



sanofi aventis

Because health matters

April 2009

Dear Healthcare Provider,

RE: Safe Use of Insulin Pens and other Diabetes Products

As a healthcare company committed to the care of patients with diabetes, we would like to bring your attention to recent alerts issued by the Institute for Safe Medication Practices (ISMP) and the U.S. Food and Drug Administration (FDA) regarding the improper use of insulin pens.^{1 2 3} These alerts were prompted after a U.S. Army hospital stated that incorrect procedures may have been used during the administration of insulin injections, such that pens meant for a single-patient use may have been used on more than one patient. This may have placed over 2000 patients with diabetes at risk for blood-borne disease. The **FDA reinforced that insulin pens and insulin cartridges are never to be shared** among patients, because each of these devices can result in blood contamination of the pen reservoir or cartridge, even if the needle is changed before each use. ISMP has previously referenced two studies demonstrating contamination of cartridges with hemoglobin and skin cells.^{4 5 6} Both ISMP and FDA advised health professionals to review their policies and educate their staff.

We also bring to your attention a recent Centers for Disease Control and Prevention (CDC) review published in the Annals of Internal Medicine.⁷ The authors report that **more than 60,000 patients in the U.S. over the last decade were placed at risk for blood-borne disease due to multiple lapses in infection control**, including reuse of syringes and fingerstick devices and failure to clean shared glucometers, in healthcare settings. Over 400 patients acquired Hepatitis B or C infection in patient-to-patient transmission due to failure to follow the fundamental principles of infection control by healthcare personnel. Thirty-three outbreaks occurred in nonhospital settings and seven occurred in hospital settings. **All institutions must remain vigilant in their practices, as highlighted in the CDC study and recent alerts.**

Ensuring patient safety is our highest priority at sanofi-aventis U.S., and we are committed to supporting healthcare professionals and institutions toward this effort. Consistent with the alerts issued by ISMP and FDA, sanofi-aventis is asking that you please exercise all necessary precautions to avoid the potential for similar risks at your institution. General recommendations for the safe use of insulin products and devices include, but are not limited to, the following:

For Insulin Pen Devices	<ul style="list-style-type: none">• Provide reminders that insulin pens are for single-patient use only• Before administration, ensure that the specific pen device is the one labeled and intended for that specific patient• Avoid placing patient-specific labels on removable caps as they may be placed erroneously on the wrong pen body• Ensure that the identifying patient label does not obstruct the dosing window or other product information such as product name and strength• Always attach a new needle prior to each injection• Prohibit the use of insulin pens as "floor stock"
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¹ ISMP Medication Safety Alert! Acute Care, Institute for Safe Medication Practices (ISMP). February 12, 2009, Vol. 14, Issue 3.

² FDA. Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens. FDA Alert. March 19, 2009.

³ Alert issued about use of insulin pens for hospitalized diabetic patients (dated 2/24/2009). Available at: www.consumermedsafety.org. Accessed March 24, 2009.

⁴ Cohen MR. Cross Contamination With Insulin Pens. Hospital Pharmacy. 2008;43(6):445-448.

⁵ Sonoki K, Yoshinari M, Iwase M, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. Diabetes Care. 2001;24(3):603-604.

⁶ LeFloch JP, Herbretreau C, Lange F, Perlemuter L. Biological material in needles and cartridges after insulin injection with a pen in diabetic patients. Diabetes Care. 1998;21(9):1502-1504.

⁷ Thompson ND, Perz JF, Moorman AC, Holmberg SD. Nonhospital Health Care-Associated Hepatitis B and C Virus Transmission: United States, 1998-2008. Ann Intern Med. 2009;150:33-39.

For Insulin Vials	<ul style="list-style-type: none"> • Prohibit the reuse of needles and syringes
For Blood Glucose Monitoring Equipment	<ul style="list-style-type: none"> • Prohibit the sharing of fingerstick devices • Mandate aseptic cleaning of glucometers before and after testing with each patient • Prohibit the storage of used and unused blood glucose monitoring equipment in common areas • Prohibit reuse of disposable end-caps on fingerstick devices shared by multiple patients
General precautions	<ul style="list-style-type: none"> • Provide frequent educational in-services to nursing staff on appropriate infection control practices and aseptic techniques • Conduct surveillance and monitor practices on a regular basis • Always wear gloves during procedures and change gloves between patients • Always perform hand hygiene before and after procedures • Exercise proper needle and device disposal

The CDC has provided a comprehensive updated guideline⁸ for preventing transmission of infectious agents in healthcare settings. This document is intended for use by healthcare personnel responsible for developing, implementing, and evaluating infection control programs for healthcare settings across the continuum of care. For this resource and other valuable references available at no cost, please refer to the CDC website (www.cdc.gov).

Please share this information with your entire healthcare professional staff. Thank you for your diligence related to this matter.

If you have further questions or require additional information, please contact our Medical Information Services department at 1-800-633-1610 (option #1) from 8am to 8pm (EST) Monday–Friday.

The FDA urges healthcare professionals to report adverse events and medication errors to the FDA's MedWatch Adverse Event Reporting program or the ISMP Medication Errors Reporting Program.

FDA's MedWatch reporting system:

Online: www.fda.gov/medwatch/report.htm

FAX: 1-800-FDA-0178

Phone: 1-800-332-1088

Mail (using form 3500): 5600 Fishers Lane, Rockville, MD 20852-9787

ISMP Medication Errors Reporting Program:

Online: www.ismp.org/orderforms/reporterrortolSMP.asp

FAX: 1-215 947 7797

Phone: 1-800-324-5723

Mail: 200 Lakeside Drive, Suite 200, Horsham, PA 19044

Sincerely,



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⁸ Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. (http://www.cdc.gov/ncidod/dhqp/gl_isolation.html)