

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/1/18/1272/001	Shingrix	-- ¹	Powder and suspension for suspension for injection	Intramuscular use	powder: vial (glass); suspension: vial (glass)	Powder: 50 µg; Suspension: 0.5 ml	1 vial (powder) + 1 vial (suspension)
EU/1/18/1272/002	Shingrix	-- ¹	Powder and suspension for suspension for injection	Intramuscular use	powder: vial (glass); suspension: vial (glass)	Powder: 50 µg; Suspension: 0.5 ml	10 vials (powder) + 10 vials (suspension)

--¹ After reconstitution, 1 dose (0.5 ml) contains 50 micrograms of gE antigen¹ adjuvanted with AS01B².

¹ Varicella Zoster Virus (VZV) glycoprotein E (gE) produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells

² AS01B Adjuvant System is composed of the plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) (50 micrograms) and 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* (50 micrograms)