

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. The Mercury-Free Vaccine Act has also banned, commencing January 1, 2008, any vaccine product that contains, or had contained prior to dilution, trace amounts levels of mercury; and

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 trace amounts of thimerosal-containing preservative, the Department Hereby Declares an EXEMPTION to the Mercury-Free Vaccine Act for use of each of the following vaccines: DTaP/Hep B/IPV (Pediarix); Hepatitis A/Hepatitis B (Twinrix); Hepatitis B (Engerix); and DTaP (Tripedia).

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

In evaluating the basis for the Exemptions 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 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 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 manufacturing process. The Department has purchased the Tripedia vaccine for use in the Vaccines for Children (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 vaccine dosage and thimerosal concentration are as follows:

Vaccine	Brand Name	Manufacturer	Thimerosal concentration
DTaP/Hep B/IPV	Pediarix	GSK	Trace concentration only
Hepatitis A/Hepatitis B	Twinrix	GSK	< 1 microgram/ml
Hepatitis B	Engerix	GSK	<0.5 micrograms/ .5 ml (pediatric) <1 microgram /1ml (adult)
DTaP	Tripedia	Sanofi	Trace concentration only

The Department 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: DTaP/Hep B/IPV (Pediarix); Hepatitis A/Hepatitis B (Twinrix); Hepatitis B (Engerix); and DTaP (Tripedia) from the requirements of the Mercury-Free Vaccine Act. This Exemption is applicable until June 30, 2008, and may be reissued or amended upon further determination by the Department.


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 Director, Illinois Department of Public Health

02 JAN 2008
 Date