EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

Shingrix vaccine

Date: March 2024

Unit: Technical Assessment Unit

Assessment report

Shingrix

Administrative information:

Trade name of the medicinal product:	Shingrix powder and suspension for suspension for injection
INN (or common name) of the active substance(s):	Varicella Zoster Virus glycoprotein Eantigen 50 mcg/0.5ml
Manufacturer of the finished product	GlaxoSmithKline Biologicals SA, Parc de la Noire Epine, Avenue Fleming 20, 1300 Wavre - BELGIUM Patheon Italia S.p.A., Viale G.B. Stucchi, 110 – 20900 Monza (MB), ITALY
Marketing Authorization holder	GlaxoSmithKline Biologicals SA 89, rue del"Institut, B-1330 Rixensart - BELGIUM
Applied Indication(s):	prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) in adults 50years of age or older
Pharmaceutical form(s) and strength(s):	Powder and suspension for suspension forinjection • Strength: 50 mcg/ 0.5 ml
Route of administration	For intramuscular injection only, preferably in the deltoid muscle.
Approved Pack	Powder for 1 dose in a vial (type I glass) with a stopper (butyl rubber) and Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber). Shingrix is available in a pack size of 1 vial of powder plus 1 vial of suspension

List of abbreviations

AS	Active substance
AS01B	Adjuvant System containing 50 µg MPL, 50 µg QS-21 and liposomes
gE	glycoprotein E
GLP	Good laboratory practice
HZ	Herpes Zoster
PHN	Postherpetic neuralgia
Qc	Quality control

Dossier initial submission and evaluation process

- The product was submitted for registration via reliance model level 1
- The dossier was submitted to the registration administration units on 7.8.2023 when the applicant provided all the reliance required documents.
- EMA list of questions was provided along with Full CTD for the product.

1. General introduction about the product including brief description of the AI, its modeof action and indications:

- Shingrix is presented as a powder and suspension containing 50 µg of glycoprotein E (gE) antigen (powder) adjuvanted with AS01B (suspension for the preparation of a suspension for injection).
- Shingrix is a vaccine used for preventing shingles (herpes zoster) in adults aged 50 and older, and in adults aged 18 and older who are at increased risk of contracting herpes zoster.
- The active substance in shingrix is varicella zoster virus glycoprotein E [1] antigen which causes the immune system of those who already possess immunity to the varicella zoster virus to produce specific antibodies and defence cells against the virus. As a result, the body's own defenses are better equipped to fight the virus and prevent shingles.

2. Quality aspects:

- **Manufacturer(s)**

-The name and address of the manufacturer involved in the manufacture and testing of the active Substance (AS) is GlaxoSmithKline Biologicals SA (Wavre Nord site): Parc de la Noire Epine, Avenue Fleming 20, 1300 Wavre (Belgium).

-The production, formulation, packaging and Qc testing of the finished product were take place in GlaxoSmithKline Biologicals SA, Parc de la Noire Epine, Avenue Fleming 20, 1300 Wavre BELGIUM and Patheon Italia S.p.A., Viale G.B. Stucchi, 110 – 20900 Monza (MB), ITALY.

- **Stability**

Drug Substance:
Approved Shelf Life
Active substance (gE Purified Bulk): 60 months
Approved Storage Conditions:
Active substance: Stored at -45°C ± 10 °C

Drug product:
Approved Shelf Life
AS01B final container: 36 months
gE final container: 60 months
Pack of (AS01B final container+ gE final container):36 month
Approved Storage Conditions
Store in a refrigerator (2°C – 8°C).
-Do not freeze.
-Store in the original package in order to protect from light.

After reconstitution:

-Chemical and physical in-use stability has been demonstrated for 24 hours at 30°C.

-From **a microbiological point** of view, the vaccine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 6 hours at 2°C to 8°C.

3. Non-clinical and Clinical aspect:

Non-clinical:

-Safety pharmacology and toxicology program was conducted in compliance with GLP regulations.

-In accordance with the international guidelines related to preclinical testing and adjuvants of vaccines for human use the nonclinical development of shingrex was performed. Generally, the preclinical studies were performed with the glycoprotein (gE) /AS01B candidate vaccine formulation, the AS01B as Adjuvant system and its immune-enhancers (QS-21 and MPL).

-The nonclinical data indicate that Shingrix vaccine has the potential to be safe and efficacious for the prophylaxis against Herpes zoster in the intended patient Therefore, the non-clinical development of Shingrix is -overall acceptable.

Clinical:

- The Clinical trials were performed in accordance with GCP.

-Shingrix is favorable in prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in: adults 50 years of age or older and adults 18 years of age or older at increased risk of HZ. The use of Shingrix should be in accordance with official recommendations.

General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/assessment-report/shingrix-epar-public-assessment-report_en.pdf