U.S.-India Trade Tensions and Medical Devices

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Medical devices have been at the center of recent trade disputes between the United States and India. In 2017, the Government of India (GOI) introduced price controls on two categories of medical devices: coronary stents and knee implants. More recently, in February 2019, the GOI proposed a series of India-specific standards on six categories of medical devices. These measures, otherwise known as Quality Control Orders (QCOs), cover roughly one-third of the value of U.S. medical device exports to India in 2018. The United States is the largest single-country supplier of medical devices to India; these latest measures, if implemented, could discourage U.S. exports by increasing compliance costs and potentially increase the time-to-market.

India's Recent Policies on Medical Devices

Since 2017, India's National Pharmaceutical Price Authority (NPPA)—the agency that establishes the country's medical device market prices—has been applying price controls to two categories of medical devices: (1) coronary stents, an implantable device that ensures adequate blood flow to the heart, and (2) knee implants. The stated intention of these policies was to make these devices affordable for patients and to encourage domestic manufacturing as part of the country's "Make in India" campaign.[1] U.S. producers primarily supply the high-end of these markets, but these price reductions—coronary stent prices fell by as much as 80 percent—were implemented without regard to quality and performance (attributes which command higher prices). As such, U.S. firms appear to have been disadvantaged by these price reductions; Indian stent production reportedly may have displaced some U.S. market share during 2018.[2]

More recently, in February 2019, India proposed QCOs that would apply country-specific standards to six specific categories of medical devices to, ostensibly, promote product safety. These devices include medical electrical equipment, sphygmomanometers, clinical electrical thermometers, blood glucose monitoring systems, gloves, and surgical blades. The QCOs would be limited in scope—focusing principally on product safety—as opposed to other aspects of product quality.

Background of India's Medical Device Regulations

Medical devices are currently reviewed by the Central Drugs Standard Control Organization (CDSCO), India's regulatory authority which ensures that devices comply with conformity assessment procedures, have fulfilled clinical data requirements when needed, and meet safety requirements.

As early as 2017, the GOI regulated 14 broad categories of devices as if they were pharmaceutical drugs, and left the vast majority unregulated. This was a sharp divergence from international best practices, which recommends that all medical devices be classified according to the relative risks they present and implicitly recognizes that medtech should be regulated apart from pharmaceuticals.

However, in 2017, the GOI passed the *Medical Device Rules* (MDR, 2017), which introduced standards based on four categories of devices, arranged from the lowest risk (Class A) to the highest risk (Class D). Further, the MDR, 2017 introduced other international recognized regulatory practices, such as a Quality Management System (a structured

[1] For more information see Torsekar, "India's Price Controls," October 2017.

[2] Venkatesh, "Coronary Stent," March 4, 2019. Further, India's share of imports from the U.S. under HS 9021.39—the category into which coronary stents fall—has declined from 51 to 39 percent during 2017-18. Notably, this category contains many other products besides coronary stents, so it is difficult to determine how much of this decline is exclusively attributable to stents. For knee implants (HS 9021.10) the shares were relatively consistent at about 52 percent.

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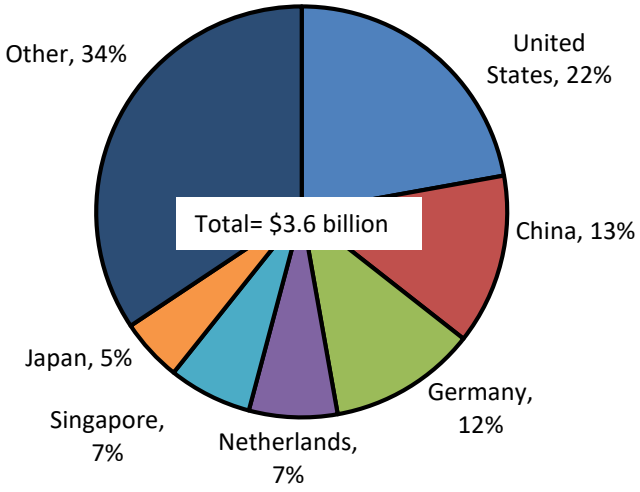
system of procedures that attests to the quality of a manufacturer's operations), Notified Bodies (to audit manufacturing facilities), and the application of clinical trials for high-risk, novel devices. The MDR, 2017 entered into force on January 1, 2018. Currently, the CDSCO regulates only 37 specific devices and estimates that it will require another 4-5 years to regulate all devices.

What's at Stake?

• An estimated 70% of India's medical device market is supplied by imports. The United States is the largest single-country supplier representing nearly one-quarter of India's medical device imports during 2018 (figure 1). Of the products that have recently been subject to price controls (coronary stents and knee implants) and the six specific categories of devices, the United States is India's leading single-country supplier.

Figure 1 India's leading import suppliers of medical devices, 2018



Source: IHS Markit, Global Trade Atlas database (accessed August 3, 2019).

• Further, the six categories of devices for which India has proposed QCOs covers more than one-third of U.S. medical device exports to India, by value (table 1).

Table 1 U.S. medical device exports to India by affected products of QCOs, total, and selected products as a share of total exports, 2018

Products affected by QCOs	**2018 U.S. exports to India, $**
Medical Electrical Equipment	180,491,078
Sphygmomanometers	749,646
Clinical Electrical Thermometers	50,031
Blood Glucose Monitoring System	38,178,611
Gloves	120,722
Surgical blades	76,980,163
Total	**296,570,251**
Total U.S. medical device exports	**877,447,514**
Share of U.S. med tech exports affected by proposed standards	**34%**

Source: IHS Market, Global Trade Atlas database.

• According to the Medical Technology Association of India (MTaI), the GOI's proposed standards on these devices would duplicate the product safety regulatory practices already being conducted by the CDSCO by adding a series of India-specific standards. MTaI has suggested that foreign firms would face increased compliance costs. These firms are likely already complying with current CDSCO requirements but would also likely have gained approval under their own country's regimes (e.g. the U.S. FDA). The U.S. concerns were made in early June to India's QCO proposals.

• The additional costs of compliance could result in delayed time to market for U.S. manufacturers. Past research has revealed that a lengthy time to market exerts a negative and statistically significant impact on trade flows.

• As part of its obligations as a signatory to the 1995 WTO Agreement on Technical Barriers to Trade (TBT), India has notified the TBT Committee of three of these QCOs. These notifications are submitted any time signatory countries consider updating their regulatory practices in ways that may significantly depart from international standards and could impact trade. It should be noted that while these notifications don't necessarily constitute TBT violations, they can suggest the imposition of trade costs and imply possible delays in gaining approval for sale.

Sources: Sources: Ayers, "India's New Medical Device Regulations," June 12, 2017; Politico, "India Plays Down Trump Move," March 5, 2019; Herman, "Competitive Conditions Affecting U.S. Exports," 2018; Qualtech, "India: Mandatory Quality Control Orders Proposed," April 11, 2019; AdvaMed, "AdvaMed Seeks Relief From India Price Controls," October 17, 2017; Drugs Controller General, "Classification," May 15, 2019.

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