular use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator
Do not freeze

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR MSD SNC
8, rue Jonas Salk
F-69007 Lyon

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/99/104/001

13. MANUFACTURER'S BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE MEDICINAL PRODUCT AND IF NECESSARY ROUTE(S) OF ADMINISTRATION

PROCOMVAX

Intramuscular use

2. METHOD OF ADMINISTRATION

Shake well before use

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose = 0.5 ml

SANOFI PASTEUR MSD SNC

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Read all of this leaflet carefully before your child is vaccinated.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine has been prescribed for your child and you should not pass it on to others.

In this leaflet:

PROCOMVAX suspension for injection in vial.
Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine.

The active substances are:

Polyribosylribitol phosphate (PRP) from *Haemophilus influenzae* type b as PRP-OMPC	7.5 µg
Neisseria meningitidis OMPC (outer membrane protein complex of the B11 strain of *Neisseria meningitidis subgroup B)*	125 µg
Adsorbed hepatitis B surface antigen produced in recombinant yeast cells (*Saccharomyces cerevisiae)*	5.0 µg

in 0.5 ml.

The other ingredients are: amorphous aluminium hydroxyphosphate sulphate and sodium borate in 0.9% sodium chloride

Marketing Authorisation Holder: Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, F-69007 Lyon

Manufactured by: Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

1 WHAT PROCOMVAX IS AND WHAT IT IS USED FOR

PROCOMVAX is an injectable vaccine in a 0.5ml single dose vial.
PROCOMVAX is indicated to help protect your child against invasive disease caused by *Haemophilus influenzae* type b (infection of brain and spinal cord tissues, infection of the blood, etc.) and against infection of the liver caused by all known subtypes of hepatitis B virus. The vaccine can be administered in most infants 6 weeks to 15 months of age.

2. BEFORE YOU USE PROCOMVAX

Do not use PROCOMVAX:
- if your child is allergic to any component of the vaccine.
- in infants younger than 6 weeks of age
- if your child has fever (vaccination should be delayed).
- in infants born to HBsAg positive mothers.

Take special care with PROCOMVAX:

- if your child has bleeding disorders such as haemophilia or thrombocytopenia , special precautions should be taken against the risk of haematoma following injection.
- if you are a hepatitis B virus surface antigen (HBsAg)-positive mother, your infant should receive Hepatitis B Immune Globulin (HBIG) and hepatitis B vaccine (Recombinant) at birth and should complete the hepatitis B vaccination series. The subsequent administration of PROCOMVAX for completion of the hepatitis B vaccination series in infants who were born of HBsAg-positive mothers and received HBIG or infants born of mothers of unknown status has not been studied.
- as with other similar vaccines, cases of Haemophilus b disease may occur in the week after vaccination prior to the onset of the protective effects of the vaccine.
- because hepatitis B infection can go undetected for a long period of time, it is possible that an individual may already be infected at the time the vaccine is given. The vaccine may not prevent hepatitis B in these individuals.

Using other vaccines

PROCOMVAX can be administered simultaneously with the primary series of diphtheria, tetanus, pertussis vaccine (DTP) and oral polio vaccine (OPV). At 12 to 15 months of age, PROCOMVAX may be given simultaneously with Merck MMR (Measles, Mumps, and Rubella Virus Vaccine Live), or OPV or with a booster dose of diphtheria, tetanus, acellular pertussis vaccine (DTaP) at 15 months of age in children who received the primary series of DTP.

PROCOMVAX has been administered simultaneously with the primary series of DTaP and enhanced inactivated poliovirus vaccine (IPV) to a limited number of infants. No serious vaccine-related side effects were reported. Immune response data are satisfactory for PROCOMVAX but are currently unavailable for DTaP.

3. HOW TO USE PROCOMVAX

Infants born of HBsAg negative mothers should be vaccinated with three 0.5 ml doses of PROCOMVAX, ideally at 2, 4, and 12-15 months of age. If the recommended schedule cannot be followed exactly, the interval between the first two doses should be approximately two months and the interval between the second and third dose should be as close as possible to eight to eleven months. All three doses must be administered to complete the vaccination regimen.

Children who receive one dose of hepatitis B vaccine at or shortly after birth may be administered PROCOMVAX on the schedule of 2, 4, and 12 -15 months of age.

Children not vaccinated according to recommended schedule
Vaccination schedules for children not vaccinated according to the recommended schedule should be considered on an individual basis.

PROCOMVAX must be injected into the muscle of the thigh.
Do not inject intravenously, intradermally, or subcutaneously

If you forget to take PROCOMVAX:
Your doctor will decide when to give the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROCOMVAX can have side effects. PROCOMVAX has been generally well tolerated in clinical trials. Side effects include injection-site reactions such as pain, soreness, redness, and swelling. Other side effects include irritability, sleepiness, fever, diarrhoea, vomiting, loss of appetite, middle ear infection, and unusual high-pitched crying. Other side effects that may occur rarely and be serious include seizure, febrile seizure, allergic reactions, allergic swelling (angioedema) and certain severe types of rash, injection site nodule.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

In addition, tell your doctor if your child experienced any symptoms that suggest an allergic reaction after any dose in the vaccination series.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING PROCOMVAX

Keep out of the reach and sight of children.
Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Do not use after the expiry date stated on the label.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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