

## **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/1/15/1079/001	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/15/1079/002	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/15/1079/003	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/15/1079/004	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/15/1079/005	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/15/1079/006	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles
EU/1/15/1079/007	Vaxelis	--1	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	50 (5x10) pre-filled syringes (multipack)

--1 One dose (0.5 ml) contains:

Diphtheria Toxoid <sup>1</sup> :	not less than 20 IU
Tetanus Toxoid <sup>1</sup> :	not less than 40 IU
<i>Bordetella pertussis</i> antigens <sup>1</sup> :	
Pertussis Toxoid (PT)	20 micrograms
Filamentous Haemagglutinin (FHA)	20 micrograms
Pertactin (PRN)	3 micrograms
Fimbriae Types 2 and 3 (FIM)	5 micrograms
Hepatitis B surface antigen <sup>2,3</sup> :	10 micrograms
Poliovirus (Inactivated) <sup>4</sup> :	
Type 1 (Mahoney)	40 D antigen units <sup>5</sup> ;
Type 2 (MEF-1)	8 D antigen units <sup>5</sup>
Type 3 (Saukett)	32 D antigen units <sup>5</sup>
<i>Haemophilus influenzae</i> type b polysaccharide (Polyribosylribitol Phosphate)	3 micrograms
Conjugated to meningococcal protein <sup>2</sup>	50 micrograms

<sup>1</sup> adsorbed on aluminium phosphate (0.17 mg Al<sup>3+</sup>)

<sup>2</sup> adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.15 mg Al<sup>3+</sup>)

<sup>3</sup> produced in yeast (*Saccharomyces cerevisiae*) cells by recombinant DNA technology

<sup>4</sup> produced in Vero cells

<sup>5</sup> or equivalent antigenic quantity determined by a suitable immunochemical method.