

1.2 Annex to Application Form
List of all authorised product presentations

<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/1/12/812/001	Bexsero	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe with needles
EU/1/12/812/002	Bexsero	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe without needles
EU/1/12/812/003	Bexsero	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes with needles
EU/1/12/812/004	Bexsero	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes without needles

--1 One dose (0.5 ml) contains:
 Recombinant *Neisseria meningitidis* group B NHBA fusion protein ^{1, 2, 3} 50 micrograms
 Recombinant *Neisseria meningitidis* group B NadA protein ^{1, 2, 3} 50 micrograms
 Recombinant *Neisseria meningitidis* group B fHbp fusion protein ^{1, 2, 3} 50 micrograms
 Outer membrane vesicles (OMV) from *Neisseria meningitidis* group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 ² 25 micrograms

¹ produced in *E. coli* cells by recombinant DNA technology

² adsorbed on aluminium hydroxide (0.5 mg Al³⁺)

³ NHBA (Neisserial Heparin Binding Antigen), NadA (*Neisseria* adhesin A), fHbp (factor H binding protein)