Medical News

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EPA Issues Stop-Sale Orders on Four Medical Solutions

The U.S. Environmental Protection Agency (EPA) ordered a stop to the sale of four medical solutions used to sterilize medical equipment. This stop order, effective December 3, 1993, includes the following products manufactured by Metrex Research Corporation of Parker, Colorado: Metricide Activated Dialdehyde Solution, Metricide Plus 14, Metricide Plus 28, and Metricide Plus 30. The stop-sale order is based on laboratory testing and other information that shows that these products failed efficacy tests for sterilants when used according to label directions (10-hour immersion at 20°C). All four Metricide products have glutaraldehyde as the active ingredient and compose a substantial part of the sterilant market.

The EPA also announced that it is negotiating with the registrants of four other sterilants that failed efficacy tests seeking voluntary agreements for limiting the marketing of their products. The products are ABQ and Exspor (Alcide Corp, Norwalk, CT), Clidox-S (Pharmacal Research Laboratories, Naugatuck, CT), and Cetylcide-G (Cetylite Industries, Pennsauken, NJ). Alcide and Cetylite voluntarily agreed to recall the affected batches of Exspor and Cetylcide from all dental and medical channels of trade. ABQ and Clidox-S are marketed primarily for disinfecting and cleaning surfaces in veterinary and laboratory animal research settings and their continued use would not directly affect human or animal health. EPA has offered to allow these four sterilants to remain temporarily on the market for limited use in veterinary and animal research laboratories as disinfectants under an amended registration pending retesting.

These actions are part of the EPA's continued testing program for sterilants and disinfectants that began in 1991. The EPA plans to complete its review of the testing of all sterilants within the next six months.

Contaminated Syringes Reused During Employee Vaccination Programs

The CDC recently reported incidents of improper infection control practices in two U.S. cities during vaccination of employees at worksite vaccination programs. The first case involved a physician who was hired to administer influenza vaccine to employees and who subsequently reused needles to vaccinate other employees. The procedure used by the physician involved aspiration of several doses of vaccine from a multidose vial into a syringe, inoculating an employee, and then, after wiping the needle with an alcohol swab, using the same needle and syringe subsequently to inoculate another employee.

The second case also involved a physician who had been hired to administer influenza and pneumococcal vaccine to employees. He was observed puncturing multidose vials of vaccine with needles that had been used previously to inoculate patients. The physician first aspirated a dose of influenza vaccine into a syringe and inoculated an employee; then, using the same syringe and needle, aspirated pneumococcal vaccine from a multidose vial of that vaccine and inoculated the same person. Although a new syringe and needle were used for each employee, the physician repeatedly punctured the multidose vials of pneumococcal vaccine with used needles.

Employees at both worksites have been counseled and offered serotesting for bloodborne pathogens and medical follow-up.

Infections have been transmitted to patients by contaminated multidose vials and reuse of syringes, including hepatitis B virus infection. Nosocomial patient-to-patient transmission of HIV has occurred when needles and syringes were reused without being sterilized properly or were reused inadvertently between patients.

These two cases represent major breaches in basic infection control practices for administering injections that are taught to physicians, nurses, and other healthcare workers during their training. In their report of these cases, the CDC urged strict adherence to long-standing precautions for administering parenteral substances. These include: 1) considering previously used syringes as contaminated and not reusing them to aspirate medication from a multidose vial that will be used on another patient; 2) using only sterile needles and syringes to administer parenteral substances; 3) discarding after use all needles and syringes that have been manufactured for

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