

WHO INFORMAL MEETING ON REMOVAL OF THIOMERSAL FROM VACCINES AND ITS IMPLICATIONS FOR GLOBAL VACCINE SUPPLY

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WHO HQ GENEVA

SUMMARY

As part of a number of other activities, WHO organized a meeting with manufacturers that supply vaccines to United Nations agencies in order to achieve a better understanding of the different approaches taken by manufactures, to discuss the implications of the current WHO policy on keeping thiomersal in multidose vial presentations and to consider the implications of different actions for manufacturers. The group considered two possible scenarios: to take thiomersal out of vaccines or to keep it in.

The main conclusions drawn from the discussions included:

- The safety of vaccines containing thiomersal as a preservative has been well established over 60 years of use worldwide , with no scientific basis to suggest that ethyl mercury derived from thiomersal results in toxicity including damage of CNS.
- Although there is evidence of mercury toxicity problems resulting from oral intake of large amounts of mercury in the methyl form, this evidence does not apply to thiomersal since it degrades to ethyl mercury, which is excreted from the body in 4 to 9 days (it is not accumulated).
- Thiomersal has proven to be highly effective in preventing contamination of multidose vaccine presentations during field usage.
- The demands by regulatory and other health authorities in industrialized countries that thiomersal be removed from vaccines are not believed to be based on scientific facts. However, manufacturers have already taken steps to reduce or remove thiomersal from their vaccines. This action has primarily impacted single dose presentations at present, but it is expected that it will impact multidose presentations as well.
- Obtaining regulatory approval for the new formulated thiomersal-reduced or-removed vaccines involves complex activities that are costly and time consuming.
- WHO is concerned about the current situation whereby manufacturers in developed countries have been forced to lower the thiomersal content of their vaccines, and is now considering the implications of changing from proven safe and effective practices, which rely on multidose vaccines containing thiomersal, to either purchasing single dose vaccines or multidose vaccines with a reduced capacity to resist the contamination likely to occur under practical field conditions in developing countries.
- The option of using single dose vaccines is not feasible for WHO due to insufficient production capacity and insufficient infrastructure for transportation and storage under cold chain conditions. Furthermore, increasing vaccine capacity and upgrading the infrastructure would result in huge increase in vaccine cost as well as in vaccine shortage in the interim.

In view of the situation, WHO is faced with four options:

1. To maintain the current multidose vial policy using new vaccines that do not meet approved preservative efficacy criteria. This option is unacceptable for safety reasons
2. To change the current policy by using that applied to freeze-dried vaccines in multidose, which is considered impractical at field level

3. Switch to single dose presentations, which would lead to global vaccine shortage
4. Support maintenance of thiomersal usage as an effective preservative in multidose- and possibly also in single dose- vaccines

If WHO develops a strong statement supporting continued use of thiomersal, it will become essential to work with regulatory agencies in developed and developing countries to establish alternative regulatory pathways to ensure continued licensing and regulatory oversight of these vaccines.

On analysis of the Pros and the Cons of the various alternatives, the group considered that the best option would be to maintain acceptance of thiomersal in vaccines for the global market.

The actions required from WHO in order to ensure continued availability of these vaccines include the following:

- Clarify the regulatory situation
- Lobby Ministry of Health and senior regulators.
- Continue dialogue with EMEA, Korea and Canada
- Learn about the potential use of the USA export provisions
- Contact potential recipient countries (of bulk) to see if they would play a bigger regulatory role and become finishers of the vaccines
- Develop a strong advocacy campaign to support ongoing use of thiomersal
- Involve developing country regulatory agencies in all these decisions

The participants recognized that risk of contamination in the field is a real and serious safety risk, whereas safety problems associated with uptake of ethyl mercury following vaccination with thiomersal-containing vaccines is as yet unproven.

They concluded that in the presence of information that continues to confirm the safety of thiomersal in vaccine production and recognizing the importance of maintaining usage of multidose vaccines in global markets that are effectively protected against field contamination, they supported WHO's plans to recommend continued use of thiomersal in vaccines.