POST-MARKETING SAFETY SURVEILLANCE FOR THE ADJUVANTED RECOMBINANT ZOSTER VACCINE: REVIEW OF SPONTANEOUS REPORTS SINCE INTRODUCTION

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METHODS

Describes analysis on spontaneous reports involving RZV

RESULTS

PLAIN LANGUAGE SUMMARY

• Despite the limitations of post-marketing passive surveillance (reporting bias, underreporting, missing information, etc.), these data provide important safety information.

• Vaccination errors accounted for a substantial proportion of spontaneous reports. Overall, following the first year of post-marketing surveillance, the safety profile of RZV is consistent with that observed in clinical trials. The benefit-risk profile remains favorable.

• Surveillance will continue to monitor RZV safety, as it is in the early stage of implementation, when near-live data are limited.

BACKGROUND AND AIMS

• The adjuvanted recombinant zoster vaccine (RZV: Shingrix, GSK), indicated for the prevention of herpes zoster (HZ) in adults ≥50 years of age, received its first marketing authorization in October 2017.

• Pre-launch data showed that RZV is highly efficacious in preventing HZ in individuals ≥50 years of age and did not identify any safety concerns.

• In this study, the post-marketing spontaneous adverse event (AE) reports submitted to GSK’s worldwide safety database since RZV introduction were reviewed.

DEMOGRAPHIC CHARACTERISTICS

Most of the 11,538 spontaneous reports received were medically verified, non-serious and mainly from individuals ≥50 years of age.

Note: Regulatory actions and company responses are shown. Includes hospitalizations, discontinuation of vaccine administration, miscellaneous (including, but not limited to, vaccine failure, marketing significant, and unknown). "PMS" is recognized for post-market surveillance.

Note: Top vaccine-related events are described in vaccine preparation and administration.

Note: The most commonly reported AEs were consistent with reactogenicity to RZV.

Note: The O/E analysis for all cause mortality was below the expected range, indicating a very high underreporting of this outcome.

The O/E analysis for RZV policy were below the expected number, considering several scenarios of underreporting and background/resident incidences (for both risk periods).

The O/E analysis for GBs were below the expected number, considering several scenarios of underreporting and background/resident incidences.