

Illinois Department of Public Health

EXEMPTION DECLARATION

NOW COMES, the Department of Public Health (hereinafter, the "Department"), by and through Damon T. Arnold, Director, pursuant to the Mercury-Free Vaccine Act 410 ILCS 51/1 et seq., 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. Vaccines are purchased by the individual providers or local health departments with local funds; and

WHEREAS, the Mercury-Free Vaccine Act, 410 ILCD 51/5, 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, 410 ILCD 51/5, has set forth that no person shall be vaccinated with a vaccine or injected with any product that contains, or prior to dilution, had contained as an additive, any mercury based product, whether at preservative or trace amount levels.

WHEREAS, the Mercury-Free Vaccine Act at 410 ILCS 51/10 also provides 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...” makes necessary the exemption;

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: Japanese Encephalitis; Tetanus and Diphtheria Toxoids Adsorbed; tetanus toxoid; Diphtheria-Tetanus, Meningococcal Polysaccharide; DTaP/Hep B/IPV (Pediatrix); Hepatitis A/Hepatitis B (Twinrix); Hepatitis B (Engerix); DTaP (Tripedia) and Influenza Vaccine 2008-2009 multi-dose formulation.

IN SUPPORT of the Exemption, the Department finds as follows:

In evaluating the basis for the Exemption for each of the vaccines, the Department established that the 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 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 and there are no plans by the manufacturer to change its formulation. JEV will be available for use in persons traveling to areas where Japanese Encephalitis is epidemic or endemic. A new formulation, in accordance with the Mercury-Free Vaccine Act is currently not available from the manufacturer. The Department finds that there exists a shortage of supply of mercury-free JEV at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for use of the vaccine is necessary.

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, the thimerosal-free formulation is more costly for health care providers and not as readily available as the thimerosal-containing product, which contains thimerosal in excess of 1.25 micrograms of mercury per dose. State school-entry vaccine requirements compel booster-doses for persons

entering secondary and post-secondary education and health care providers use the thimerosal-containing formulation to ensure that these mandatory vaccination requirements are met. The Department finds that there exists a shortage of supply of mercury-free Td Vaccine at a reasonable cost to meet the needs of the people of the State of Illinois, such that an exemption for use of the vaccine is necessary.

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. TT vaccine is purchased by health care providers and hospitals for use in wound management. It is not possible to determine availability of current usage of any preservative-free products to private provider practice needs. The Department no longer distributes the preservative-containing product in its Vaccines for Children (VFC) program in order to assure compliance with the Mercury Free Vaccine Act. However, the Department is aware that private providers in Illinois do have the ability to purchase and administer tetanus containing vaccines, including tetanus toxoid, referred to as TT and Diphtheria-Tetanus vaccine, referred to as DT vaccine, particularly in the hospital emergency department setting for wound management. 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 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. During 2006, the United States experienced a severe shortage of thimerosal-free MPV, thus forcing health care providers to utilize the thimerosal-containing formulation. Should a similar situation arise, it is imperative that health care providers have access to this vaccine. The Department finds that that there exists an actual or potential shortage of supply of MPV at reasonable costs to meet the needs of the people of the State of Illinois, such that an exemption for the use of the multi-dose presentation of MPV is necessary.

The Department's review of DTaP/Hep B/IPV Vaccine (hereinafter, "Pediarix").

Pediarix is the only combination vaccine available on the market that offers protection against the DTaP, Hepatitis B and IPV antigens simultaneously. Routine use of combination products to combat multiple antigens is beneficial to patients and health care providers in that combination products reduce the number of health care visits, reduce the number of needle sticks to the patient, improves record keeping and reduces overall costs for both the patient and the health care provider. Without the availability of a combination vaccine, health care providers would have to administer a separate vaccine for each antigen. The use of separate antigen vaccines has the potential to leave the patient unprotected between doses of the vaccine. Additionally, the costs of office visits could increase as providers pass along to the patients the additional costs incurred for the purchase of separate vaccines for each antigen. Although a preservative-free formula of Pediarix was released for distribution in January 2007, vaccines delivered prior to January 1, 2007 may still be in stock in health care provider's offices as expiration dates generally extend 18-24 months following the date of manufacture. If health care providers are required to destroy their current inventory, the costs of inventory replacement may be passed along to the patients. Thus, the Department finds that there exists a shortage of supply of mercury-free Pediarix at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for use of the vaccine is necessary.

The Department's review of Hepatitis A/Hepatitis B Vaccine (hereinafter "Twinrix").

Twinrix is the only combination vaccine available on the market that offers protection against the Hepatitis A and Hepatitis B antigens simultaneously. Twinrix is licensed for administration to individuals 18 years of age or older and is a valuable means to protect adults at high risk of both Hepatitis A and Hepatitis B infections. Routine use of combination products to combat multiple antigens is beneficial to patients and health care providers in that combination products reduce the number of health care visits, reduce the number of needle sticks to the patient, improves record keeping and reduces overall costs for both the patient and the health care provider. Without the availability of a combination vaccine, health care providers would have to administer a separate vaccine for each antigen. The use of separate antigen vaccines has the potential to leave the patient unprotected between doses of the vaccine. Additionally, the costs of office visits could increase as providers pass along to the patients the additional costs incurred for the purchase of separate vaccines for each antigen. The Department finds that there exists a shortage of supply of mercury-free Twinrix vaccine at a reasonable cost to meet the needs of the people of the State of Illinois, such that an exemption for use of the vaccine is necessary.

The Department's review of Hepatitis B vaccine (hereinafter referred to as "Engerix").

A thimerosal-free version of Engerix B was released for distribution in January 2007. However, Engerix may remain in the inventories of health care providers as expiration dates of vaccines generally extend 18-24 months following the date of manufacture. If health care providers are required to destroy their current inventory, the costs of inventory replacement may be passed along to the patients. The Department finds that there exists an actual or potential shortage of supply of Engerix at a reasonable cost to meet the needs of the people of the State of Illinois, such that an exemption for the use of the vaccine is necessary.

The Department's review of DTaP vaccine (hereinafter referred to as "Tripedia").

The Tripedia vaccine is a combination vaccine that protects children against diphtheria, tetanus, and pertussis. Although considered thimerosal-free by the federal Food and Drug Administration (FDA), Tripedia contains trace amounts of thimerosal as a result of the production process. The Department has purchased the Tripedia vaccine for use in the VFC program through a federal contract with the manufacturer. Although the Department has limited its purchases of Tripedia through the VFC program during the last 12 months, inventory of the Tripedia vaccine remains. The Department plans to discontinue purchasing this product in 2008 provided other DTaP products are in adequate supply on the federal contract. Therefore, the Department finds that there exists a shortage of supply of preservative-free Tripedia vaccine at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for the use of the vaccine is necessary.

The Department's review of Influenza Vaccine 2008 - 2009 multi-dose formulation (hereinafter referred to as influenza vaccine).

It shall be the Department's policy that it will preferentially distribute thimerosal-free influenza vaccine to children under 3 years of age as available from the Centers for Disease Control (CDC) for the VFC program. The Department has established that the influenza vaccine for the VFC program was procured from the CDC through a federal contract with the manufacturer. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers nationwide. For VFC program needs, the Department submitted an order for 100% preservative-free product in February 2008. It is expected that the CDC will not be able to fulfill the Department's order because the amount of preservative-free vaccine requested by federal grantees always exceeds the amount of thimerosal

preservative-free vaccine available under the federal contract and thus, the CDC instituted an allocation formula to ensure equitable distribution to all grantees. It is unknown what the final percentage will be until the manufacturing process and total yield is completed. As a result of the reduced allocation, the Department will have insufficient vaccine supply available to serve all individuals eligible through the VFC program without the use of thimerosal containing formulations. In addition, anyone over 3 years of age, including high risk adults and senior citizens would not have access to influenza vaccine without the use of thimerosal containing products administered by their primary health care provider. The manufacturer does not reserve preservative-free influenza vaccine doses for any state, and it can not target the vaccine for any one state. Therefore, the Department finds that there exists a shortage of supply of preservative-free influenza vaccine at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for the use of the vaccine is necessary.

The vaccine dosage and thimerosal concentration are as follows:

Vaccine	Brand Name	Manufacturer	Thimerosal Concentration *
Japanese Encephalitis	JE-VAX	BIKEN	35 µg/1.0 mL dose 17.5 µg/0.5 mL dose
DT	Diphtheria & Tetanus Toxoids Adsorbed USP - multi-dose	Sanofi pasteur	25 µg/0.5 mL dose
Td	No Trade Name	Mass Public Health	8.3 µg/0.5 mL dose
TT	No Trade Name	Aventis Pasteur, Inc.	25 µg/0.5 mL dose
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	Aventis Pasteur, Inc	25 µg/0.5 mL dose (multi-dose)
DTaP/Hep B/IPV	Pediarix	GSK	Trace concentration only
Hepatitis A/Hepatitis B	Twinrix	GSK	< 1microgram/ml
Hepatitis B	Engerix	GSK	<0.5 micrograms/ .5 ml (pediatric) <1 microgram /1ml (adult)
DTaP	Tripedia	Sanofi	Trace concentration only
Influenza	Fluzone Fluvirin FluLaval	Aventis Pasteur, Inc Evans ID Biomedical Corporation of Quebec	25 µg/0.5 mL dose 25 µg/0.5 mL dose 25 µg/0.5 mL dose

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

The Department supports efforts to ensure vaccine safety; however, it finds that an exemption for use of the above listed vaccines is necessary due to evidence that insufficient supplies of these vaccines are available at a reasonable cost. Without the exemption, this shortage of supply-would prevent persons in the

State of Illinois from receiving the needed vaccines and reasonably constitutes an actual or potential public health emergency under 410 ILCS 51/10.

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: Japanese Encephalitis; Tetanus and Diphtheria Toxoids Adsorbed; tetanus toxoid; Diphtheria-Tetanus, Meningococcal Polysaccharide; DTaP/Hep B/IPV (Pediarix); Hepatitis A/Hepatitis B (Twinrix); Hepatitis B (Engerix); DTaP (Tripedia) and Influenza Vaccine 2008-2009 multi-dose formulation from the requirements of the Mercury-Free Vaccine Act. This Exemption is applicable for 12 months from the date of signature, and may be reissued or amended upon further determination by the Department.



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Director, Illinois Department of Public Health

Date