Comments by the
Advanced Medical Technology Association
Regarding Generalized System of Preferences (GSP): Initiation of the 2017 Annual GSP Product and Country Practices Review
USTR-2017-0014
2017 GSP Annual Review: India
October 17, 2017

Pursuant to section 2007.0(b) of Title 15 of the Code of Federal Regulations, the Advanced Medical Technology Association (AdvaMed) respectfully requests that USTR suspend or withdraw, in whole or in part, India's benefits under the Generalized System of Preferences (GSP), in view of its failure to provide equitable and reasonable access to its market for medical devices (19 U.S.C. § 2462(c)(4)).

AdvaMed is a trade association, representing nearly 350 companies, which leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. Our member companies, which include the leading US producers in the industry, range from the largest to the smallest medical technology innovators and companies. AdvaMed acts as the common voice for companies producing medical devices, diagnostic products and health information systems. Our association promotes competitive policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

With particular respect to the Indian market, AdvaMed's efforts are designed to help address India's public health challenges by introducing the value of innovative medical technologies to the country's healthcare system. These efforts include:

- Contributing towards building India's healthcare capacity;
- Engaging in India's efforts to develop an appropriate regulatory system that provides a high level of patient safety while fostering innovation and investment; and
- Advancing fair and appropriate pricing and reimbursement policies that recognize India's public health challenges and the value of medical technology.

As detailed below, as a result of its recent series of actions against innovative medical device technology, including price controls that discriminate against imports of high-technology products and measures that effectively force US producers to sell in India at a loss, India fails to provide equitable and reasonable access to its market.

Background on India's drug and medical device price control regime:

India regulates the prices of drugs and medical devices under the Drugs (Prices Control) Order, 2013 (DPCO).[1] The DPCO is based on Section 3 of India's Essential Commodities Act of 1955. Pursuant to this section, the government may regulate prices, prohibit any essential commodity from being withheld from sale, compel any holder of essential commodities to sell them, and even confiscate stocks of essential commodities. Violation of government orders under this Act is punishable by imprisonment and fines.[2]

The DPCO applies to both drugs and medical devices. Article 3(b) of the Drugs and Cosmetics Act (1940) provides that the term "drug" includes, *inter alia*, "such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the [Drugs Technical Advisory] Board".[3]

The DPCO includes a National List of Essential Medicines (NLEM), and provides for the Ministry of Health and Family Welfare (MHFW) to update that list. The MHFW has notified ("gazetted") 22 devices as drugs. As of early 2016, only contraceptive devices had been included in the NLEM such that they were subject to price controls; all other devices, including cardiac stents and drug-eluting stents (DES), were treated as non-scheduled drugs, subject to annual price monitoring by NPPA to ensure that prices did not increase more than 10% per year.[4] Otherwise, as of March 2016, the NLEM listed 814 scheduled formulations in 30 therapeutic groups of drugs, vaccines, and blood products.

The DPCO is administered by the National Pharmaceutical Pricing Authority (NPPA), under the Department of Pharmaceuticals of India's Ministry of Chemicals and Fertilizers. The DPCO's general approach to drug price regulation calls for the NPPA to work out the simple average price to retailers, for all generic and branded-generic (i.e., previously patented drugs/devices sold under a brand name) versions of a particular formulation that have a market share of 1% or

[1] Drugs (Prices Control) Order, 2013, as amended up to March 22, 2016, available at http://nppaindia.nic.in/DPCO2013_03082016.pdf.

[2] Essential Commodities Act, 1955 (Act No. 10, of 1955), Section 3, available at http://fcatripura.gov.in/sites/default/files/quick_tabs_files/Essential%20Commodities%20Act%201955.pdf.

[3] Drugs and Cosmetics Act (1940), text as notified to WHO, available at http://apps.who.int/medicinedocs/documents/s20107en/s20107en.pdf. Article 2(2) of the DPCO provides that its terms follow the definitions in the Drugs and Cosmetics Act (1940), unless otherwise provided.

[4] NPPA "Report on Pricing of Stents", Feb. 4, 2016, para. 7, available at http://nppaindia.nic.in/order/REPORT%20ON%20PRICING%20OF%20STENTS04022016.pdf. The 22 device categories were: disposable syringes; disposable hypodermic needles; disposable perfusion sets; in-vitro diagnostic devices for HiV, HBsAg and HCV; cardiac stents; drug eluting stents; catheters; intraocular lenses; IV cannulae; bone cements; heart valves; scalp vein sets; orthopedic implants; internal prosthetic replacements; blood grouping sera; ligatures, sutures and staplers; intra-uterine devices (Cu-T); condoms; tubal rings; surgical dressings; umbilical tapes; and blood/blood component bags. *Id.*

above. NPPA then adds a retailer margin of 16%. The maximum retail price for that formulation must not exceed the notified ceiling price plus applicable local taxes. The prices are notified in the Gazette of India, and enter into force when published.[5]

Paragraph 3 of the DPCO provides that, with a view to achieving adequate availability of drugs, the Government may, in case of emergency or in circumstances of urgency, direct any manufacturer (including any importer or marketer) of a drug (or gazette device) to increase its production and to sell to institutions, hospitals or any agency.

In understanding the reasoning behind the recent developments in India's medical device price controls, it is important to highlight that the Department of Pharmaceuticals also has a mission of promoting the growth of the *domestic* drug and device industries, and *reducing imports*.[6] As stated in its 2016-17 Annual Report: "The vision of the Department of Pharmaceutical (DoP), Ministry of Chemicals & Fertilizers is to catalyze and encourage quality, productivity and innovation in Medical Device Sector and to enable the Indian Medical Device Industry to reduce the dependency on import of Medical Devices."[7]

The DPCO discriminates on its face in favor of drugs and devices developed and produced in India, and against drugs and devices that are produced abroad. In particular, Article 32 of the DPCO provides a five-year holiday from DPCO price controls for (i) a new drug developed through indigenous R&D, and protected by an Indian product patent, when it is produced in India; (ii) a new drug developed through indigenous R&D, and protected by an Indian process patent, when it is produced in India; (iii) a new drug involving a new delivery system, to the extent it is developed through indigenous R&D. (Recall that "drug", under India's law, includes notified devices.)

Price controls on coronary stents

On July 19, 2016, MHFW issued a Notification adding coronary stents to the NLEM.[8] Then, on December 21, 2016, the Department of Pharmaceuticals issued a notification adding bare metal stents (BMS) and DES to Schedule I of the DPCO, thereby triggering requirements for

[5] These notifications are also available on the NPPA website, http://www.nppaindia.nic.in/.

[6] Department of Pharmaceuticals: http://pharmaceuticals.gov.in/about-department

[7] Department of Pharmaceuticals, Ministry or Chemicals & Fertilizers, 2016-2017 Annual Report, p. 25, available at http://pharmaceuticals.gov.in/sites/default/files/Chemical%20Pharma%20-2016-17%20English%20Final%20%20for%20mail%20%282%29.pdf.

[8] Notification No. X-11035/344/2015-DQFC, Ministry of Health and Family Welfare (Drug Quality Control Section).

manufacturers to submit price-related data.[9] Paragraph 17 of the DPCO then required NPPA to set prices for the notified products within 60 days.

2016-17: Setting of low ceiling prices for coronary stents

Following the notification, there was considerable debate concerning whether and how to set higher ceiling prices for more advanced types of DES. The Confederation of Indian Industry and the Cardiological Society of India argued for differential pricing for more technologically advanced stents to encourage continued innovation. On the other side, trade associations representing local Indian device manufacturers sought a single price for all DES, in its continuing attempt to gain a larger share of the stent market from foreign competitors.[10]

The NPPA proceeded to set one ceiling price for DES, and one ceiling price for BMS, without any differentiation among different kinds of DES or BMS. On February 13, 2017, the Gazette of India published NPAA's order setting ceiling prices of coronary stents, not based on the normal methodology prescribed in the DPCO, but on paragraph 19 of the DPCO, which allows the government "in case of extra-ordinary circumstances" to fix the ceiling price or retail price of any drug for such period, as it may deem fit. It set the ceiling price for BMS at Rs. 7,260, and for DES (both metallic and bioresorbable vascular scaffolds (BVS)) at Rs. 29,600 (both prices exclusive of applicable local taxes). This price applies to the maximum retail price and is applicable until February 13, 2018, unless revised by another gazette notification.[11]

As a result of NPPA's February 13, 2017 order, all stock of coronary stents required immediate downward price revision, and new stent technologies saw immediate reductions of up to 75%-85%. Stent manufacturers or importers were ordered to issue a price list, and report their production, imports and sales of stents to NPPA. Any manufacturer/importer intending to discontinue production or import of a stent, was required to seek permission from NPPA at least 6 months in advance.

NPAA later released the minutes of the February 13 NPPA meeting that led to the price-fixing order for stents.[12] This document noted the factors that were weighed and considered by the NPPA in determining how to set the prices. The minutes explained as follows:

- Importers and foreign manufacturers strongly favored sub-categorization and differential ceiling prices for different categories of DES. Many eminent

[9] Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Notification No. S.O. 4100 (E) amending the Drugs (Prices Control) Order, 2013, Dec. 21, 2016, available at http://pharmaceuticals.gov.in/sites/default/files/Notification_2.pdf.

[10] Rema Nagarajan, "Policy on stent unleashes war in industry", *Times of India*, Sept. 25, 2016.

[11] Notification PN/73/41/2017, Gazette number F.No 8(41)/2017/DP/NPPA/Div II, Feb. 13, 2017.

[12] "Minutes of the 173rd and 41st Meeting of Authority under DPCO, 2013 held on 13.02.2017 at 11:00 A.M.", Proceeding No: 173/41/2016/F, F.No.8(41)/2017/DP/NPPA-Div.11, available at http://nppaindia.nic.in/minutes/minutes-2016-17/minutes-172mt-20-02-17.pdf.

cardiologists supported sub-classification within the DES category, and few cardiologists viewed all DES products as the same. Industry associations also supported differentiation within DES.

- Indian coronary stent manufacturers opposed sub-categorization, with the minutes reflecting as follows: "Indigenous manufacturers also emphasized that if any differential and higher prices were given to imported stents, that would cause a death-blow to the Indian industry and would be against the spirit of the Government's 'Make in India' campaign."[13]

- NPPA found there were large markups on price by hospitals (654% for DES), but only modest margins for manufacturers/importers (27% for DES).

An NPPA office memorandum, dated January 16, 2017, shows how NPPA's criteria applied to the cost structure of domestic and imported stents, disproportionately harming imported stents. Based on the data collected by NPPA, the average-price-to-distributors for DES ranged from Rs. 15,193 – 101,000 for imports, and from Rs. 9,500 – 42,000 for domestic stents. If the average-price-to-distributors is the selling price for both domestic and imported stents, then at a price ceiling of Rs. 29,600, some domestic and imported stents can sell above the previous selling price, and some domestic and imported stents will be forced to sell at below the previous selling price, but with the imported stents disproportionately affected, particularly those toward the higher end of the spectrum. The landed cost for imported DES ranged from Rs. 5,126 to 40,820.[14]

Forced sales at a loss

As a result of the Rs. 29,600 ceiling price, high-end imported DES – including those produced and sold by AdvaMed members – can be sold in India only at a loss. Indeed, in general, to the extent they had already entered India's market prior to the imposition of the price controls, such DES *must*, by law, continue to be sold, even with such loss.

In particular, on February 21, 2017, NPPA issued orders to certain manufacturers based on the emergency powers of paragraph 3 of DPCO. Through these orders, these companies were required to maintain uninterrupted supplies of all of their coronary stents for a period of six months from that date. The orders also required these companies to submit weekly reports on domestic production, distribution, and domestic production plans for coronary stents.

Numerous attempts by companies to seek differential pricing for newer technology or permission to withdraw products, because they were no longer commercially viable, have been rejected. In

[13] *Id.*, p. 3.

[14] Office Memorandum, "Sub: Clarification reg. display of draft version of Proposed Price calculation Sheet for proposed notified ceiling price/retail price of Coronary Stents on NPPA's website", Jan. 16, 2017, available at http://www.nppaindia.nic.in/order/ClarificationRegCoronary%20Stents_16-01-2017.pdf.

each case, the NPPA ruled that no request for withdrawal was permissible for the first six months, beginning February 21, 2017, and advised the company to explore price revision before exercising an exit route.[15] On April 28, 2017, the NPPA directed all stent importers, distributors and manufacturers to maintain import, production and supply of stents; to report weekly on stent production and distribution; and to submit a weekly production plan.[16]

In August 2017, six months after the February price control order, stent importers continued to seek higher price caps for the newest-generation stents, and their continuing losses on sales had forced them to pull back on expensive training activities.[17] The medical technology industry continued to argue that price controls must have separate prices by subsector and sub-category of device – urging that before imposing price controls, the government first examine geographical access barriers, quality of outcomes, reverse medical tourism (e.g., Indian patients and surgeons going outside of India for treatment, to access high-end stents that have not been introduced on the Indian market due to price controls), and decreased incentives to innovate.[18]

Reacting to additional applications for withdrawal of new stent technology, on September 28, 2017, the Department of Pharmaceuticals again issued a three-month order directing stent manufacturers (which under the law include importers and distributors) to maintain production, import and supply of coronary stents, and to submit a weekly report on the coronary stents produced and distributed.[19] AdvaMed members remain subject to the DoP's order requiring that they import and sell advanced technology stents, with no restriction, at a price that results in losing money on every sale.

Spreading of price controls to other medical devices

India's pricing policies on stents have recently begun spreading to other medical device categories. Most recently, on August 16, 2017, NPPA issued an order, effective immediately, cutting the price of knee implants by as much as 70%.[20] NPPA exercised a rarely invoked

[15] "Pharma body quashes firms' request to withdraw stents from market", *Hindustan Times*, Apr. 24, 2017, available at http://www.hindustantimes.com/mumbai-news/pharma-body-quashes-firms-request-to-withdraw-stents-from-market/story-wvr0UWbbTQiWBt78ljG1WN.html.

[16] Office Memorandum, "Ensuring compliance of the price capping of the coronary stents along with maintaining its uninterrupted supply – regarding", Apr. 28, 2017, available at http://nppaindia.nic.in/order/memorandum28042017.pdf.

[17] "Price cap on knee implants, stents could deter latest technology, allow hospitals to cheat", *Hindustan Times*, Aug. 18, 2017, available at http://www.hindustantimes.com/india-news/price-cap-on-knee-implants-stents-could-deter-latest-technology-allow-hospitals-to-cheat/story-2VAyIwwyKpCCz8SZVrN4aL.html.

[18] N.C.Sharma," Medical technology industry urges govt to look at sub-categorization of devices", *Mint*, Sept. 19, 2017.

[19] https://twitter.com/Pharmadept/status/913304753437683712; Sept. 27, 2017 Notice at http://pharmaceuticals.gov.in/sites/default/files/Para%203%20order%20dated%2027-09-2017.pdf .

[20] Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), Notification No. S.O. 2668(E), August 16, 2017.

provision of the DPCO, Paragraph 19, which permits the Government of India (GOI) in extraordinary circumstance to raise or lower the price of non-scheduled drugs. The extraordinary circumstances have never been communicated. Knee replacement surgery is an elective procedure, which typically addresses osteoarthritis of the knee joint. The GOI has never declared osteoarthritis a national medical epidemic requiring special government intervention. This order came despite repeated assurance by GOI officials that they would not expand price controls beyond stents.

US knee implant manufacturers have begun to experience significant reduction of revenue as a result of the price control order and, in some circumstances, companies are being forced to sell their most innovative products at a loss or to forgo launching new generation products into India. Just as in the case of stents, the GOI has denied manufacturers' freedom to withdraw some of their higher end products from the market – those that are being sold at a loss – even though the companies have assured the GOI that they will maintain a stable supply of other quality products. In addition, knee manufacturers are experiencing difficulty in continuing to fully service the market, especially as some distributors exit because of diminishing financial incentives.

Further, NPPA issued an Office Memorandum on August 25, 2017, clarifying that bone cement and the free use of instruments are covered by the order. This puts significant additional pricing pressure on importers, as bone cement is not part of a knee replacement system, and not all knee implant manufacturers also manufacture bone cement but instead, purchase it through unrelated suppliers. Additionally, the cost of purchase and maintenance of instruments is very high and another cost that manufacturers must bear. [21]

In addition, as noted above this policy is discriminatory ─ by design and effect ─ against US manufacturers. For example, the policy does not reflect different levels of knee implant technologies or advancements, which more adversely affects US firms over locals. The NPPA meeting minutes on the knee order decision demonstrate the intended bias against higher-end technologies manufactured by US firms, and the intent of using the price control policy to boost domestic device manufacturers by targeting US firms' products in categories where there are domestic manufacturers to benefit.[22]

The below quotes from the meeting minutes from August 14 demonstrate the GOI's bias and motivation to help domestic manufacturers.

> Since the knee implant market is dominated by overseas manufacturers, (85% to 90%) a ceiling price based on import prices can be taken as a benchmark which will take care of the production cost of Indian manufacturers very well. (page 18)

[21] Office Memorandum, "Sub: Compliance of price fixation of Orthopedic knee Implant system and related issues", Aug. 25, 2017, available athttp://nppaindia.nic.in

[22] Minutes of the 180th and 48th Meeting of the Authority (continued) under DPCO, 2013 held on 14.8.2017 at 11:00 A.M." available at http://nppaindia.nic.in/minutes/minutes-2017-18/minutes-180th-17-08-17.pdf

> The Authority was also conscious, of the fact that in case of orthopedic implants it is almost a monopoly situation in the hand of MNCs… (page 20)
>
> The rationalised trade structure will stand to the benefit of Indian manufacturers as well with fixed margins where they can get their products adopted by orthopaedic surgeons based on pure merit and therapeutic benefits... (page 23)

At the same time, the Authority states its belief that the price control will force MNCs to localize, aiding the GOI's "Make in India" initiative.

> The new prices will encourage MNCs to make long term commitment in India which is going to be the future market for implants based on the huge numbers of unserved patients who could not afford high cost of arthroplasty. (pages 23-24)

And, the NPPA contradicts itself on product differentiation. That is, while compressing almost all knees into a common category for purposes of price cuts, NPPA acknowledges the superior quality of imported knee replacements. NPPA initially argues that the margins will allow Indian manufacturers to "get their products adopted by orthopedic surgeons based on pure merits." However, NPAA later agreed that there are problems with the quality of Indian companies' products.

> Issue of quality standards of the existing Indian companies in the sector was flagged by all the surgeons NPPA interacted with and NPPA did find substance in it.

AdvaMed is deeply concerned that this is just the beginning of a growing trend in India. AdvaMed recently learned that NPPA has already calculated ceiling prices for a number of other medical devices and is just waiting for the Prime Minister's order. If price controls extend to all US exports of medical devices, except capital equipment and in vitro diagnostics (because neither category has ever been mention as candidates for price controls), over $700 million of US exports could be adversely affected.

<u>Spreading of price controls to other countries</u>

Other countries are watching the India price control situation. Indonesia, Bangladesh and Pakistan are reportedly considering India-type price controls. Even more troubling, China recently published a national pricing policy, in which it explicitly required manufactures to report prices in India. And, India has proposed requiring manufacturers to print landed prices of medical devices on each product. India's unreasonable price control levels, combined with this printing requirement, would represent an existential threat to the US medical device industry if other countries depressed prices to India's levels.

<u>Denial of Equitable and Reasonable Market Access:</u>

According to section 502(c)(4) of the Trade Act of 1974, codified at 19 U.S.C. § 2462(c)(4), in determining whether to designate any country as a beneficiary developing country for GSP, the President shall take into account "the extent to which such country . . . will provide equitable and reasonable access to the markets . . . of such country."

Indian price controls deny effective equality of opportunities for imported products, because they deny (for example) high-end medical devices (e.g., stents and knee implants) the opportunity to compete, to the extent that they limit profit margins solely or primarily for imported medical devices. These price controls have a detrimental impact on the conditions of competition for imported products, but not (or primarily not) for like domestic products. It is only exporters, not domestic producers, who are losing so much money that they desire to withdraw popular products from the Indian market, or are unable to introduce new products into the Indian market. Moreover, the burden of enforced below-cost sales, resulting in a steady loss of revenue, is only affecting sellers of imported products, not sellers of domestic products. It is telling that, according to publicly available information, no Indian producer of stents has asked for a price increase or for withdrawal from the market.

Moreover, as explained above, this discrimination against imports is evident not just from the facts of the Indian marketplace, but also pursuant to the terms of India's law, itself. The DPCO provides an exemption (for five years) from price controls with respect to new medical devices if they are produced in and/or developed in India.

Finally, for those medical devices that are protected by Indian patents, the effect of these price controls is to greatly diminish the value of those intellectual property rights. As explained above, however, this is subject to an important, discriminatory exception. In the case where the innovations took place in India, any diminishment in patent value is minimized by a five-year exemption from price controls.

Conclusion:

Accordingly, AdvaMed urges USTR to suspend or withdraw GSP benefits, in whole or in part, in light of India's failure to provide equitable and reasonable access to its market for medical devices.

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