Adverse events following immunization with a meningococcal serogroup B vaccine: Report from a German passive surveillance system

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Background: Invasive meningococcal disease (IMD) can be fatal and may lead to permanent neurological sequelae and disabilities. In January 2013, a novel vaccine against Neisseria meningitis serogroup B, 4CMenB, was approved by the European Medicines Agency. We aimed at evaluating the safety profile of this vaccine.

Methods: All adverse events following immunization (AEFI) reported from Germany since launch on the European market through December 2016 were reviewed and analyzed.

Results: Through December 2016, a total of 664 individual case safety reports (ICSR) notifying 1960 AEFI were received. A majority of vaccines were children aged two to 11 years (n=280, 42.2%) as well as infants and toddlers aged 28 days to 23 months (n=170, 25.6%). General disorders and administrations site conditions was the system organ class (SOC) with the majority of AEFI (n=977, 49.8%) followed by the SOCs nervous system disorders (n=249, 12.7%) and skin and subcutaneous tissue disorders (n=191, 9.7%). Screening for immune-mediated and neurological diseases did not raise any safety signal in terms of an increased proportional reporting ratio (PRR).

Conclusions: The safety profile described in the summary of product characteristics, in general, is confirmed by data from spontaneous reporting. No safety concerns were identified.

Biography
Doris Oberle is a Physician and Biostatistician at the pharmacovigilance department of the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Langen, Germany. Her research focuses on the investigation of adverse events following immunization. For example, within the scope of a case-control study, she investigated the association between pandemic influenza A (H1N1) vaccination and narcolepsy in Germany. She is also involved in the detection and evaluation of safety signals especially regarding newly approved pharmaceutical products like the meningococcal B vaccine.

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