

NIFDC's comments on the use of thiomersal in vaccines

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1. The use of thiomersal as the preservative is necessary to ensure the safety of multi-dose vaccines, those vaccines are important for the less developed countries. Elimination of thiomersal from these vaccines may cause serious problems, which will damage the confidence of vaccines in general public.

2. Thiomersal may be a safety concern, but the safety of vaccines without thiomersal is another serious concern. Considering the difficulties of replacement of thiomersal in short time, WHO can compromise and suggest that the elimination of thiomersal should be the long-term goal and shall be completed gradually, thus to ensure the balance of these two sides.

3. Considering the availability of vaccines at affordable price in less developed countries and the uncertainty linkage between the possible health hazard and the amounts of thiomersal currently used, it's better to step by step from reduction to elimination or replacement of thiomersal in vaccine. With development of economy and technology, the manufacturers can be encouraged to minimize the production of multi-dose vaccines and to enlarge the production of single-dose vaccines.

4. Chinese situation on use of thiomersal in vaccines

4.1 The use of preservatives is indicated as followings in Chinese Pharmacopoeia 2010 Edition.

4.2 The addition of preservatives, especially those containing mercury, to the intermediates and final product of an injection shall be avoided as much as possible.

4.3 Preservatives shall be not included in single-dose injections in freeze-dried form. For single-dose injections in liquid form, the addition of preservatives shall be avoided as far as possible.

4.4 Any preservatives must not be added in the injections for intravenous use.

4.5 For multi-dose preparations the need for effective preservation is evaluated taking into account likely contamination during use and the maximum recommended period of use after opening of the container.