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**EMEA PUBLIC STATEMENT ON THIOMERSAL IN VACCINES FOR HUMAN USE –
RECENT EVIDENCE SUPPORTS SAFETY OF THIOMERSAL-CONTAINING VACCINES**

The EMEA issued statements on the use of thiomersal in vaccines in 1999 and 2000 (EMEA/20962/99, EMEA/CPMP/1578/00). In light of recent reassuring data on the safety of thiomersal-containing vaccines, this new statement updates previous recommendations.

Thiomersal, is an antimicrobial organic mercury compound that continues to be used either in the early stages of manufacturing, or as a preservative, in some vaccines. The antimicrobial action of thiomersal relates to ethylmercury, which is released after breakdown of thiomersal into ethylmercury and thiosalicylate.

The Committee for Proprietary Medicinal Products (CPMP) previously advised that although there was no evidence of harm from thiomersal in vaccines other than hypersensitivity (allergic) reactions, it would be prudent to promote the general use of vaccines without thiomersal and other mercury containing preservatives, particularly for single dose vaccines. Since then, several vaccines licensed in the European Union have had thiomersal removed or levels reduced and new vaccines without thiomersal have been licensed. CPMP advice was in line with the global goal of reducing environmental exposure to mercury. The previous assessment of risks associated with ethylmercury had been based on data on methylmercury, as the toxicity profile of the two compounds was assumed to be similar.

In March 2004, the CPMP reviewed the latest evidence relating to the safety of thiomersal-containing vaccines. A number of well-designed population-based epidemiological studies documenting the safety profile of thiomersal are now available. These studies show no association between the vaccination with thiomersal-containing vaccines and neurodevelopmental disorders such as speech disorders and autism. Furthermore, new data in infants indicate that ethylmercury is more rapidly excreted and therefore has substantially different pharmacokinetics than methylmercury. The new data suggest that ethylmercury may be less toxic than previously assumed, and therefore caution is needed in extrapolating the toxicity profile of methylmercury to ethylmercury.

Taking into account all the above, the CPMP concludes the following:

- The latest epidemiologic studies show no association between the vaccination with thiomersal-containing vaccines and specific neurodevelopmental disorders.
- The CPMP re-emphasises 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 CPMP acknowledges that, during some manufacturing processes, the use of organic mercury compounds is necessary and in such cases, residual levels might be present in the final product.
- In line with the global goal of reducing exposure to mercury, the development of vaccines without thiomersal or with the lowest possible levels of thiomersal and other mercury containing preservatives should continue to be promoted.

- When a preservative is required, as in multidose preparations, the use of thiomersal can be considered.
- Applications for vaccines containing thiomersal as a preservative will be evaluated on a case-by-case basis, taking into account in particular efficacy and public health needs.
- The presence of thiomersal (and other preservatives) in the composition of vaccines will 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.

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