12 July 2018

Shri Amitabh Kant
Chief Executive Officer
NITI Aayog (National Institution for Transforming India)
New Delhi
Government of India

Subject: Asia Pacific Medical Technology Association (APACMed) Comments on "Rationalization of Trade Margins in Medical Devices – A Consultation Paper" dated 8 June 2018

Dear Shri Amitabh Kant,

We are writing on the above matter and express our appreciation for the opportunity to provide views on the same. The Asia Pacific Medical Technology Association (APACMed) represents medical device manufacturers (multinational corporations as well as small and medium enterprises) across the region, together with several national industry associations. We are committed to ensuring patient access to safe, innovative and high-quality medical devices.

Medical devices, whether notified or not under the Medical Device Rules, 2017 ("MDR") issued under the Drugs and Cosmetics Act, 1940 (D & C Act), include a vast range of products, from simple high-volume consumables such as tongue depressors or syringes; to life saving implantable devices such as pacemakers, to capital equipment such as CT and MRI imaging systems. There are more than 500,000 medical technologies that, unlike most pharmaceuticals, rely on complex global manufacturing and distribution supply chains.

We commend the Indian Government's efforts "to encourage the medical devices industry and keep it by and large a free and unregulated industry" and agree that "it is a highly capital-intensive industry with long gestation period of development and requires development/induction of new technologies." We have reviewed your consultation paper on the "Rationalization of Trade Margins in Medical Devices" and provide our views as follows:

- We support Government's plan to rationalize trade margins to "ensure reasonable prices to consumers and at the same time allow reasonable profits to all stakeholders in the medical device industry, including those involved in the supply-chain." However, such a plan must not disrupt the availability and supply of innovative, high quality medical devices, 80% of which are imported and 70% of which represent imported, critical care medical devices. The success of healthcare programs like Ayushman Bharat depend on continuous access to such technology.

- We support the second option mentioned in the concept paper providing for a maximum retail price (MRP) equivalent to Price at the First Point of Sale (Distributor/Stockist) + %age of Trade Margins (as decided by the government). We also endorse and strongly submit that trade margins should "start from the First Point of Sale, that is, the Stockist." For imported products, the First Point of Sale is and should be the Price to Trade. Your paper correctly points out that "after importing, many expenditures are incurred by the importing companies in clinical education on deployment and use of such devices." A maximum retail price (MRP) based on landed costs do not and will not be able to cover a company's substantial operational expenses in India – such as the training of health care professionals, product liability, technical product

support, instrumentation handling and servicing, financing sales and collection costs, salaries and wages, advertisement and promotional expenses, corporate taxes, and other expenses for developing and serving the market in India.

- You will recall that the National Pharmaceutical Pricing Policy (NPPP) 2012 has discarded the cost-based approach to regulation and moved to market-based approach. The reasons for discarding the same, as stated in NPPP 2012, include: “possible manipulation,” “virtually no space for new entrants to come in,” “production activity and competition in the product segment tend to stagnate,” “serious implication for the availability of NLEM medicines in the future,” and its “impact on industry’s investment ability in enhancing capabilities.”

- Note that the Drugs (Prices Control) Order, 2013 issued on 15 May 2013 by the Department of Pharmaceuticals does not differentiate between indigenous manufacturers and importers for purposes of price control. Section 2 (1) (n) of the Order defines a "manufacturer" as “any person who manufactures, imports and markets drugs for distribution or sale in the country. To ensure policy consistency, we respectfully recommend that the same definition be adopted.

We remain fully committed to collaborating with the people and government of India to advance our common objectives of increasing patient access to quality, affordable medical technology, while ensuring a robust and sustainable ecosystem that encourages investment and innovation.

Sincerely,

Fredrik Nyberg
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

About APACMed -

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed, 亚太医疗技术协会) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonisation. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, code of ethics and share best practices.

APACMed Corporate Members