

# Novartis Hazard Alert

To: Employees and employers in Health Care Industry

## Risk of Needle-sticks from Unprotected Prefilled Flu Vaccine Syringes

The California Division of Occupational Safety and Health has recently been alerted to the sale in California and nationwide of prefilled syringes with fixed needles containing Fluvirin, manufactured by Novartis, which is one of the 2008 seasonal influenza vaccines. The needles do not have engineered sharps injury protection (ESIP), and they cannot be removed and replaced with needle products that have sheaths or shields. Cal/OSHA standards require needles used by healthcare workers who administer flu vaccinations to have built in anti-stick protection unless there is no acceptable alternative available on the market, because using unprotected syringes increases the hazard of a needlestick to those administering the vaccine. While unprotected syringes pose a safety risk to employees, **they do not affect the safety or efficacy of the vaccine in patients.**



In response to an inquiry by Cal/OSHA and CDPH, Novartis states that it has:

- replaced the fixed needle syringes provided to public health departments in California and offered replacement Fluvirin products to its direct customers;
- contacted its distributors and provided replacement products for their customers;
- provided Cal/OSHA with a list of distributors so that Cal/OSHA can make direct contact with them to provide information to their customers; and
- obtained “add on” safety devices that can be attached to the fixed needle syringe prior to administering the vaccine. Please note: In California, these “add-on” devices can only be used if there is no acceptable needle-less or ESIP device available, including vaccine products from other manufacturers.

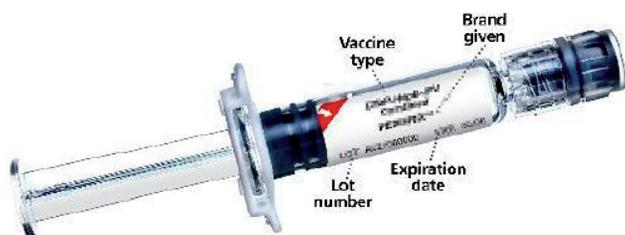
Novartis customers who want additional information can contact Novartis at (800) 244-7668 or the California supplier for Novartis, FFF Enterprises at (800) 843-7477.

Employees who are stuck with contaminated needles and other sharps are at risk of infection from a number of pathogens that are spread through contact with blood, including HIV and Hepatitis B and C. The medications often administered after a needle stick as preventive or early treatments can also have adverse health consequences. In addition, workers who have experienced a needle stick may suffer significant emotional and psychological stress, as well as disruption of their personal lives due to their potential to become infected.

Unless there is no acceptable device available<sup>1</sup>, needle-less systems or devices with engineered sharps injury protection must be used for withdrawal of body fluids, accessing a vein or artery, administration of medications or fluids, or any other procedure involving the potential for inadvertent penetration of the skin by an object contaminated with blood or other potentially infectious body fluids. Where there is no acceptable needle-less system or ESIP device available, then employers must evaluate and use other appropriate engineering controls, such as a shield that may be added onto a device that will reduce the risk of needlesticks.

## Novartis Hazard Alert

As of October 22, 2008, the federal Food and Drug Administration has licensed a number of influenza vaccine products from six manufacturers that can be used in compliance with Cal/OSHA standards. These include single-dose and multi-dose vials, which can be used with safety syringes. Prefilled syringes are also available with a connector (Luer connector) that can be used to attach the syringe to a safety needle cartridge. An additional type of flu vaccine, which is administered by a nasal spray and has no needle, is also available for use with some patients. A list of approved Influenza vaccine products can be found at: <http://www.cdc.gov/flu/about/qa/vaxsupply.htm>



*Syringe with connector*



*Syringe with ESIP*

In 1998 California passed AB 1208, Safe Needles, which was the first law in the nation to specifically require the use of safety syringes and other safety devices. This was followed in 1999 by the passage of amendments to Cal/OSHA's Bloodborne Pathogens Standard, Section 5193, requiring the use of needleless systems for administration of medication, and when those systems are not available, the use of sharps with Engineered Sharps Injury Protection. This was followed in 2000 by the federal Needlestick Safety and Prevention Act, and amendments to federal OSHA regulations in 2001. At the time of the adoption of the Federal OSHA regulation, the U.S. Centers for Disease Control and Prevention estimated that 590,164 health care workers sustained percutaneous injuries each year, of which 384,325 occurred in hospital settings. The CDC also reported that 29 percent of reported sharps injuries in surveyed hospitals were from hypodermic needles attached to disposable syringes.

For more information on Cal/OSHA's Bloodborne Pathogen Standard and safety devices please see:

- Cal/OSHA Bloodborne Pathogen Regulation  
<http://www.dir.ca.gov/title8/5193.html>
- A Best Practices Approach for Reducing Bloodborne Pathogens Exposure,  
[http://www.dir.ca.gov/dosh/dosh\\_publications/BBPBest1.pdf](http://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf)
- Bloodborne Pathogens and Needlestick Prevention - Federal OSHA Safety & Health Topic  
<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>
- California Department of Public Health Advisory – includes a picture of the non-compliant syringe  
<http://www.cdph.ca.gov/programs/ohb/Documents/novartis.pdf>
- Bloodborne Infectious Diseases - NIOSH Safety & Health Topic  
<http://www.cdc.gov/niosh/topics/bbp/>