

Manufacturing sectors meet with local, federal regulatory agencies

First time industry meets with regulatory agencies as a group

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Representatives from the pharmaceutical drugs, medical devices, contract manufacturing, cosmetic, and orphan products manufacturing sectors recently met in San Juan with federal and local regulatory agencies to discuss government laws and regulations during the Regulatory Industry Outreach Conference.

"This was the first time that various manufacturing-sector representatives in Puerto Rico had met as a group with local and federal regulatory agencies," said Regulatory Compliance Services (ReComS) Vice President Eric Olivieri, who organized the conference. "In addition, it was a first for getting representatives from the U.S. Food & Drug Administration (FDA), the U.S. Drug Enforcement Administration, the U.S. Bureau of Customs & Border Protection, plus Puerto Rico's Mental Health & Addiction Services Administration on a panel."

"Pharmaceutical industry meetings are usually held by sector, which doesn't allow for interaction. During this conference, the pharmaceutical and generic-drug sectors were able to discuss issues relevant to both. Sitting next to each other were general managers, quality assurance directors, and engineers; marketing, human resources, and security directors; and industry representatives from Puerto Rico, the U.S. mainland, Brazil, Mexico, and the Dominican Republic. The success of the conference was how much information was available for all," said Olivieri.

The FDA was represented at the conference by San Juan District Director Don Voeller. Accompanying him were local FDA Investigations Director H. Gordon Cox, Compliance Director Andres Toro, and Supervisory Investigator Maridalia Torres (CB March 18).

Pharmaceutical drugs

Janssen Ortho LLC General Manager Rafael Espinal offered an overview of pharmaceutical drug manufacturing in Puerto Rico and the challenges the sector faces. "In 2001, research-based pharmaceutical companies invested more than \$25 billion in research & development," he said. "The percentage of sales allocated to R&D also increased from 11.9% in 1980 to 22% in 2001. This occurred at the same time that the cost of developing a pharmaceutical drug grew to \$600 million in 2001 [in 2003, the cost was estimated at \$800 million]"

Industry challenges identified by Espinal included the effect of major mergers between pharmaceutical companies; tough economic times, war, and the threat of terrorism; pressures of pharmaceutical drugs' price control; generic competition; focus on biotechnology; concentration on production of new delivery forms; and talent search.

Espinal said he remains confident about the island's pharmaceutical drug manufacturing sector, which contributes up to 25% of Puerto Rico's gross domestic product and generates approximately 120,000 direct and indirect jobs. Currently, 16 of the top 20 pharmaceutical products sold in the U.S. are manufactured in Puerto Rico, and 14 of the top 20 pharmaceutical companies worldwide have operations in Puerto Rico.

Medical devices

Anthony Calaf, vice president of Fajardo-based medical devices manufacturer Pall Medical, cautioned local manufacturing companies about expanding to markets that don't embrace global business agreements. "The Chinese market may be huge, with a lot of potential, but there are

serious problems with protection of intellectual property,” he said. “Companies have been more successful in Singapore and Taiwan, and there may be other countries ready to compete in this market.”

Contract manufacturing

Vivian Borrero, quality assurance director of contract manufacturer Cardinal Health, spoke about the benefits of outsourcing to companies that specialize in specific functions and can provide quick turnaround. “In 2002, the market for outsourced medical devices was estimated at \$8 billion,” she said. “It is now expected to grow over the next several years at a 20% annual rate to more than \$10 billion.”

Borrero said the FDA approves of ceding pharmaceutical drug, medical devices, and biologic manufacturing processes to contract manufacturers as long as these comply with applicable quality guidelines. Cosmetics manufacturers don’t require approval before they are sold to the public, as they fall under the FDA’s Federal Food, Drug, and Cosmetic Act. However, the FDA still recommends using known and appropriately licensed contract manufacturers to ensure quality.

Orphan products

The topic of orphan products manufacturing was raised by Marlene Haffner, rear admiral with the FDA Office of Orphan Products Development (CB June 14, 2001). Orphan drugs are treatments for conditions that affect fewer than 200,000 people in the U.S. and thus won’t be profitable within seven years after FDA approval. According to Haffner, the established public policy is meant to assist in the development of treatments for rare diseases, such as when AIDS first appeared in the 1970s.

“Today, there are 251 orphan products available in the U.S. to more than 12 million patients; of these, 195 are pharmaceutical drugs and 56 are biologics,” said Haffner. “Approximately 20 new research grants for orphan products are approved each year, but most are for supporting Phase 1 and Phase 2 clinical trials. Approximately \$150,000 to \$300,000 is awarded per grant, for up to three years.”

According to Haffner, more than one billion people are covered by an orphan drug policy worldwide. The U.S. Orphan Drug Act was approved in 1983; Japan’s in 1993; Australia’s in 1997; the European Union’s in 1999; and Taiwan’s and Korea’s around 2000. Such policies are under revision in Canada, Israel, and China.