CLAIMS

1. A method for immunising a human patient against a disease caused by *Neisseria meningitidis*, comprising the step of administering to the human patient a composition that comprises at least two of: (a) a conjugate of (i) the capsular saccharide of serogroup A *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; (b) a conjugate of (i) the capsular saccharide of serogroup C *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; (c) a conjugate of (i) the capsular saccharide of serogroup W135 *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; and (d) a conjugate of (i) the capsular saccharide of serogroup Y *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof.

2. A method for immunising a human patient against a disease caused by *Neisseria meningitidis*, comprising the step of administering to the human patient a composition that comprises at least two of: (a) a conjugate of (i) the capsular saccharide of serogroup A *N.meningitidis* and (ii) a tetanus toxoid; (b) a conjugate of (i) the capsular saccharide of serogroup C *N.meningitidis* and (ii) a tetanus toxoid; (c) a conjugate of (i) the capsular saccharide of serogroup W135 *N.meningitidis* and (ii) a tetanus toxoid; and (d) a conjugate of (i) the capsular saccharide of serogroup Y *N.meningitidis* and (ii) a tetanus toxoid, wherein the patient has been pre-immunised with (a) a tetanus toxoid and/or (b) a conjugate of (i) a capsular saccharide of an organism other than *N.meningitidis* and (ii) a tetanus toxoid.

3. The use of at least two of: (a) a conjugate of (i) the capsular saccharide of serogroup A *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; (b) a conjugate of (i) the capsular saccharide of serogroup C *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; (c) a conjugate of (i) the capsular saccharide of serogroup W135 *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof; and (d) a conjugate of (i) the capsular saccharide of serogroup Y *N.meningitidis* and (ii) a tetanus toxoid or derivative thereof, in the manufacture of a medicament for immunising a human patient against a disease caused by *Neisseria meningitidis*, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than *N.meningitidis* and (ii) a tetanus toxoid.

4. The use of at least two of: (a) a conjugate of (i) the capsular saccharide of serogroup A *N.meningitidis* and (ii) a tetanus toxoid; (b) a conjugate of (i) the capsular saccharide of serogroup C *N.meningitidis* and (ii) a tetanus toxoid; (c) a conjugate of (i) the capsular saccharide of serogroup W135 *N.meningitidis* and (ii) a tetanus toxoid; and (d) a conjugate of (i) the capsular saccharide of serogroup Y *N.meningitidis* and (ii) a tetanus toxoid, in the manufacture of a medicament for immunising a human patient against a disease caused by *Neisseria meningitidis*, wherein the patient has been pre-immunised with (a) a tetanus toxoid and/or (b) a conjugate of (i) a capsular saccharide of an organism other than *N.meningitidis* and (ii) a tetanus toxoid.

5. The method of claim 1 or 2, wherein the composition comprises (a) and (b), (b) and (d), or all four of (a), (b), (c) and (d).

6. The use of claim 3 or 4, wherein the use is of (a) and (b), (b) and (d), or all four of (a), (b), (c) and (d).
7. The method or use of any preceding claim, wherein the patient has been pre-immunised with a vaccine comprising a tetanus toxoid.

8. The method or use of any preceding claim, wherein the patient has been pre-immunised with a vaccine comprising a Hib conjugate.

9. The method or use of any preceding claim, wherein the patient has been pre-immunised with a vaccine comprising at least one pneumococcal conjugate.

10. The method or use of any preceding claim, wherein the patient was pre-immunised at least 0.5, 1, 2, 4 or 6 months before the method or use.

11. The method or use of claim 10, wherein the patient was pre-immunised at least 8 years before the method or use.

12. The method or use of any preceding claim, wherein the pre-immunisation took place within 1 year of the patient's birth.

13. The method or use of any preceding claim, wherein the saccharides in the meningococcal conjugates (a) to (d) are shorter than the native capsular saccharides seen in meningococcus.

14. The method or use of any preceding claim, wherein the meningococcal conjugates comprise a tetanus toxoid carrier and an adipic acid linker.

15. The method or use of claim 14, comprising no more than 50μg of tetanus toxoid carrier.

16. The method or use of any preceding claim, wherein the composition or medicament further comprises a conjugated capsular saccharide from *Streptococcus pneumoniae*.

17. The method or use of any preceding claim, wherein the composition or medicament further comprises a conjugated capsular saccharide from *Haemophilus influenzae* type B.

18. The method or use of any preceding claim, wherein the composition or medicament further comprises a protein antigen from serogroup B of *Neisseria meningitidis*.

19. The method or use of any preceding claim, wherein the composition or medicament includes an aluminium hydroxide adjuvant and/or an aluminium phosphate adjuvant.

20. The method or use of any preceding claim, wherein the disease caused by *Neisseria meningitidis* is meningococcal meningitis.

21. The method or use of claims 1-6, wherein: - the patient has been pre-immunised, at least five years before the method or use, with a vaccine comprising a tetanus toxoid; - the meningococcal conjugates comprise a tetanus toxoid carrier and, optionally, an adipic acid linker; - the meningococcal conjugates are present at 2-15 μg/ml (measured as meningococcal saccharide) per serogroup; - the
saccharide:carrier weight ratio for at least one conjugate is about 1:3; and - the medicament includes 20-50 μg/ml of tetanus toxoid.

22. A method for immunising a human patient against a disease caused by *Streptococcus pneumoniae*, comprising the step of administering to the human patient a composition that comprises at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which conjugated to a diphtheria toxoid or CRM197 or a derivative thereof, wherein the patient has been pre-immunised with (a) a diphtheria toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a diphtheria toxoid or CRM197 or derivative thereof.

23. A method for immunising a human patient against a disease caused by *Streptococcus pneumoniae*, comprising the step of administering to the human patient a composition that comprises at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which conjugated to tetanus toxoid or a derivative thereof, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a tetanus toxoid or derivative thereof.

24. A method for immunising a human patient against a disease caused by *Streptococcus pneumoniae*, comprising the step of administering to the human patient a composition that comprises at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which conjugated to tetanus toxoid or a derivative thereof and at least one of which is conjugated to diphtheria toxoid or CRM197 or a derivative thereof, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a diphtheria toxoid or CRM197 or derivative thereof and/or (c) a diphtheria toxoid or derivative thereof and/or (d) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a diphtheria toxoid or CRM197 or derivative thereof.

25. The use of at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which conjugated to a diphtheria toxoid or CRM197 or a derivative thereof, in the manufacture of a medicament for immunising a human patient against a disease caused by pneumococcus, wherein the patient has been pre-immunised with (a) a diphtheria toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a diphtheria toxoid or CRM197 or derivative thereof.

26. The use of at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which conjugated to a tetanus toxoid or a derivative thereof, in the manufacture of a medicament for immunising a human patient against a disease caused by pneumococcus, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a tetanus toxoid or derivative thereof.

27. The use of at least seven, ten, eleven, thirteen or fourteen conjugates of different capsular saccharide serotypes of pneumococcus, at least one of which is conjugated to tetanus toxoid or a derivative thereof and at least one of which is conjugated to...
diphtheria toxoid or CRM197 or a derivative thereof, in the manufacture of a medicament for immunising a human patient against a disease caused by pneumococcus, wherein the patient has been pre-immunised with (a) a tetanus toxoid or derivative thereof and/or (b) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a tetanus toxoid or derivative thereof and (c) a diphtheria toxoid or derivative thereof and/or (d) a conjugate of (i) a capsular saccharide of an organism other than pneumococcus and (ii) a diphtheria toxoid or CRM197 or derivative thereof.

28. The method or use of claims 22-27, wherein a meningococcal capsular saccharide conjugate is not present in the composition or medicament.

29. The method or use of claims 22-28, wherein the patient has been pre-immunised with a vaccine comprising a diphtheria toxoid.

30. The method or use of claims 22-29, wherein the patient has been pre-immunised with a vaccine comprising a tetanus toxoid.

31. The method or use of claims 22-30, wherein the patient has been pre-immunised with a vaccine comprising a Hib conjugate.

32. The method or use of claims 22-31, wherein the patient has been pre-immunised with a vaccine comprising at least one meningococcal capsular saccharide conjugate.

33. The method or use of claims 22-32, wherein the patient was pre-immunised at least 0.5, 1, 2, 4 or 6 months before the method or use.

34. The method or use of claim 33, wherein the patient was pre-immunised at least 8 years before the method or use.

35. The method or use of claims 22-34, wherein the pre-immunisation took place within 1 year of the patient's birth.

36. The method or use of claims 22-35, wherein at least one of the saccharides in the pneumococcal conjugates are shorter than the native capsular saccharides seen in pneumococcus.

37. The method or use of claims 22-36, wherein at least one of the pneumococcal conjugates comprises a diphtheria toxoid carrier and, optionally, an adipic acid linker.

38. The method or use of claims 22-37, wherein at least one of the pneumococcal conjugates comprises a CRM197 carrier and, optionally, an adipic acid linker.

39. The method or use of claims 22-38, wherein at least one of the pneumococcal conjugates comprises a tetanus toxoid carrier and, optionally, an adipic acid linker.

40. The method or use of claim 37 or 38, comprising no more than 60μg of diphtheria toxoid or CRM197 carrier.

41. The method or use of claim 39, comprising no more than 50μg of tetanus toxoid carrier.
42. The method or use of claims 22-41, wherein the composition or medicament further comprises a conjugated capsular saccharide from *Haemophilus influenzae* type B.

43. The method or use of claims 22-42, wherein the composition or medicament further comprises a protein antigen from serogroup B of *Neisseria meningitidis*.

44. The method or use of claims 22-43, wherein the composition or medicament includes an aluminium hydroxide adjuvant and/or an aluminium phosphate adjuvant.

45. A method for immunising a human patient against a disease caused by *Neisseria meningitidis*, *Bordetella pertussis*, *Clostridium tetani*, *Corynebacterium diphtheriae* and *Streptococcus pneumoniae* comprising the step of administering to the human patient the following vaccines with the following administration scheme:

<table>
<thead>
<tr>
<th></th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTP</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Strep</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>MenC</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

wherein the visit to the medical practitioner all occur in the first 8 months of life, wherein there is at least 2 weeks between each consecutive visit, wherein DTP comprises DT, TT, and either whole cell (Pw) or acellular (Pa) pertussis antigens, wherein Strep is a multivalent pneumococcal capsular saccharide conjugate vaccine comprising at least 7, 10, 11, 13 or 14 conjugated serotypes, wherein MenC comprises a conjugated *N. meningitidis* serogroup C capsular saccharide, wherein at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to DT or CRM197, or at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to TT.

46. A method for immunising a human patient against a disease caused by *Neisseria meningitidis*, *Bordetella pertussis*, *Clostridium tetani*, *Corynebacterium diphtheriae* and *Streptococcus pneumoniae* comprising the step of administering to the human patient the following vaccines with the following administration scheme:

<table>
<thead>
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<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTP</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Strep</td>
<td>X</td>
<td></td>
<td></td>
<td>Optionally X</td>
</tr>
<tr>
<td>MenC</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

wherein the visit to the medical practitioner all occur in the first 8 months of life, wherein there is at least 2 weeks between each consecutive visit, wherein DTP comprises DT, TT, and either whole cell (Pw) or acellular (Pa) pertussis antigens, wherein Strep is a multivalent pneumococcal capsular saccharide conjugate vaccine comprising at least 7, 10, 11, 13 or 14 conjugated serotypes, wherein MenC comprises a conjugated *N. meningitidis* serogroup C capsular saccharide,
wherein at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to DT or CRM197, or at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to TT.

47. A method for immunising a human patient against a disease caused by Neisseria meningitidis, Bordetella pertussis, Clostridium tetani, Corynebacterium diphtheriae and Streptococcus pneumoniae comprising the step of administering to the human patient the following vaccines with the following administration scheme:

<table>
<thead>
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<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTP</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Strep</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>MenC</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

wherein the visit to the medical practitioner all occur in the first 8 months of life, wherein there is at least 2 weeks between each consecutive visit, wherein DTP comprises DT, TT, and either whole cell (Pw) or acellular (Pa) pertussis antigens, wherein Strep is a multivalent pneumococcal capsular saccharide conjugate vaccine comprising at least 7, 10, 11, 13 or 14 conjugated serotypes, wherein MenC comprises a conjugated N. meningitidis serogroup C capsular saccharide, wherein at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to DT or CRM197, or at least one conjugated saccharide in each of the Strep and MenC vaccines is conjugated to TT.

48. The method of claims 45-47, wherein Visits 1, 2 and 3 occur at: 2, 3, 4 months of age; 3, 4, 5 months of age; 2, 4, 6 months of age; or 6, 10, 14 weeks of age.

49. The method of claims 45-48, wherein visit 4 occurs at 5 months of age.

50. The method of claims 45-49, wherein DTP, MenC and Strep are administered as separate injections at any one visit.

51. The method of claims 45-49, wherein DTP, MenC and Strep are administered as a combination vaccine at any one visit.

52. The method of claims 45-51, wherein MenB, a N. meningitidis subunit protein vaccine or a N. meningitidis outer membrane vesicle vaccine (preferably isolated from a serogroup B strain), is administered at Visit 1 and Visit 3.

53. The method of claim 52, wherein MenB is given as a booster dose at a further visit at 11-15 months of age.

54. The method of claims 45-53, wherein DTP is given as a booster dose at a further visit at 11-15 months of age.

55. The method of claims 45-54, wherein MenC is given as a booster dose at a further visit at 11-15 months of age.

56. The method of claims 45-55, wherein Strep is given as a booster dose at a further visit at 11-15 months of age.
57. The method of claims 45-56, wherein DTP further comprises HepB surface antigen (optionally adsorbed onto aluminium phosphate).

58. The method of claims 45-57, wherein DTP further comprises inactivated poliovirus.

59. The method of claims 45-58, wherein MenC further comprises a conjugated \textit{N. meningitidis} serogroup A capsular saccharide which is optionally conjugated to the same protein carrier as MenC.

60. The method of claims 45-59, wherein MenC further comprises a conjugated \textit{N. meningitidis} serogroup Y capsular saccharide which is optionally conjugated to the same protein carrier as MenC.

61. The method of claims 45-60, wherein MenC further comprises a conjugated \textit{N. meningitidis} serogroup W135 capsular saccharide which is optionally conjugated to the same protein carrier as MenC.

62. The method of claims 45-61, wherein MenC further comprises a conjugated \textit{H. influenzae} type B capsular saccharide which is optionally conjugated to the same protein carrier as MenC.

63. The method of claims 45-62, wherein DTP further comprises a conjugated \textit{H. influenzae} type B capsular saccharide which is optionally conjugated to the same protein carrier as MenC.

64. The method of claims 45-63, wherein at least one capsular saccharide is conjugated to TT in the MenC and Strep vaccines.

65. The method of claims 45-64, wherein at least one capsular saccharide is conjugated to DT in the MenC and Strep vaccines.

66. The method of claims 45-65, wherein at least one capsular saccharide is conjugated to CRM197 in the MenC and Strep vaccines.

67. The use of the vaccines of claims 45-66 in the manufacture of a medicament for immunising a human patient against a disease caused by \textit{Neisseria meningitidis}, \textit{Bordetella pertussis}, \textit{Clostridium tetani}, \textit{Corynebacterium diphtheriae} and \textit{Streptococcus pneumoniae}, wherein the patient is administered vaccine according to the vaccination schedule of claims 45-67.

68. A kit comprising all the vaccines required for Visit 1 vaccine administration of claims 45-67, and instructions for its use.

69. A kit comprising all the vaccines required for Visit 2 vaccine administration of claims 45-67, and instructions for its use.

70. A kit comprising all the vaccines required for Visit 3 vaccine administration of claims 45-67, and instructions for its use.