

Candela S, Pergolizzi S, Ragni P, Cavuto S, Nobilio L, Di Mario S, Dragosevic V, Groth N, Magrini N; for the SaFoH1N1 working group.

An early (3-6 weeks) active surveillance study to assess the safety of pandemic influenza vaccine Focetria(®) in a province of Emilia-Romagna region, Italy - Part one.

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Abstract

INTRODUCTION: An observational, non-comparative, prospective, surveillance study of individuals vaccinated with the MF59-adjuvanted A/H1N1 influenza vaccine, Focetria(®), (Novartis Vaccines & Diagnostics, Siena, Italy), was performed in Italy during the 2009 A/H1N1 influenza pandemic.

METHOD: This study assessed the short-term (six-week) safety profile of the investigational vaccine in real time. After vaccination (N=7943), adverse events (AE) were assessed using both active (telephone) and passive (healthcare database) follow-up in enrolled vaccinated subjects, including infants (6-23 months), pregnant women, and the immunosuppressed. The treating physicians of all subjects experiencing AEs post-vaccination were consulted for clinical information on the conditions reported. All AEs were coded according to ICD-10.

RESULTS: A total of 1583 AEs occurred during the study, 67 (4.2%) of which were serious adverse events (SAEs). One SAE was considered to be possibly related to vaccination (transitory and ill-defined neurologic disorder experienced by a 16-year-old asthmatic male). Three adverse events of special interest (AESI) were identified (convulsions experienced by two epileptic subjects), none of which were considered to be vaccine-related. Six individuals died during the study period, in each case the cause of death was not related to vaccination (four cases of severe underlying co-morbidity, one case of psychoactive drug misuse, and one case of acute myocardial infarction).

CONCLUSIONS: No cases of clinically relevant AEs, SAEs, or AESI were observed within a six-week period of vaccine administration. In accordance with existing clinical and post-marketing safety data, the results of this active surveillance study demonstrate a good safety profile for the MF59-adjuvanted A/H1N1 vaccine, Focetria, within the general population.