Medicines Adverse Reactions Committee

Meeting date	12/09/2019	Agenda item	3.2.4
Title	**Shingrix (Recombinant Varicella Zoster Virus Vaccine) Risk Management Plan (RMP)**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For advice
Product name *Shingrix*	**Active ingredient** Recombinant varicella zoster virus glycoprotein E 50µg	**Sponsor** GlaxoSmithKline NZ Ltd (GSK)	
Funding	Not applicable.		
Previous MARC meetings	This particular vaccine has not been discussed previously. Previous MARC papers relating to other varicella zoster virus vaccine(s): • 169th MARC meeting (9 March 2017) - Varicella vaccine: Overview of benefits and harm This paper outlined the benefits and risks of harm of varicella vaccination (against chickenpox) in response to amendments to the immunisation schedule. This paper did not discuss the use of varicella vaccines for shingles. The Committee considered Medsafe's proposed monitoring for the inclusion of varicella vaccine on the National Immunisation Schedule to be adequate.		
International action	At the time of Medsafe's initial clinical evaluation (October 2018), Shingrix was approved in the EU, USA, Canada, Australia and Japan.		
Prescriber Update	None for this particular vaccine. Previous *Prescriber Update* articles relating to other varicella zoster virus vaccine(s): • Varicella Zoster Virus Vaccines – Medication Errors (September 2015) • Zostavax Vaccine for Shingles – Do Not Use in Immunocompromised Patients (September 2017)		
Usage data	[redacted]		
Advice sought	**The Committee is asked to advise on the following:** • Is the Committee satisfied with the RMP? • Are there any elements that require clarification or further information from the company? • Are the additional proposed studies and pharmacovigilance activities sufficient?		

Table of Contents

1 PURPOSE

Medsafe has received a new medicine application (NMA) from GlaxoSmithKline (GSK) for Shingrix (recombinant varicella zoster virus vaccine). As part of their application, GSK provided a Risk Management Plan (RMP) to Medsafe.

The purpose of this paper is to seek the Committee's advice on the Risk Management Plan (RMP) for Shingrix, including whether any additional post-market activities are required in New Zealand should Shingrix be approved.

A full copy of the Shingrix RMP is attached as Annex 1. Additionally, Medsafe's clinical evaluation report for Shingrix is attached as Annex 2.

2 BACKGROUND

2.1 Shingrix

2.1.1 Indication

The proposed indication for *Shingrix* is for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older.

2.1.2 Description of the product

[redacted]

2.1.3 Dosage

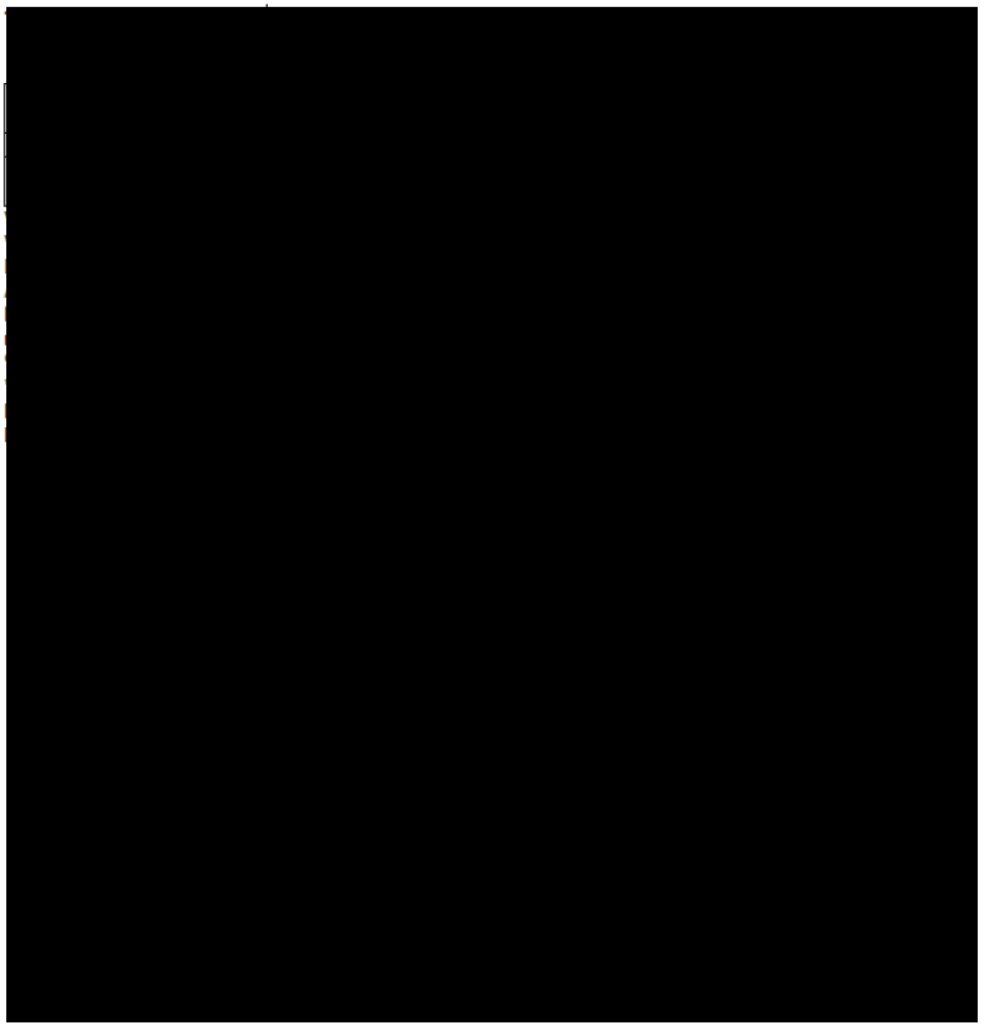
[redacted]

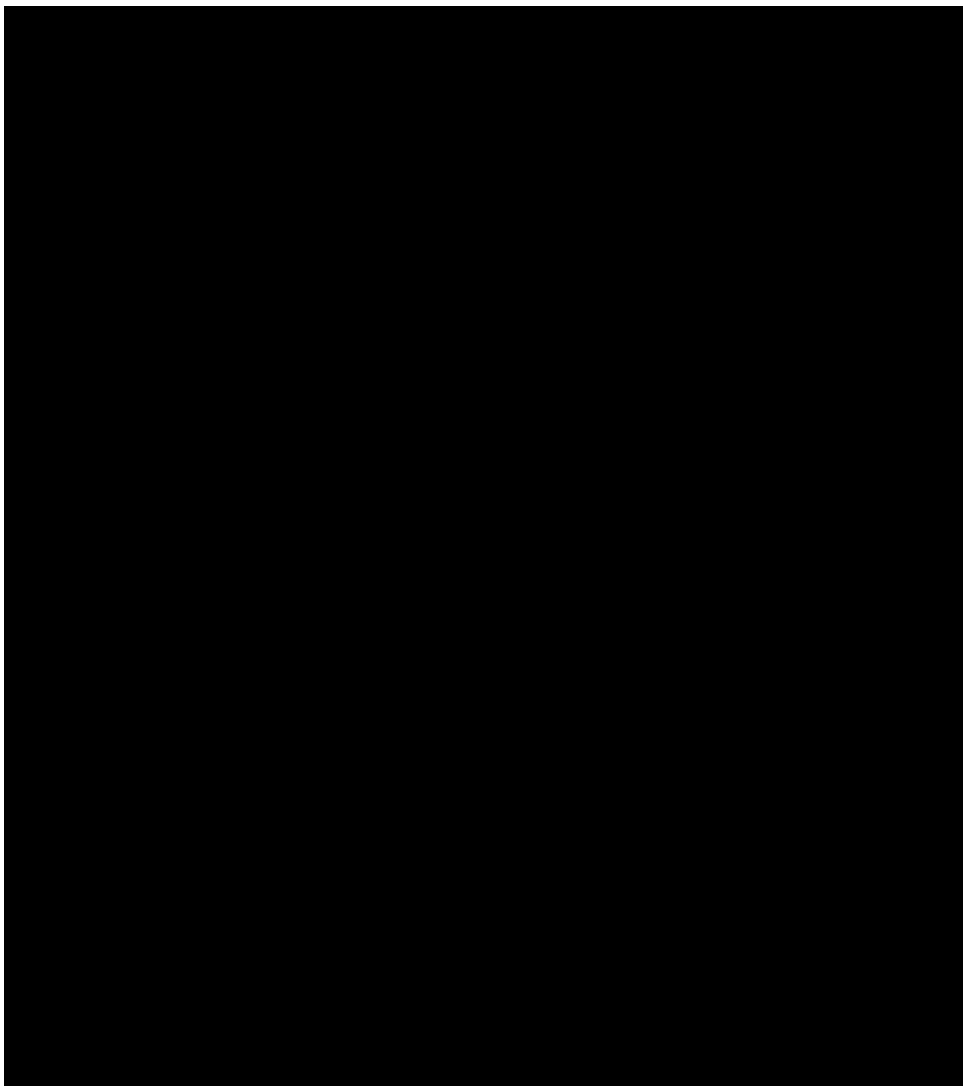
3 RISK MANAGEMENT PLAN

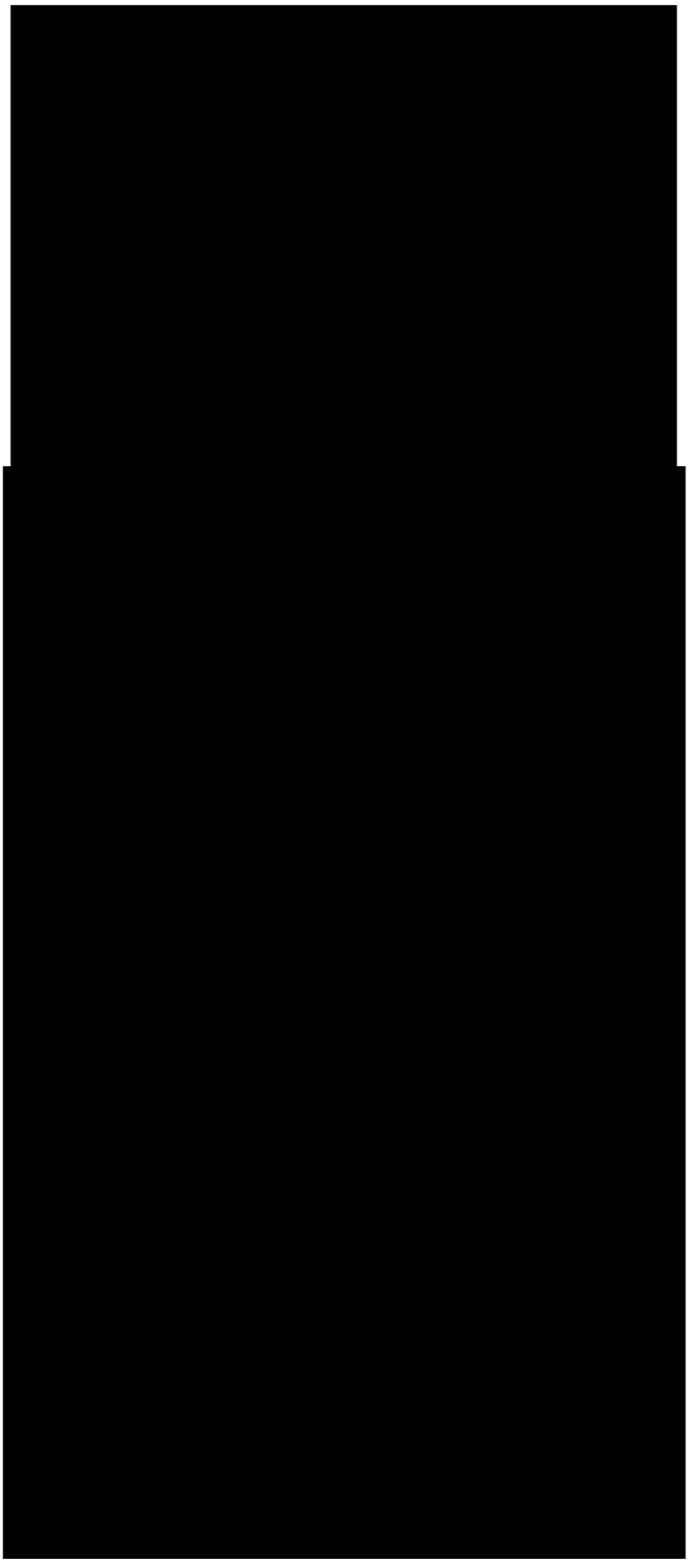
[redacted]

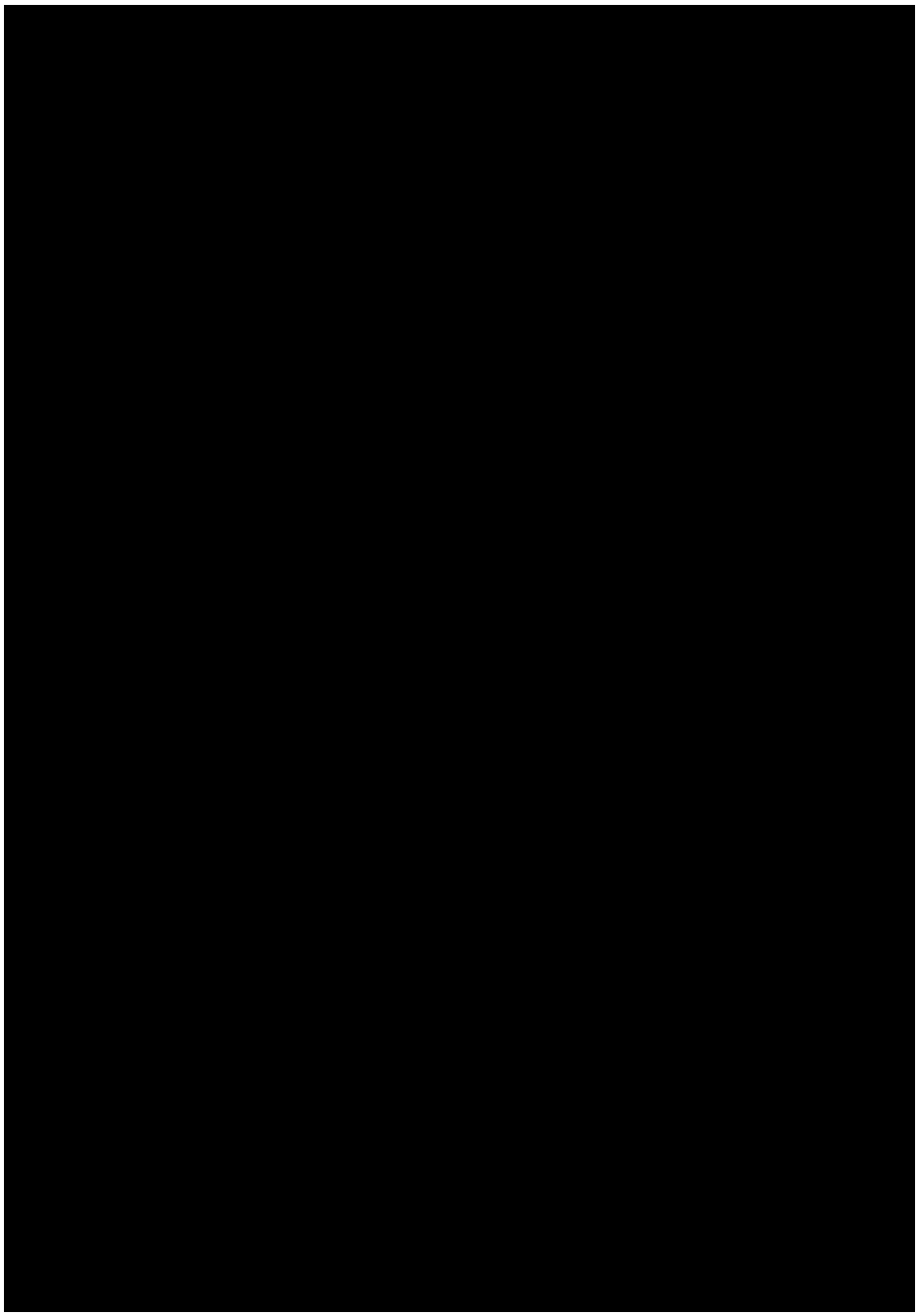
[redacted]

[redacted]









[redacted]

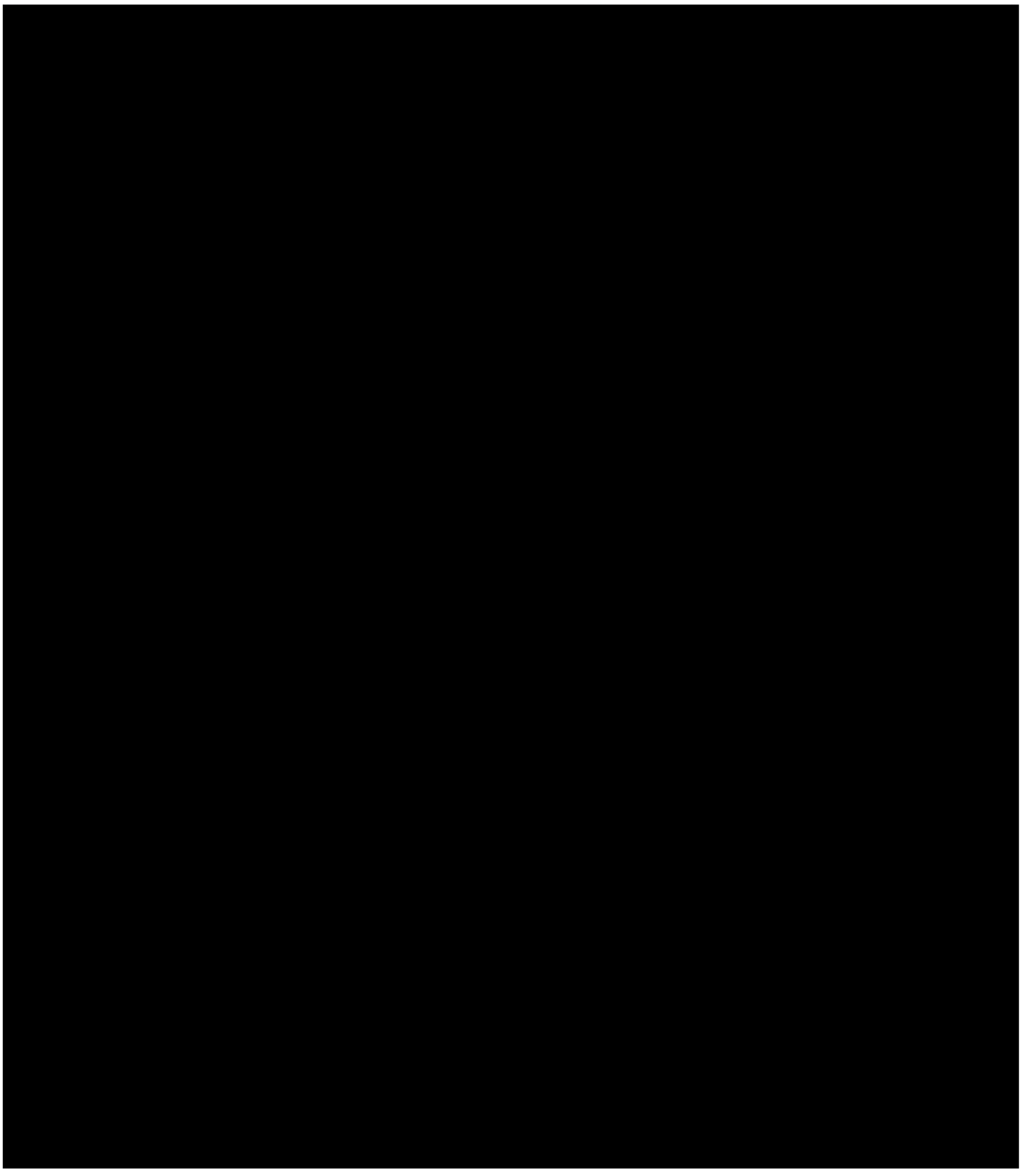
[redacted]

3.1.8 Summary of ongoing safety concerns

Table 6 Summary of safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	• Risk of potential Immune Mediated Disorders (pIMDs) following *Shingrix* vaccination • Virus reactivation in immunocompetent individuals with a history of Herpes Zoster
Missing information	• Long-term efficacy and assessment of the need for additional doses in adults 50 years of age and older. • Long-term immunogenicity in adults 50 years of age and older. • Use of *Shingrix* in frail adults 50 years of age or older • Use of *Shingrix* in immunocompromised adults • Use of *Shingrix* in adults with pre-existing pIMD • Effectiveness of *Shingrix* in preventing HZ, PHN and other HZ-related complications

[redacted]



[redacted]

[redacted]

[redacted]

4 DISCUSSION AND CONCLUSIONS

Shringrix is a new recombinant vaccine containing a novel adjuvant designed to protect against varicella reactivation and shingles. The RMP describes the extensive pre-market studies conducted by the company and the extensive ongoing studies to investigate the important potential risks and missing information.

5 ADVICE SOUGHT

The Committee is asked to advise on the following:

- Is the Committee satisfied with the RMP?
- Are there any elements that require clarification or further information from the company?
- Are the additional proposed studies and pharmacovigilance activities sufficient?

6 ANNEXES

1. EU Risk Management Plan (EU-RMP) for Shingrix - Version 2.
2. Medsafe Clinical Evaluation Report.