**8th June 2018**

# Rationalization of Trade Margins in Medical Devices – A Consultation Paper

Medical devices industry has been growing at a rapid pace and is currently estimated to have a market size of $ 10 billion. It is likely to reach a size of $ 20 billion in next couple of years. It has been the effort of the Government to encourage the medical devices industry and keep it by and large a free and unregulated industry. It is a highly capital intensive industry with long gestation period of development and requires development/induction of new technologies. The medical devices industry can be broadly classified as consisting of (a) medical disposables and consumables; (b) medical electronics, hospital equipment, surgical instruments; (c) Implants; and (d) Diagnostic Reagents. India imports more than 75% of all its medical device needs and approximately 80% of the imports are in categories (b), (c) and (d).

2. As on date, 23 medical devices have been notified as drugs and are regulated under Drugs and Cosmetics Act. Of these, only 4 devices viz. Cardiac Stents, Drug Eluting Stents, Condoms and Intra Uterine Devices have been included in the National List of Essential Medicines (NLEM) and by virtue thereof are subject to notified price ceilings. Besides, Knee implants have been brought under price control under Para 19 of the Drugs (Prices Control) Order 2013. The remaining Medical Devices are not covered under any form of price regulation.

3. With a view to achieve the overall goal of affordable Healthcare for All, the Government intends to make available critical and lifesaving medical devices to the needy masses at affordable prices. The aim is 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 by rationalizing trade margins and thereby passing the benefits of the reduced cost to the final consumer.

4. The trade margin is the difference between the price at which the manufacturers/importers sell to trade (price to trade) and the price to patients (maximum retail price). The issue of unreasonably high trade margins in medical devices has been adversely affecting both the industry as well as consumer interest. Various representations regarding rationalization of trade margins on medical devices from industry/trade associations/indigenous manufacturers/ importers have also been

received. The Government has had stake-holders consultations on this subject beginning from October 2017 to ascertain their view points.

5. While there has been more or less a consensus on the concept of regulation of Trade margin on medical devices as also on the quantum of the margins; there is a debate on the location of the "First Point of Sale" (from where to calculate the Trade Margins?) in case of imported medical devices.

One view is that importers are also traders and the journey of trade margins should start from the import price itself. It means, the MRP will be decided as follows:

> MRP = Landed Cost + %age of Trade Margins (as decided by the Government)

There is, however, another view that after importing, many expenditures are incurred by the importing companies in clinical education on deployment and use of such devices therefore it not the starting point of trade and therefore, rightfully the trade margins should start, as in other cases, from the First Point of Sale, that is, the Stockist. In this case the MRP will be decided as follows:

> MRP = Price at the First Point of Sale (Stockist) + %age of Trade Margins (as decided by the Government)

A third view is that the companies may be allowed to separately show the mark-up due to services rendered viz. clinical education etc. over and above the landed cost. In other words, the companies will arrive at the MRP as follows:

MRP = Landed cost + mark-up due to services rendered(as declared by the manufacturer) + %age of Trade Margins (as decided by the Government)

6. There is a growing perception that medical devices that have till now been treated as 'drugs' should be given an independent identity and the calculation of trade margins in pharmaceutical products should not be directly applied to medical devices as it may not be suitable in the face of technical diversities in terms of material used, longevity, precision, efficacy etc.

7. In order to arrive at a well-informed conclusion it may be necessary to look into the landed cost of high value imported medical devices, their subsequent cost at the First Point of Sale, i.e. Stockist and finally their MRP. While the National Pharmaceutical Pricing Authority has already called for such data from importers companies, the government would like to elicit the formal responses from all stakeholders wishing to contribute, on:

(i) the concept of trade margin regulation as such;

(ii) the margin caps i.e., the maximum margin to be allowed;

(iii) clarity on First Point of Sale in case of imported products;

(iv) classification of Medical Devices for application of trade margin caps

(v) any other issues pertaining to the present concept paper.

8. It is expected that the approach to trade margin rationalization on medical devices, by encouraging market development, manufacturing and ease of doing business in India, would provide the right environment for ensuring quality and affordable access to medical technologies in the country.

9. Any response to the issues raised in the consultation paper may be kindly e-mailed to medical.devices.consultation@gmail.com by 15th June 2018.

UPDATE: Last date for submission extended to 15th July 2018.