

Annex A

<u>MA (EU) number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/22/1709/001	BIMERVAX	--1	Emulsion for injection	Intramuscular use	vial (glass)	5 ml (10 doses)	10 multidose vials (100 doses)
EU/1/22/1709/002	BIMERVAX	--1	Emulsion for injection	Intramuscular use	vial (glass)	0.5 ml (1 doses)	5 single dose vials (5 doses)
EU/1/22/1709/003	BIMERVAX	--1	Emulsion for injection	Intramuscular use	vial (glass)	0.5 ml (1 doses)	10 single dose vials (10 doses)
EU/1/22/1709/004	BIMERVAX	--1	Emulsion for injection	Intramuscular use	vial (glass)	0.5 ml (1 doses)	20 single dose vials (20 doses)

--1

One dose (0.5 mL) contains:

40 micrograms of selvacovatein adjuvanted with SQBA.

Selvacovatein is a SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion heterodimer (B.1.351 and B.1.1.7 strains) produced by recombinant DNA technology using a plasmid expression vector in a CHO cell line.

SQBA adjuvant containing per 0.5 mL dose: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) and water for injections.