

Thiomersal – Frequently asked questions

Thiomersal and vaccines

In 1999, concerns were raised in the United States of America about exposure to mercury in vaccines. This was based on the realisation that the cumulative amount of mercury in the infant immunisation schedule potentially exceeded the recommended threshold set by one of the United States government agencies for methyl mercury. However thiomersal, the preservative in some vaccines, contains ethyl mercury and not methyl mercury.

In the most recent Public Statement from the European Medicines Agency (2004), the Committee for Human Medicinal Products concluded that the latest epidemiological studies show no association between vaccination with thiomersal-containing vaccines and specific neurodevelopmental disorders. The CHMP re-emphasised that immunisation with vaccines containing thiomersal continues to offer outstanding benefits to the general population, including infants. The benefits of vaccination far outweigh the risks, if any, of exposure to thiomersal-containing vaccines. The European review concluded that there is no evidence of harm from thiomersal in vaccines other than hypersensitivity (allergic) reactions. The presence of thiomersal (and other preservatives) in the composition of vaccines should be stated on the label and a warning regarding the risk of sensitisation in relation to thiomersal and other preservatives will be included in the Summary of Product Characteristics and Package Leaflet of such products.

The World Health Organization's (WHO) Global Advisory Committee on Vaccine Safety (GACVS) first assessed this issue in a special meeting in August 2000 and continues to review the safety aspect of thiomersal-containing vaccines as new evidence emerges. In the latest review by the committee (June 2006) the conclusion previously reached was reaffirmed that there is no evidence of toxicity in infants, children or adults exposed to thiomersal in vaccines.

What is thiomersal?

Thiomersal (also known as thimerosal, mercuriothiolate and sodium 2-ethylmercuriothio-benzoate) is a mercury-containing compound used to prevent bacterial and fungal growth in some vaccines during storage, and especially during use of opened multi-dose vials. It has also been used during vaccine production both to inactivate certain organisms and toxins and to maintain a sterile production line. Thiomersal has been used since the 1930s in the manufacture of some vaccines and other medical products.

What Irish vaccines contain trace amounts of thiomersal?

All the vaccines used in the routine infant immunisation programme are thiomersal free. Some vaccines used in older children or adults may contain trace amounts of thiomersal. The trace amounts were equivalent to values below the limit of detection corresponding to less than 18 nanograms per vaccine dose. These trace amounts of mercury have no biologic effect and such products should be considered equivalent to thiomersal-free products. As with any agent, hypersensitivity reactions can occur in sensitised individuals despite the very low concentration. The presence of thiomersal (and other preservatives) in the composition of vaccines is stated on the label and a warning regarding the risk of

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sensitisation in relation to thiomersal and other preservatives is included in the Summary of Product Characteristics and Package Leaflet of such products.

Why do some vaccines still contain thiomersal?

The use of thiomersal as a preservative in multidose vials has been scientifically justified. A European Review of the available evidence concluded that there is no evidence of harm from thiomersal in vaccines other than hypersensitivity (allergic) reactions (EMA Public Statement on Thiomersal and Safety of Thiomersal-Containing Vaccines dated 24 March 2004) . Based on a precautionary principle of reducing exposure to mercury, regulatory authorities within the EU have promoted the development of vaccines without thiomersal particularly for single dose vaccines. This is in line with the global goal of reducing exposure to mercury rather than in response to any evidence of a safety concern associated with thiomersal exposure in vaccines. Any change in the formulation of a licensed vaccine, including changes to the thiomersal content, may have an impact on the quality, safety and efficacy of vaccines and further trials are likely to be required before the reformulated product can be licensed. Replacing thiomersal with a different inactivating agent and/or preservative during the production process and/or in the final product, requires a new licensing process with a series of preclinical and clinical trials to ensure the quality, safety and efficacy of the vaccine. For vaccines used in multi-dose formulations thiomersal offers better protection from contamination than other preservatives such as 2-phenoxy ethanol.

What is the World Health Organisation's (WHO) recommendation on the safety of thiomersal-containing vaccines?

Following review of the current epidemiologic evidence and pharmacokinetic profile of thiomersal, the World Health Organisation have concluded that there is currently no evidence of mercury toxicity in infants, children, or adults exposed to thiomersal in vaccines. It also concluded that there is no reason to change current immunisation practices with thiomersal-containing vaccines on the grounds of safety. The safety of thiomersal-containing vaccines is reviewed at regular intervals. In the meantime, the available evidence warrants the recommendation that current WHO immunisation policy with respect to thiomersal-containing vaccines should not be changed.

Is thiomersal the same as methyl mercury?

No, there are several forms of mercury occurring in the environment, however by far the most common organic mercury compound is methyl mercury. The main hazard for methyl mercury is its ability to accumulate in the body and to remain there for a long time. The exposure to this naturally-occurring compound and its toxic effects on humans have been well studied. As most humans are exposed to mercury in some form, WHO and some national regulatory authorities defined safe levels for exposure to mercury and the values reflect exposure mainly to methyl mercury. Thiomersal contains a different form of mercury i.e. ethyl mercury which does not accumulate and is metabolized and removed from the body much faster than is methyl mercury.

[Links and references](#)

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- Thiomersal and vaccines. Statement on safety of Thiomersal from the Global Advisory Committee on Vaccine Safety (2006)

- Weekly Epidemiological Record. 75(2):12-6, 2000 [pdf 207Kb]
Thiomersal as a vaccine preservative.

- Weekly Epidemiological Record. 76(48):373-80, 2001 [pdf 133Kb]
Strategic Advisory Group of Experts. Vaccines and Biologicals. Part I.

- EMEA public statement on thiomersal in vaccines for human use –Recent evidence supports safety of thiomersal containing vaccines (24 March 2004)

- EMEA CHMP Position Statement on Thiomersal and Implementation of the Warning Statement Relating to Sensitisation (11 January 2007)

- Immunisation Guidelines for Ireland 2008

- Thimerosal in Seasonal influenza vaccine <http://www.cdc.gov/FLU/ABOUT/QA/thimerosal.htm>