

No.31A(1)/2017/Div.III/NPPA
Government of India
Ministry of Chemical and Fertilizers
National Pharmaceutical Pricing Authority

3rd & 5th Floor
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001.

Dated: 26th April, 2017

OFFICE MEMORANDUM

Sub: Discontinuation request of Resolute Onyx Zotarolimus Eluting Coronary Stent System notified under Schedule-I of DPCO, 2013 by India Medtronic Pvt. Ltd.

A letter of withdrawal of 'Resolute Onyx Zotarolimus Eluting Coronary Stent System' was submitted by M/s. India Medtronic Pvt. Ltd. on 03.04.2017 to NPPA on the ground of "commercial unviability post fixation of ceiling price". The matter was discussed in the Authority meeting No.176 dated 26.04.2017.

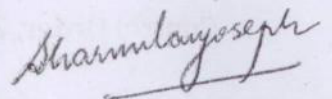
2. The Authority examined the request letter and found that the statutory Form IV attached with the request letter is not duly signed by the company which makes the application null and void. Covering letter cannot replace the mandatory Form IV. Consequently, the request as such cannot be considered as an application under Para 21(2) of the Drug Prices Control Order, 2013.
3. The Authority also took note of the Government Order No.31026/05/2017-Pricing dated 21.02.2017 addressed to M/s. India Medtronic Pvt. Ltd., where the Government has invoked its power under Para 3 of the Drugs Prices Control Order, 2013 and directed the company to maintain the uninterrupted supplies of all its coronary stents for six months from the date of the orders. The company was also under obligation to provide weekly report of coronary stents produced and distributed in the country along with weekly production plan for the next week to NPPA. Status check taken from the Monitoring and Enforcement Division reveals that company had neither complied with the directions of the Government nor submitted the weekly reports.

The Authority after examining the legal status of the application was of the view that once the Government has invoked Para 3 of the DPCO, 2013, no request under Para 21(2) can be considered during the period of restriction.

4. The Authority also observed that the company has sought the withdrawal of 'Resolute Onyx Zotarolimus Eluting Coronary Stent System' with "immediate effect". There is no provision under DPCO, 2013 under which such request is permissible.

5. Accordingly, the Authority, for reasons mentioned in para 2, 3 and 4, rejected the request of the Company with following observations: -

- a) M/s. India Medtronic Pvt. Ltd. shall be free to resubmit its request two weeks before the expiry of the Para 3 restrictions, which are currently in operation.
- b) The Company is advised to explore the options of price revision provided under Para 11(3), 11(4) and Para 19 of the DPCO, 2013 before exercising an exit route under Para 21(2).
- c) The Authority also decided to advise M/s. India Medtronic Pvt. Ltd. to be more cautious and responsible in taking such business decisions in the light of Government's commitment to ensure affordability and availability of all essential drugs to the people.



(Dr. Sharmila Mary Joseph K.)
Member Secretary, NPPA