



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2018
EMA/CHMP/811150/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Shingrix

Herpes zoster vaccine (recombinant, adjuvanted)

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Shingrix, intended for prophylaxis of herpes zoster. The applicant for this medicinal product is GlaxoSmithkline Biologicals SA.

Shingrix will be available as a powder and suspension liquid to be made into a suspension for injection. The active substance of Shingrix is varicella zoster virus glycoprotein E antigen (VZV gE) (ATC code: J07BK03). In Shingrix, VZV gE is combined with an adjuvant (AS01B), and is designed to induce antigen-specific cellular and humoral immune responses in individuals with pre-existing immunity against varicella zoster virus.

The benefits with Shingrix are its ability to significantly decrease the incidence of herpes zoster and consequently of post-herpetic neuralgia compared with placebo. The most common side effects are pain at the injection site, myalgia, fatigue and headache.

The full indication is: "Shingrix is indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older (see section 5.1). The use of Shingrix should be in accordance with official recommendations".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

