FDA, Multilaterals Team Up for Product Safety

From the time you take your morning vitamin until you brush your teeth at night, U.S. consumers use many products imported from other countries.

Margaret Chan (left), head of the World Health Organization, prepares to speak during a meeting with FDA Commissioner Margaret Hamburg (right) at FDA headquarters in Maryland. The agency is teaming up with multilateral organizations to enhance product safety initiatives around the world.

The Food and Drug Administration says 40 percent of fresh produce and 80 percent of the active ingredients in medications come into the United States from outside our borders. And that doesn't count animal feed, medical devices, cosmetics, and other FDA-regulated products that flood the U.S. from abroad.

Sometimes these products may contain only one ingredient or component part from another country, while other times the entire product may come from one or many countries.

Because the neighborhood grocery and corner drug store are now global marketplaces, FDA ensures the safety and effectiveness of products sold domestically by working through multilateral organizations to improve cooperation and collaboration with other countries, says Mary Lou Valdez, FDA's associate commissioner for international programs.

Multilateral organizations are groups of more than two countries banded together to work on specific issues. Participation in these groups offers FDA opportunities to expand reach and increase knowledge.

"We work with the World Health Organization and other groups to effect changes in the policies and procedures of manufacturers and farmers in developing nations, so they can produce the safest and most effective products for themselves and the U.S. market," Valdez says.

FDA is working with three multilateral organizations on projects that aim to improve food safety, as well as the safety of medical products for people and animals. FDA's partners are:

- **World Health Organization (WHO)**—FDA is helping the WHO develop a global surveillance and monitoring system to track substandard medicines. FDA is supporting this effort with a $961,500 grant so that regulatory agencies around the world will be aware when the pharmaceutical supply chain has been compromised. "It will be a platform member states can use as we try to wrap our arms around the scope of the substandard product problem," Valdez says. With a $847,500 grant, FDA is also supporting WHO's effort to minimize the resistance of germs to antimicrobial drugs, which can destroy or inhibit the growth of disease-causing microbes. Resistance to these drugs means that a drug might not be effective when a person is sick with a normally treatable

illness. Experts say the use of antimicrobial drugs contributes to antimicrobial-resistant organisms, so these important drugs must be used judiciously in animals and people to slow the development of resistance. In addition, FDA has given WHO nearly $400,000 to help develop a plan for a global information system to make it easier to share information on food safety problems, including contamination that leads to a product recall.

- **Pan American Health Organization (PAHO)**—FDA, through a $904,000 award, is helping PAHO develop an information hub for the Americas through which countries in the region can share data, standards, and guidelines for regulators. FDA has also worked with PAHO to establish technical standards for drugs and biologics in the Americas. Established in 1902, PAHO works to improve the health and the quality of life of people of the Americas and serves as the regional office of the World Health Organization. PAHO's member nations include 38 countries in the Caribbean and North, Central, and South America.
- **World Organization for Animal Health**—With a grant of $565,000, FDA is aiding the World Organization for Animal Health in its effort to strengthen agencies that regulate veterinary medical products. This effort includes adoption of international standards for veterinary products through training and improvement of laboratories.

Through its work with multilateral organizations and FDA's own international offices, the agency is supporting efforts to strengthen regulatory agencies in developing nations and create internationally accepted standards of safety, efficacy, and quality.

FDA also has strong, individual relationships and confidentiality agreements with regulatory counterparts in 29 countries. This enables the agency to share scientific knowledge and expertise and promote responsible international activities that promote product safety.

"The presence of a strong regulatory network ultimately benefits developing nations because it ensures that their manufacturers adhere to standards that promote public health at home and in the countries that import their goods," Valdez says.

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