



London, 8 July, 1999  
Doc. Ref: EMEA/20962/99

## **EMEA PUBLIC STATEMENT ON THIOMERSAL CONTAINING MEDICINAL PRODUCTS**

- Thiomersal is an organomercuric preservative mainly used in vaccines, immunoglobulins and some eye/nasal medicinal products. Thiomersal's antimicrobial action is related to the release of ethylmercury, after either spontaneous or enzymatic breakdown of thiomersal into ethylmercury and thiosalicylate.
- Thiomersal has been used for many years in medicinal products and continues to be used. The level of ethylmercury in any single medicinal product is not considered a risk. Cumulative exposure to ethylmercury from a range of sources (food, medicinal products), however, could lead to a potential cause for concern.
- With a view to limiting exposure to mercury and organomercurial compounds, the EMEA's scientific committee, the Committee for Proprietary Medicinal Products (CPMP) in April 1998 agreed on an action plan to evaluate the benefit/risk of medicinal products containing thiomersal.
- Data on methylmercury has been used in the assessment of risks associated with ethylmercury, as the toxicity profile of the two compounds would appear to be similar.
- The CPMP reviewed the thiomersal containing medicinal products to see if patients could be exposed to cumulative levels of ethylmercury that exceed acceptable limits based on WHO recommendations for intake of methylmercury.
- The following recommendations have been agreed by the CPMP in June 1999:
  - For vaccination in infants and toddlers, the CPMP 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 thiomersal and other mercurial containing preservatives, particularly for single dose vaccines. This should be done within the shortest possible time-frame.
  - In the interests of public health and in order not to jeopardize vaccine supplies and immunisation programs, the EMEA will continue to work with the World Health Organisation, the European Pharmacopoeia, the Food and Drug Administration and vaccine manufacturers with the objective to eliminate organomercurial preservatives in vaccines, in follow-up to the joint workshop which was held at the EMEA in April 1999.
  - The CPMP would like to stress that this is only a precautionary measure. There is no evidence of harm from the use of such thiomersal containing medicinal products. While reformulation work on vaccines proceeds it is imperative that vaccination continues in accordance with national vaccination schedules to prevent disease outbreaks.
  - For immunoglobulins and eye/nasal preparations containing thiomersal no further action is deemed necessary at this time. Nevertheless, the presence of thiomersal (and other preservatives) in the composition of medicinal products should be stated on the label and a warning regarding the risk of sensitisation in relation to thiomersal and other preservatives should be included in the Summary of Product Characteristics and Package Leaflet of such products.

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