A report of the postmarketing spontaneous safety data over 24 years for GSK’s measles-mumps-rubella (MMR) vaccine

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Results

Background

Monitoring the vaccine’s real-world safety profile in the general population continues, and rapid collection of data on its real-world use is a strength of passive safety surveillance.

Objectives

We provide an overview of the postmarketing spontaneous safety data over 24 years for GSK’s MMR vaccine.

Methods


Analysis of annual reporting trends for AEs of clinical interest (1998–2021)

- Pyrexia
- Rash
- Febrile convulsions
- Neurological conditions

GSK’s MMR vaccine

Live-attenuated MMR virus

Individuals aged ≥32 months and older

Licensed in >100 countries worldwide

DD and spontaneous AE reports retrieved (4 Dec 1997–1 Mar 2022)

Spontaneous AE reports

Seriousness of spontaneous AEs reported cumulatively

Serious   Non-serious

29,504    33.76%   66.24%

Spontaneous AE reports

1,175 FC reported

Percentage of FC with TTO occurring from 6 to 11 days

56.15%

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Note: As of 31 Mar 2023, a large number of AE notifications for several vaccines were received from one country’s pharmacovigilance website, which is managed by their regulatory authority. This increased reporting was due to their initiative to improve information about vaccine safety with the aim of encouraging AE reporting by both physicians and patients. These reports did not constitute a safety concern.

Conclusion

Post-licensure experience from spontaneous AE reporting for GSK’s MMR vaccine showed that its safety profile is consistent with that observed in clinical trials.

Feverile convulsions. More than half of the reports of FC with known TTO, occurred from 6 to 11 days following MMR vaccination, aligned to several published articles.

GSK continues monitoring the safety of its MMR vaccine worldwide.

Serious   Non-serious

66.24%    33.76%

Spontaneous AEs reported over 24 years (1998–2021), following vaccination with GSK’s MMR vaccine.

Pyrexia, rash and febrile convulsions were amongst the frequently reported AEs following vaccination with GSK’s MMR vaccine. The reporting rate for neurological conditions did not show an increasing trend over time.

Seriousness of spontaneous AEs

Spontaneous AEs reported over 24 years (1998–2021), following vaccination with GSK’s MMR vaccine.

For the period analyzed, pyrexia, rash and febrile convulsions were amongst the frequently reported AEs following vaccination with GSK’s MMR vaccine. The reporting rate for neurological conditions did not show an increasing trend over time.