

MERCURY AND VACCINES

FACT SHEET, OCTOBER 2006



What is the concern about mercury in vaccines?

Thimerosal, also known as thiomersal, is a preservative used in a number of biological and pharmaceutical products, including some flu and many multi-dose vaccines used for child immunisation. Mercury makes up approximately 50% of the weight of thimerosal in the organic form of ethylmercury. Thimerosal has been added to products to help prevent the growth of microbes since the 1930s. As more has become known about the effects of mercury on human health, the use of thimerosal in vaccines became an issue of increasing concern. Over the years, with more and more childhood vaccinations recommended or required, the amount of mercury to which infants and young children are being exposed has significantly increased.

While there were no toxic effects reported in the first study of thimerosal use in humans, published in 1931, the study was not specifically designed to examine toxicity and was flawed in a number of other ways.¹ Studies of any potential effects of thimerosal exposure in humans are ongoing and no general scientific consensus currently exists. Questions have particularly arisen around a possible connection between thimerosal and autism. Additionally, research is being conducted into the relationship between mercury exposure and Alzheimer's disease.

In 2004, a statement from the European Agency for the Evaluation of Medicinal Products (EMEA) noted that new toxicity studies demonstrate that ethylmercury is less toxic than methylmercury, the form people ingest by eating some types of fish.² The following year, the report of the Immunisation Safety Review Committee produced by the US Institute of Medicine found again that reviewed evidence "favours a rejection of a causal relationship between thimerosal-containing vaccines and autism."³ Yet, others have suggested that new toxicological data shows that there could be a plausible connection between thimerosal and neurological effects in animals and humans. While at this point the evidence that thimerosal in vaccines causes adverse health effects in humans is still disputed, mercury is documented as a human neurotoxicant. In 1991, the World Health Organization (WHO) concluded that a safe level of mercury exposure – that is, below which no adverse effects occur – had not been established.⁴



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None of the “live” vaccines, including measles, MMR (measles, mumps, rubella), oral polio, yellow fever, and BCG (tuberculosis) have ever contained thimerosal. However, thimerosal is used in many Hepatitis B, DTP (diphtheria, tetanus, and pertussis), diphtheria and tetanus toxoids (DT and Td), tetanus toxoid (TT), influenza, and other vaccines.⁵

It is relatively easy to replace, reduce, or eliminate thimerosal as a preservative in single and multi-dose vaccines that are widely used in most industrialised countries. However, multi-dose vials used for vaccinations in the Global South must contain a preservative to prevent vaccine contamination in the absence of refrigeration.⁶ The World Health Organization says thimerosal-containing multi-dose vaccines are necessary in these countries because single-dose vaccines are more expensive and often require refrigeration.⁷

What do other authorities recommend?

A preventative public health approach requires minimising the amount of mercury to which people are exposed, especially vulnerable groups such as infants, young children, pregnant women, and the elderly. Regulators, public health officials and pharmaceutical companies have recognised that the level of concern that has arisen in relation to this issue justifies such preventative approach. Both the USA and Europe have begun to take action to phase out thimerosal use.

EXAMPLE FROM THE UNITED STATES

In 1999, the United States Food and Drug Administration (FDA) undertook a comprehensive review of the use of thimerosal in childhood vaccines. Although they found no evidence of harm, they did find that some infants could be exposed to cumulative levels of mercury that exceeded the Environmental Protection Agency's (EPA) guidelines for safe intake of methylmercury. As a precautionary measure, the US Public Health Service (which includes the Food and Drug Administration, National Institutes of Health, Center for Disease Control and Prevention, and Health Resources and Services Administration) and the American Academy of Pediatrics issued two joint statements, which recommended that thimerosal be phased out of all vaccines administered to infants and children as soon as possible.⁸

Significant progress has been made since 1999. All vaccines routinely recommended for children under six are thimerosal-free or contain only trace amounts (defined as 1 microgram of mercury per gram or less). However, some flu vaccinations still contain thimerosal. The Food and Drug Administration is currently working with manufacturers to increase supplies of both thimerosal-free flu vaccines and other vaccines. Flu vaccines are most often used for adults but may be given to children.⁹

EU POLICY

In June 1999, the European Agency for the Evaluation of Medicinal Products (EMEA) completed an 18-month inquiry into the risks and benefits of using thimerosal in vaccines. The EMEA concluded that: "Although there is no evidence of harm caused by the level of exposure from vaccines, it would be prudent to promote the general use of vaccines without thimerosal...within the shortest possible time-frame."¹⁰

The EMEA updated its advice on use of thimerosal in vaccines in March 2004. While it again rejects any possible connection between thimerosal and “specific neurodevelopmental disorders”, it continues to promote the development of vaccines without thimerosal, or which contain the lowest possible levels. In addition, the EMEA included a labelling requirement for thimerosal-containing vaccines and a warning with regard to sensitisation to thimerosal,¹¹ which was first outlined in 1999.¹²

In June 2005, the European Council endorsed the European Commission's Mercury Strategy and underlined the importance of addressing residual uses of mercury, including in vaccines.¹³ The European Parliament, in its March 2006 resolution on the Mercury Strategy, called upon the Commission to address the issue with a view to achieving a restriction of thimerosal use, and eventually a total ban when safe alternatives exist.¹⁴ In addition, the Parliament called upon the Commission to support research for thimerosal-free multi-dose vaccines for use in Global South countries.

NATIONAL POLICIES AND ACTIONS

The EU member states vary widely in their approach to mercury preservatives in vaccines. Some countries, such as Hungary and Luxembourg, do not have any guidelines on the use of thimerosal-containing vaccines, whereas others follow the EMEA advice. Below are some examples.

DENMARK In Denmark, the National Central Laboratory of the Danish Health System has not used thimerosal in vaccines for children since 1992.¹⁵

UNITED KINGDOM The Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunisation endorsed the March 2004 EMEA position. In line with this recommendation, levels of thimerosal in a number of UK-licensed vaccines were reduced or removed completely either from the manufacture of the component antigens or from the final vaccine.¹⁶

In August 2004, the Department of Health announced it would no longer use thimerosal in infant vaccines. Dr David Salisbury, the head of immunisations for the UK Department

of Health, said that the UK agreed with the US and Europe that thimerosal should be phased out.¹⁷

In efforts to eliminate mercury from infant vaccines, a new combined vaccine for diphtheria, tetanus, pertussis (whooping cough), Haemophilus Influenza type b (Hib) and polio without thimerosal was released in the UK in September 2004.¹⁸

FRANCE In line with the EMEA recommendations, the French authorities recommend the use of thimerosal-free vaccinations when available for the vaccination of newborn babies.¹⁹

ITALY The Italian authorities have no guidelines on the use of thimerosal-containing vaccines, as these vaccines are no

longer available in Italy. In 2001, a first Decree required all vaccines containing thimerosal to be replaced by 2003. In June 2003, a second Decree authorised thimerosal-containing vaccines only if no alternatives exist.

SWEDEN Three vaccines containing thiomersal as a preservative, including one for flu, are approved by Swedish authorities but they are not used in Sweden. The extensive phase-out of thimerosal is a result of voluntary measures. Sweden's Children's Vaccine Program has not used mercury-based preservatives since 1993-1994.²⁰

HEAL & HCWH Recommendations

Health & Environment Alliance and Health Care Without Harm Europe advocate a precautionary approach to the use of thimerosal in vaccines, both in Europe and globally. We support a phase-out of thimerosal use but recognise that single dose vaccine preparations (which do not contain thimerosal) are not always a viable option in countries of the Global South. Nevertheless, we cannot support the exportation of thimerosal-containing vaccines, which are no longer accepted or recommended in Europe, to other countries. Accordingly, alternatives to thimerosal as a preservative should be developed. This initiative should be led by the WHO and with the participation of other intergovernmental agencies, national

governments, pharmaceutical companies, international NGOs and foundations. Support for the development of viable thimerosal-free options for multi-dose vaccines should be a priority.

In Europe, the EMEA should publish a comprehensive list of the thimerosal content in all vaccines licensed in Europe as the Food and Drug Administration does in the United States. The European Commission should issue guidelines promoting a precautionary approach and call on the EMEA to work with manufacturers to reduce, and ultimately eliminate, mercury in vaccines.

References

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4. International Programme on Chemical Safety (1991) Environmental Health Criteria 118. Inorganic Mercury. World Health Organisation. Geneva. www.inchem.org/documents/ehc/ehc118.htm accessed 11 August 2005
5. A toxin is a toxin rendered nontoxic by treatment with chemical agents or by physical means and used for administration into the body in order to produce specific immunity by stimulating the production of antibodies.
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7. World Health Organisation. Thiomersal and vaccines: questions and answers. www.who.int/vaccine_safety/topics/thiomersal/questions/en/ accessed 23 August 2005
8. CDC NVPO Bulletin: Thimerosal (1999) Joint Statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service. July 7, 1999. "http://www.hhs.gov/nvpo/vacc_safe/bth1.htm" accessed 13 October 2006
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11. Sensitisation is the act or process of inducing an acquired sensitivity or allergy. European Agency for the Evaluation of Medicinal Products (2004) EMEA Public Statement on Thiomersal in Vaccines for Human Use – Recent Evidence Supports Safety of Thiomersal-Containing Vaccines. London, 24 March 2004. Doc. Ref: EMEA/CPMP/Veg/1194/04/Adopted <http://www.emea.eu.int/pdfs/human/press/pus/119404en.pdf> accessed 17 June 2005
12. European Agency for the Evaluation of Medicinal Products. CPMP Position Paper on Thiomersal Implementation of the Warning Statement Relating to Sensitisation. www.fda.gov/cber/vaccine/thimerosal.htm accessed 11 August 2005
13. Council conclusions on the Community strategy concerning mercury 2670th Environment Council meeting. Luxembourg. 24 June 2005. p. 2.
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17. Manning, B.(2004) Lawmakers get mercury out of vaccines. Mothering Nov-Dec 2004, www.findarticles.com/p/articles/mi_m0838/is_127ai_n6366770 accessed 17 June 2005
18. NHS press release 9 August 2004: Improvements to childhood immunisation programme, www.immunisation.org.uk/newsitem.php?id=21 accessed 17 June 2005
19. AFSSAPS Press Release 4 July 2000. Thiomersal. <http://agmed.sante.gouv.fr/htm/10/filcoprs/excom.htm#vaccins>
20. Response to the HEAL/HCWH questionnaire to EU Member States, by Mats Welin, Medical Products Agency, mats.welin@mpa.se

What can you do?

- ☞ 1. Ask your doctor, paediatrician and/or pharmacist which vaccines contain thimerosal and whether there are other formulations of the same vaccine without thimerosal.
- ☞ 2. Avoid thimerosal vaccines where possible, especially for the vaccination of vulnerable groups including infants, young children, pregnant women, and the elderly.

Resources

World Health Organisation

www.who.int/vaccine_safety/topics/thimerosal/en/
www.who.int/vaccine_safety/topics/thimerosal/questions/en/

EMEA 2004 Public Statement on Thimerosal in Vaccines for Human Use

www.emea.eu.int/pdfs/human/press/pus/119404en.pdf

Thimerosal Content in Vaccines in Scotland

www.show.scot.nhs.uk/gghbpharmacy/NHS_Glasgow/vaccines/thimerosal.htm

Thimerosal Content in Hepatitis B vaccines in Europe

www.vhpb.org/files/html/Meetings_and_publications/VHPB_Meetings/Kyiv2004/pdf/S7B1enVandamme.pdf

Residual Thimerosal in Some Vaccines in Europe 2004

www.sam.ee/orb.aw/class=file/action=preview/id=5077/EU+Vaccination+Policies.pdf

Thimerosal fact sheet, which includes tables of mercury content of vaccines in Australia

www.ncirs.usyd.edu.au/facts/f-thimerosal.html

Thimerosal in Vaccines from the United States Food and Drug Administration

www.fda.gov/cber/vaccine/thimerosal.htm

Thimerosal Content in Some US Licensed Vaccines, updated July 2005

www.vaccinesafety.edu/thi-table.htm

National Vaccine Information Center, Vaccine Mercury Calculator for the USA

www.nvic.org/calc.htm



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"Stay Healthy, Stop Mercury" campaign

Health and Environment Alliance (HEAL) and Health Care Without Harm Europe (HCWH) are joining forces to mobilise the health community in Europe for a global ban on mercury. The activities are focused on raising awareness of the risks to health, especially for babies and pregnant women, and on working with women and health care professionals on how they can protect themselves and the environment from mercury exposure.

