

- [Combined hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type B vaccine; Infanrix™ hexa: twelve years of experience in Italy.](#)

Baldo V.Hum Vaccin Immunother. 2014.

[Jacob Puliye2015 Feb 06](#)

Dear Dr Ferenci

The EMA I understand is obliged by European Union law to engage the precautionary principle. Until the full scientific evidence is available, where there is evidence of risk, it must take precautionary measures. The comments here indicate the evidence is of more than a risk, but of the harm itself.

You say Dr. Franco cited studies that Infanrix Hexa is safe. Which ones and where? I can see Dr Franco has cited WHO and CDC statements. The TOKEN study I cited is the largest study done prospectively, as far as I am aware.

You claim I dishonestly "only cited half of the results" of the TOKEN study. Not so. You cite a different analysis using a different model (Model 2). It is scientifically untenable to claim one cancels out the other.

The second model does not show statistically significant decrease in risk in the relevant period [4 to 7 days] as you claim. The absence of significance in one model where the comparator and risk periods are completely different does not cancel out the statistically significant difference shown in the first analysis covering the relevant period.

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