

Illinois Department of Public Health

EXEMPTION DECLARATION

NOW COMES, the Department of Public Health (hereinafter, the “Department”), by and through Eric E. Whitaker, Director, pursuant to the Mercury-Free Vaccine Act or Public Act 094-0614, sets forth this Exemption Declaration, and herein, states as follows:

RECITALS

WHEREAS, pursuant to 20 ILCS 2305/2, the Department “has general supervision of the interests of the health and lives of the people of the State” of Illinois; and

WHEREAS, pursuant to 410 ILCS 315/2, the Department has been charged with upholding “the public policy of this State that all children shall be protected, as soon after birth as medically indicated, by the appropriate vaccines and immunizing procedures to prevent communicable diseases which are or which may in the future become preventable by immunization”; and

WHEREAS, the State of Illinois has recognized and acknowledged through the Communicable Disease Prevention Act, 410 ILCS 315/1, that the general usage of “effective, safe and widely used vaccines and immunization procedures have been developed and are available to prevent ...diseases and to limit their spread”; and

WHEREAS, historically in Illinois, local health departments and private providers have provided immunization services to adults, children and other high risk individuals since the mid-1970’s. The vaccines are purchased by the individual providers or local health departments with local funds; and

WHEREAS, Public Act 93-0384 requires vaccination of residents in long term care facilities statewide annually with influenza and pneumococcal vaccines. The vaccines or immunization services for these individuals are provided by the private providers that sign the medical standing orders; and

WHEREAS, the Mercury-Free Vaccine Act, or Public Act 094-0614, has set forth that any mercury-containing vaccines that contain more than 1.25 micrograms of mercury per dose are to be banned commencing on January 1, 2006; and

WHEREAS, the Mercury-Free Vaccine Act also provides in Section 10 that the Department “may exempt the use of a vaccine from this Act if the Department finds that...(an) actual shortage of supply of a vaccine at a reasonable cost that would prevent a person from receiving the needed vaccine...”

WHEREFORE, after conducting a review of vaccines containing thimerosal, the Department Hereby Declares an EXEMPTION to the Mercury-Free Vaccine Act for use of each of the following vaccines: “Influenza 2005/2006 Formula”, “Japanese Encephalitis”, “DT”, Td, TT and Meningococcal polysaccharide vaccine.

IN SUPPORT of this Exemption to the vaccines, the Department states as follows:

In evaluating the basis for the Exemptions for each of the vaccines, the Department established that vaccine was procured either directly from the manufacturer, or via a distributor/reseller. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers.

The Department’s evaluation involving the influenza vaccine supply.

Based upon the information provided by vaccine supplier, sanofi pasteur, limited amounts of Influenza vaccine are available for use in Illinois and lesser quantities of preservative-free vaccine (thimerosal free) is available for use in Illinois. The Department concludes that inadequate amounts of influenza vaccine containing less than 1.25 micrograms of preservative exist to meet the needs of the people of the State of Illinois for the upcoming year. The multidose formulation is the primary presentation administered by public and private providers throughout Illinois and must be exempted from the Act.

The Department’s review of Japanese Encephalitis Vaccine (hereinafter, “JEV”).

Based upon information provided by vaccine suppliers, all currently manufactured JEV contains thimerosal in quantities greater than trace amounts. JEV will be available for use in persons traveling to areas where Japanese Encephalitis is epidemic or endemic. A new formulation, in accordance with Public Act 94-0614 is currently not available from the manufacturer. The Department concludes that a limited supply of Mercury-free JEV exists to meet the needs of the people of the State of Illinois, and an exemption for use of the vaccine is needed.

The Department’s review of Tetanus and Diphtheria Toxoids Adsorbed Vaccine (hereinafter “Td Vaccine”).

Based upon information provided by the vaccine manufacturer Sanofi, Td Vaccine is available in a single-dose, pre-filled, preservative-free formulation. However, if the Department were to purchase sufficient amounts of the Td Vaccine from Sanofi to meet the Department’s projected supply needs for 2006, the total cost would exceed the Department’s budget. The Department is able to purchase from another manufacturer sufficient quantities of Td Vaccine at a reasonable cost within the Department’s budget. However, these vaccines exceed 1.25 micrograms of mercury per dose. The Department

concludes that inadequate amounts of Mercury-free Td Vaccine exist at a reasonable cost to meet the needs of the people of the State of Illinois, and an exemption for use of the vaccine is needed. In addition, private providers in Illinois purchase and administer tetanus containing vaccines, including tetanus toxoid, referred to as TT and Diphtheria-Tetanus vaccine, referred to as DT vaccine. It is not possible to determine availability of current usage of any preservative-free products to address private provider practice needs. These products currently contain preservatives in excess of 1.25 micrograms and must be exempted to assure protection of those requiring these products according to physician's medical judgment.

The Department's review of Meningococcal Polysaccharide vaccine, hereinafter referred to as MPV.

Based on information from the manufacturer, MPV is currently produced in a single dose and multi-dose presentation. The multi-dose presentation exceeds 1.25 micrograms of preservative. However, it is unknown how much of single dose formulation is available to both public and private providers in Illinois. In the event of an outbreak of meningococcal disease (i.e. university setting), it is critical to provide prevention and protection of at-risk individuals with a readily available product. Delays in procuring a preservative-free formulation may result in illness and death of exposed individuals. The Department concludes that in order to meet the needs of the people of the State of Illinois, an exemption for the use of the multi-dose presentation of MPV is needed.

The vaccine dosage and thimerosal concentration are as follows:

Vaccine	Brand Name	Manufacturer	Thimerosal Concentration *
Influenza 2005/2006Formula	Fluzone - prefilled syringe (0.5 mL)	sanofi pasteur	0.01%
	Fluzone - multi-dose (5 mL)	sanofi pasteur	0.01%
	Fluvirin	Evans	0.01%
Japanese Encephalitis	JE-VAX	BIKEN	.007%
DT	Diphtheria & Tetanus Toxoids Adsorbed USP – multi-dose	Sanofi pasteur	0.01%
Td	No Trade Name	Mass Public Health	8.3 µg/0.5 mL dose
TT	No Trade Name		25 µg/0.5 mL dose
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Aventis Pasteur, Inc	0.01% (multidose)

* A concentration of 1:10,000 is equivalent to a 0.01% concentration. A 1:10,000 concentration contains 25 micograms of Hg per 0.5 mL.

The Department concludes an exemption for use of the above listed vaccines is needed due to findings of a shortage of supply at a reasonable cost. Such a shortage, without issuing an exemption could reasonably constitute an actual, or potential public health emergency.

Accordingly, the Department, by and through its Director, pursuant to Section 10 of the Mercury-Free Vaccine Act, hereby exempts the use of the following vaccines: “Influenza 2005/2006 Formula”, “Japanese Encephalitis”, Td, DT, TT and MPV” from the requirements of Public Act 094-0614. This Exemption is applicable for twelve (12) months from the date of signature, and may be reissued or amended upon further determination by the Department.



January 1, 2006

Eric E. Whitaker, M.D., M.P.H.
Director, Illinois Department of Public Health

Date