Notice to Readers: FDA Approval of an Alternate Dosing Schedule for a Combined Hepatitis A and B Vaccine (Twinrix®)

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In April 2007, GlaxoSmithKline Vaccine Division (GlaxoSmithKline Biologicals, King of Prussia, Pennsylvania) received approval from the Food and Drug Administration (FDA) for an alternate schedule for Twinrix®, a combined hepatitis A and hepatitis B vaccine. Twinrix was first licensed by FDA in 2001 on a 3-dose schedule (0, 1, and 6 months) for vaccination of persons aged ≥18 years (*1*). Using the newly licensed, alternate 4-dose schedule, Twinrix doses can be administered at 0, 7, and 21--30 days, followed by a dose at 12 months.

In immunogenicity studies among adults aged ≥18 years, the first 3 doses of the alternate schedule provided equivalent protection to the first 2 doses in the standard 3-dose Twinrix series (*2*). The first 3 doses of the alternate schedule also have proven effective in providing protection equivalent to a single dose of monovalent hepatitis A vaccine and to 2 doses of monovalent hepatitis B vaccine, administered using the licensed schedules for the monvalent vaccines (*3*). Thus, the alternate 4-dose schedule can be useful if vaccination with Twinrix has been initiated and travel or other potential exposure is anticipated before the second dose of Twinrix (or monovalent hepatitis B vaccine) is due, according to the standard 3-dose schedule (i.e., 1 month after the first dose). Additional information is available from the manufacturer's package insert (*4*) and GlaxoSmithKline Vaccines, telephone 800-366-8900.

References

1. CDC. FDA approval for a combined hepatitis A and B vaccine. MMWR 2001;50:806--7.
2. Joines RW, Blatter M, Abraham B, et al. A prospective, randomized, comparative US trial of a combination hepatitis A and B vaccine (Twinrix®) with corresponding monovalent vaccines (Havrix® and Engerix-B®) in adults. Vaccine 2001;19:4710--9.
3. Nothdurft HD, Dietrich M, Zuckerman JN, et al. A new accelerated vaccination schedule for rapid protection against hepatitis A and B. Vaccine 2002;20:1157--62.
4. GlaxoSmithKline. Revised package insert. Twinrix® (hepatitis A inactivated & hepatitis B [recombinant] vaccine). Available at http://www.fda.gov/cber/label/hahbgsk032807lb.pdf.

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