to be classified according to risk, how they are to be designed, manufactured, labeled, and evaluated for safety and performance. Many of the GHTF documents utilize the European Medical Regulations, since more than 30 countries currently use them and most U.S. manufacturers abide by them. The FDA has had its hand in modifying the guidance and had a tremendous impact on how medical devices should be manufactured.

There is however a problem with trying get all countries to agree on one approach to regulating all medical devices, which include dental products. Too often the representatives from industry and government are shaping their regulations around high-risk devices. In fact, all industry representatives in one of the most critical study groups made what are termed “best practice” recommendations, which include dental products such as artificial kidneys, business that “represent industry” are all from very large corporations with annual sales revenues reported at $500 million to $5 billion.

This consensus building with large corporations making high-risk medical devices has “harmonized” the GHTF recommendations without giving adequate attention to its impact on the dental industry of oral health care worldwide. To complicate matters further, many of the ministries of health that helped create the recommendations in substantial ways by adding national requirements on top of the GHTF recommendations, which have seriously hurt industry and oral health care within their country.

Canada’s trial

In January 2005, Health Canada adopted a new medical device regulation based on many different GHTF guidance documents, which they had helped create. Along with adopting a variation from the GHTF risk classification recommendations, Health Canada also adopted unique Canadian requirements on how manufactures should have factories inspected.

Though their requirements for designing and manufacturing dental products was based on the international standard ISO 13485, many dental companies around the world, who already had certified to ISO 13485, found that Health Canada would not accept their existing ISO 13485 certificates. Health Canada sent notices to dental manufacturers threatened to revoke their licenses if they did not have inspections performed to their version of the inspection, called the Canadian Medical Device Conformity Assessment System.

As a result, many dental products ceased to become legally available in Canada. For two years, many niche products became impossible to legally obtain, even though many of them had been licensed and legally available for many years previous to Canada’s new “harmonized regulation.”

At one point, Canadian dentists pressed the Canadian Dental Association to look into why they were no longer able to buy dental products they had been using. Dentists continued to buy whatever they could, regardless of whether the products were properly licensed in Canada or not. However, many members of the dental industry refused to continue selling their product to Canadian dentists for risk of being caught by Health Canada. Health Canada’s New Medical Device Regulation put the entire health-care system in jeopardy.

Though the Canadian inspection is remarkably similar to the international inspection, few inspectors were available for performing it when the regulation went into affect, especially in Europe and Asia. As a result, entire medical device categories suddenly ceased to legally exist in Canada. Several years into the enforcement of the new “global-like” regulation, Health Canada still struggles to get industry to cooperate with their new regulation, while dentists still look for any way they can to maintain a steady stream of dental products.

The future

It is important to note that the lack of availability of dental products in Canada has not prevented Canada from being the largest of any country the United States exports to.

“Accepted once, accepted everywhere” seems to be an elusive pipe dream, but the more similar regulations are to each other, the more trade will improve. Globalization can be a good thing and will continue to be pursued by industry and regulators. It is our responsibility to actively represent the dental industries’ concerns and help preserve oral health care worldwide.

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