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Interchangeable use of pertussis antigen-containing vaccines independent of age indication

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Background: Increased demand and supply shortages of pertussis antigen containing vaccines repeatedly poses issues in regards to age indication, in particular use in individuals from 3 years onwards. This is due to incongruent indications that were based on the available data and the need for guidance at the particular time of licensure. Furthermore, only few products are licensed for use in subjects with missing or unclear vaccination history. The purpose of this study was to evaluate product interchangeability.

Material/methods: Systematic review and meta-analysis of study data supplied to European national regulatory authorities during licensure. Evaluated outcomes were 1.) Immunogenicity: event rates and respective geometric means one month post immunization; 2.) Safety signals: fever, pain and swelling at injection site. Similarity was presumed when 1.) seropositivity or vaccine response was achieved in >80% with a 95% confidence interval of 10% of subjects (event rate >0.8) and 2.) the total event rate of the product ranged within $\pm 20\%$ that of all products in the same age group. If comparability could be shown in different age groups similarity of vaccine responses was extrapolated to missing age groups.

Results: Within the defined thresholds similarity of all vaccines included could be shown. A single dose of Tdap(-IPV) results in similar event rates and titres. For some antigens higher titers in children and adolescents were found with Tdap(-IPV) than when using high antigen content vaccines (DTaP). Primary immunization in adolescents and adults with Tdap(-IPV) results in titers and event rates comparable to those achieved with a booster dose.

Conclusions: An interchangeable use of the evaluated vaccine products for boosting or as vaccines for primary immunization in individuals >3 years of age is supported by the analysis.