FDA CLEARS GLAXOSMITHKLINE’S NEW SAFE SYRINGE FOR VACCINE DELIVERY

On June 15th, 2001, GlaxoSmithKline received clearance from the US Food and Drug Administration (FDA) to market its Safety Tip-Lock syringes for administering vaccines to pediatric patients.

The syringes, which comply with the US Occupational Safety and Health Administration’s (OSHA) newly revised blood-borne pathogens standard, will be available loaded with Becton Dickenson & Co.’s SafetyGlide Needles for pediatric doses of Havrix (hepatitis A vaccine, inactivated) and Engerix-B (hepatitis B vaccine, recombinant).

The two products are now the only pediatric vaccines with the Safety Tip-Lock feature and the first to be administered in an all-in-one delivery system, Glaxo said in a news release.

The system was designed to comply with the OSHA guidelines, which are intended to help prevent healthcare workers from experiencing needlestick injuries. The OSHA guidelines took effect in April.

One of the safety features of the Safety Tip-Lock is a shield that covers the tip of the needle after it is activated, according to GlaxoSmithKline.

The company estimates that up to 800,000 needlestick injuries and potential exposures to infectious diseases occur each year in the healthcare field. The prevention of this mishap saves costs associated with testing, diagnosing and treating needlestick injuries, the company noted.

DEPLETED SUPPLY OF SINGLE ANTIGEN MEASLES, MUMPS VACCINES

Merck has informed the National Immunization Program that the supplies of Attenuvax (Measles Virus Vaccine Live) and Mumpsax (mumps Virus Vaccine Live) are depleted for the remainder of 2001 and the supply of Meruvax (Rubella Vaccine) is limited with consideration given to the needs of hospitals, obstetricians and gynecologists. Merck noted that it anticipates that the shortages of these single antigen vaccines will last throughout the remainder of 2001. To provide some perspective on the actual meaning of these shortages, nationwide in 2000, total purchases of single antigen measles vaccine were 104,000 doses, of single antigen mumps, 17,000 doses, and of single antigen rubella, 267,000 doses. Total purchases of the combined MMR vaccine equaled approximately 12,700,000 doses.

Merck also informed NIP that its inventory supply of the combined vaccination, MMR II, will not be affected, and will remain fully available to all customers.

In their statement, Merck regretted any inconvenience this shortage may have caused their customers and indicated that customers may wish to contact the Merck National Service Center in December to inquire as to the availability status of these vaccines.

NEW CPT CODES FOR IMMUNIZATION NOW PUBLISHED ON AMA’S WEBSITE

The American Medical Association (AMA) has announced that, in conjunction with the Centers for Disease Control and Prevention’s National Immunization Program, they recently restructured Current Procedure Terminology (CPT) to better support current and future reporting requirements for immunizations. CPT is the standard code for reporting health care services in electronic transactions in the US.

To avoid delays during the CPT code review process, the AMA has added new CPT codes for vaccines under development, in anticipation of Food and Drug Administration approval. With codes readily available, new vaccines can be implemented immediately. To further streamline the process of implementing new vaccine codes, the CPT Editorial Panel has developed a website so that any new or revised immunization and vaccine product codes will be released electronically twice a year at: www.ama-assn.org cpt

This means that new codes are now available for use effective January 1 and July 1 each year, instead of waiting until the next annual code book release. For example, if a new vaccine product code is approved at an August CPT Editorial Panel meeting, it can now be released for electronic publication in January and made available for use then, instead of waiting until the release of the next CPT book approximately fourteen months later. For CPT coding questions, please contact the AMA’s CPT Information Services at (800) 634-6922.
vaccine
Update

DTaP
On July 11, 2001, the Connecticut Immunization Program was notified by the Centers for Disease Control and Prevention (CDC) that Aventis Pasteur would not be able to supply any further doses of their DTaP vaccine (Brand Name: Tripedia) for a least the next 8 weeks. We are currently out of Tripedia and will be filling all outstanding and future orders with Glaxo SmithKline’s DTaP vaccine (Brand Name: Infanrix) until further notice. Providers filling out their order forms should only order Infanrix until further notice. The Immunization Program will notify providers when we have Tripedia back in stock and available for distribution. The Aventis Pasteur and Glaxo SmithKline vaccines can be used interchangeably. The CDC’s Advisory Committee for Immunization Practices has already established a recommendation regarding DTaP vaccine interchangeability. The recommendation states: “When administered according to their licensed indications, different diphtheria and tetanus toxoids and pertussis vaccines as single antigens or various combinations can be used interchangeably” At the present time we have sufficient supply of DTaP (Infanrix) available so that deferral of the DTaP booster dose is not recommended.

Td
The shortage situation remains unchanged. The State Immunization Program is still limiting orders to 10-20 doses per month. If an older child (age 7 or older) has not completed the primary series by having a dose of DTP on or after the fourth birthday, TD may be used to complete the series. It can not be used however for the 10 year booster shot after a primary series has been completed.

Influenza
Manufacturing problems of the flu vaccine during the 2000-2001 influenza season resulted in significant delays in vaccine availability. As a result of the temporary shortage, some high risk patents were unable to receive the vaccine in a timely manner. Numerous factors contributed to the shortage, and because new vaccine must be formulated every year, there is always the potential for delays in the production and distribution of the vaccine. Ordering patterns also play a role in influenza vaccine supply. Manufacturers need to be able to assess the demand for their product as accurately and as early as possible so they can produce adequate supplies without producing too much. Currently, flu vaccine manufacturers, Aventis Pasteur, Wyeth Lederle, and Evans (formerly Medeva) are projected to produce a combined estimated total of 79 million doses, which is above the amount produced last flu season but short of ideal quantities. This flu season’s delays are due to only three manufacturers producing the vaccine, and the fact that resources for one company have been devoted to upgrading their facility to accommodate increased production. According to CDC, 56% of the supply should be delivered by the end of October, 31% by the end of November, and 13% in early December. For these reasons and in an effort to prevent last season’s problems from recurring, the Connecticut Immunization Program is strongly urging all nursing home caregivers to order influenza vaccine now (if you haven’t already) for both residents and employees. Doing so will ensure that high risk patients have the opportunity to receive the vaccine as early in the season as possible. The Centers for Disease Control (CDC) is also recommending, based on morbidity studies conducted over the last 19 seasons, that high risk patients be vaccinated closer to the end of November rather than in mid November.

During the last 19 flu seasons it was determined that the majority of cases of influenza did not peak until January or February. The National Immunization Program of the CDC has developed an “Influenza Vaccine Availability” website that will provide information about the availability of influenza vaccine from manufacturers and wholesale distributors and will list state health departments that may have information about vaccine availability among local providers. This website will be updated weekly. The website can be accessed at www.cdc.gov/nip/flu. The updated ACIP recommendations for influenza vaccine for the 2001 season and other influenza-related information can be accessed at www.cdc.gov/ncidod/diseases/flu/fluavirus.htm. Additional information on influenza vaccine supply can be found on the Center of Biologics Evaluation (CBER) web page: www.fda/cber/flu/flu.htm. This site includes lot release information and will be continually updated throughout the flu season.

Meningococcal
There is a limited supply. Aventis has indicated that the situation should improve by October or November.

Congratulations Connecticut!

The results of the National Immunization Survey show that for the 7th consecutive year, Connecticut is ranked in the top five in the U.S. When looking at the 4:3:1 (4 doses of DTP, 3 doses of Polio, and 1 dose of MMR) Connecticut has immunized 85.3% of its two-year old population. That rate is fourth highest in the country and well above the national rate of 77.6%. When adding in three doses of Hib vaccine, CT’s rate is 84.6%, compared to 76.2% nationally, and when factoring in a full series of Hepatitis B vaccine the state is at 81.6%, versus a national rate of 72.8%
Do you have the most current VIS?

Several new Vaccine Information Statements (VIS’s) have been released by CDC this year. Health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Hib, pneumococcal conjugate, or varicella vaccine are required by law, prior to administration of each dose of the vaccine, to provide a copy of the relevant VIS to the patient or parent/guardian. For the vaccine-preventable diseases not listed above, use of the VIS is recommended, but not required. The following is a list of the most current VIS’s with the date that each was last updated. (Found at the bottom of each sheet)

Most Current VIS’s as of 10/01

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<th>Vaccine</th>
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<tr>
<td>Lyme</td>
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REGISTRY UPDATE

CIRTS staff will be upgrading the current CIRTS system. New equipment has been purchased which will allow providers to generate health forms for school, day care and camp. Installations have begun and registry staff are now being trained to use this new piece of software. There will be two pilot sites with other existing on-line sites gradually being brought on one section of the state at a time.

CT is looking into several software packages that are currently being used in other states to determine which of these will best suit the needs of our state.

What has CIRTS done for me lately?

- Allowed providers to obtain immunization histories of children who transfer from one practice to another
- Identified children who are late with immunizations in need of follow-up.
- Allowed parents to obtain their child’s immunization history at any time even if the pediatrician has retired or moved
- Provided immunization coverage levels for children in any practice in the state

Want to get on-line? Call (860) 543-8816

You can now find answers to many of your questions in black and white on the State Health Department website. Go to www.state.ct.us/dph and click on Agency Service Directory, then scroll down to Immunization Services. On our recently launched site you will find:

- Vaccine-Preventable Disease Incidence Table
- Educational Materials
- Religious/Medical Exemption Forms
- VFC Enrollment Packet Forms
- Description of the Immunization Action Plan
- Back issues of IAP On Time
- School and Day Care Laws and Regulations Re: Immunization
- Links to other useful immunization Websites
- Regional Immunization Service Areas
- Vaccine Adverse Reporting System (Forms & Procedures)
SUMMARY OF SCHOOL ENTRY IMMUNIZATION REQUIREMENTS FOR CT SCHOOL YEAR 2001-02

KINDERGARTEN OR ANY NEW ENTERER:
DTaP/DTP
- Minimum of 4 doses, but most children will have 5 doses
- Last dose must be given on or after the 4th birthday
- Minimum interval between dose 1 and 2 is 4 weeks
- Minimum interval between dose 2 and 3 is 4 weeks
- Minimum interval between dose 3 and 4 is 6 months
- If child is >7, pertussis is not needed Td should be given

Polio
- Minimum of 3 doses, but most children will have 4 doses
- Last dose must be given on or after the 4th birthday
- Minimum interval between dose 1 and 2 is 4 weeks
- Minimum interval between dose 2 and 3 is 4 weeks

Hib
Children < 5
- One dose given on or after the first birthday

Children > 5
- No HIB is required

MMR
- 2 doses of measles-containing vaccine, 1 dose of mumps, 1 dose of rubella
- 1st given on or after 1st birthday
- Minimum interval between dose 1 and 2 is 4 weeks

Hepatitis B
- 3 doses
- 2nd dose must be at least 4 weeks after the 1st dose
- Third dose must be given at least 4 months after the 1st dose and at least 2 months after the second dose
- Third dose must not have been given before 6 months of age

ALL 7TH GRADERS
Chicken Pox
Proof of immunity to chicken pox by either:
- Documentation from a physician of having had the disease, OR,
- a blood test showing immunity, OR,
- If under 13 years of age, 1 dose varicella vaccine
- If 13 or older, 2 doses separated by a minimum of 4 weeks

Hepatitis B
At least 1 dose given prior to entry

ALL 8TH GRADERS
Hepatitis B
- Completion of 3 dose series
- 2nd dose must be at least 4 weeks after the 1st dose
- Third dose must be given at least 4 months after the 1st dose and at least 2 months after the second dose

DEPARTMENT OF PUBLIC HEALTH IMMUNIZATION PROGRAM
MORBIDITY REPORT

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