CLAIMS

1. A combined influenza-COVID-19 vaccine comprising:

(a) an influenza haemagglutinin (HA) or an immunogenic fragment thereof; and

(b) one or more antigen derived from SARS-CoV-2 or an immunogenic fragment thereof;

wherein the antigens are capable of eliciting immune response and protection against both influenza and COVID-19.

2. The combined influenza-COVID-19 vaccine of claim 1, which further comprises an influenza neuraminidase (NA) or an immunogenic fragment thereof.

3. The combined influenza-COVID-19 vaccine of claim 1 or 2, wherein:

(a) the influenza HA or immunogenic fragment thereof is:
    (i) comprised in an inactivated influenza virion;
    (ii) a recombinant HA or immunogenic fragment thereof;
    (iii) a fusion protein comprising HA or an immunogenic fragment thereof; or
    (iv) encoded by an RNA or DNA vaccine; and/or

(b) the influenza NA or immunogenic fragment thereof is:
    (i) comprised in an inactivated influenza virion;
    (ii) a recombinant NA or immunogenic fragment thereof;
    (iii) a fusion protein comprising NA or an immunogenic fragment thereof; or
    (iv) encoded by an RNA or DNA vaccine; and/or

(c) the one or more antigen derived from SARS-CoV-2 or an immunogenic fragment thereof is:
    (i) at least one recombinant SARS-CoV-2 spike protein or immunogenic fragment thereof;
    (ii) at least one fusion protein comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof;
    (iii) at least one virus-like particle (VLP) comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof;

(iv) at least one polynucleotide encoding a recombinant SARS-CoV-2 spike protein or immunogenic fragment thereof; or

(v) encoded by at least one RNA or DNA vaccine.

4. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein the influenza HA or immunogenic fragment thereof and the influenza NA or immunogenic fragment thereof are comprised in an inactivated influenza virion and the one or more antigen derived from SARS-CoV-2 or an immunogenic fragment thereof is: (i) at least one fusion protein comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof or (ii) at least one virus-like particle (VLP) comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof.

5. The combined influenza-COVID-19 vaccine of claim 1 or 2, wherein:

(a) the influenza HA or immunogenic fragment thereof is comprised in a live attenuated influenza virion;

(b) the influenza NA or immunogenic fragment thereof is comprised in a live attenuated influenza virion; and/or

(c) the one or more antigen derived from SARS-CoV-2 or an immunogenic fragment thereof is comprised in a live viral vector.

6. The combined influenza-COVID-19 vaccine of claim 5, wherein the live viral vector comprising the one or more antigen derived from SARS-CoV-2 or an immunogenic fragment thereof is:

(a) an adenoviral vector;

(b) a measles virus vector;

(c) a mumps virus vector;

(d) a rubella virus vector;

(e) a varicella virus vector;

(f) a polio virus vector; or

(g) a yellow fever virus vector.

7. The combined influenza-COVID-19 vaccine of any one of the preceding claims, further comprising an adjuvant.

8. The combined influenza-COVID-19 vaccine of claim 7, wherein said adjuvant a stimulator of cellular (Th1) and humoral (Th2) immune responses.

9. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein said adjuvant comprises a squalene oil-in-water emulsion, an aluminium salt or a monophosphoryl Lipid A (MPL).

10. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein the one or more antigen derived from SARS-CoV-2 is selected from:

(a) a spike protein from SARS-CoV-2 having at least 90% identity with SEQ ID NO: 1, or a fragment thereof that has a common antigenic cross-reactivity with said spike protein;
(b) a fusion protein comprising a spike protein from SARS-CoV-2 having at least 90% identity with SEQ ID NO: 1, or a fragment thereof that has a common antigenic cross-reactivity with said spike protein;
(c) a VLP comprising a spike protein from SARS-CoV-2 having at least 90% identity with SEQ ID NO: 1, or a fragment thereof that has a common antigenic cross-reactivity with said spike protein;
(d) a polynucleotide encoding a spike protein from SARS-CoV-2 having at least 90% identity with SEQ ID NO: 1, or a fragment thereof that has a common antigenic cross-reactivity with said spike protein; or
(e) a viral vector, RNA vaccine or DNA plasmid that expresses a spike protein from SARS-CoV-2 having at least 90% identity with SEQ ID NO: 1, or a fragment thereof, that has a common antigenic cross-reactivity with said spike protein

wherein optionally the fragment of the SARS-CoV-2 spike protein comprises or consists of the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein, preferably having at least 90% identity with SEQ ID NO: 15.

11. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein the one or more antigen derived from SARS-CoV-2 is a fusion protein comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof and further comprising:

(a) the Hepatitis B surface antigen, or a fragment thereof that has a common antigenic cross-reactivity with said Hepatitis B surface antigen;

(b) the HPV 18 L1 protein, or a fragment thereof that has a common antigenic cross-reactivity with said HPV 18 L1 protein;

(c) the Hepatitis E P239 protein, or a fragment thereof that has a common antigenic cross-reactivity with said Hepatitis E P239 protein; and/or

(d) the HPV 16 L1 protein, or a fragment thereof that has a common antigenic cross-reactivity with said HPV 16 L1 protein.

12. The combined influenza-COVID-19 vaccine of claim 11, wherein:

(a) the fusion protein is encoded by a polynucleotide which comprises or consists of a nucleic acid sequence having at least 90% identity with any one of SEQ ID NO: 3, 5, 6,8, 26, 27, 29, 30 or 32; and/or

(b) the fusion protein comprises or consists of an amino acid sequence having at least 90% identity with any one of SEQ ID NO: 9, 10, 11, 12, 28, 31 or 33.

13. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein the one or more antigen derived from SARS-CoV-2 is a VLP comprising a SARS-CoV-2 spike protein or immunogenic fragment thereof, wherein said VLP comprises or consists of a fusion protein as defined in claim 11 or 12.

14. The combined influenza-COVID-19 vaccine of any one of the preceding claims, wherein the influenza HA or immunogenic fragment thereof and the influenza NA or immunogenic fragment thereof are comprised in:

(a) a seasonal influenza vaccine, in particular the seasonal 3-valent influenza vaccine or the seasonal 4-valent influenza vaccine;

(b) a monovalent pandemic influenza vaccine; or

(c) a universal influenza vaccine.

15. The combined influenza-COVID-19 vaccine of any one of the preceding claims for use in a method of treatment and/or prevention of COVID-19 and influenza.

16. Use of an influenza HA or an immunogenic fragment thereof; and an antigen derived from SARS-CoV-2 or an immunogenic fragment thereof, and optionally an influenza NA or an immunogenic fragment thereof in the manufacture of a medicament for use in the treatment and/or prevention of COVID-19 and influenza, wherein said medicament is a combined influenza-COVID-19 vaccine as defined in any one of claims 1 to 14.

~~17. A method of immunising a subject against both influenza and COVID-19 comprising administering to said subject a therapeutically effective amount of a combined influenza-COVID-19 vaccine as defined in any one of claims 1 to 14.~~

~~18.~~17. The combined influenza-COVID-19 vaccine for use according to~~of~~ claim 15, or the use of claim 16~~, or the method of claim 17,~~ wherein the combined influenza-COVID-19 vaccine is to be administered at intervals of 10 to 14 months, optionally wherein the combined influenza-COVID-19 vaccine is to be administered at intervals of about 12 months.