

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

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

Dated: 26th April, 2017

OFFICE MEMORANDUM

Sub: Discontinuation request of Absorb BVS Medical Device (cardiac stent) notified under Para 21(2) of the DPCO, 2013 by Abbott Healthcare Pvt. Ltd.

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A letter of withdrawal of 'Absorb GT1-Bioresorbable Vascular Scaffold (BVS)' was submitted by M/s. Abbott Healthcare Pvt. Ltd. to NPPA on 21.04.2017 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.

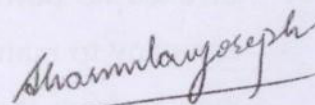
2. The Authority examined the request letter and found that the statutory Form IV attached with the request letter has not been duly signed by the company which makes the application technically and legally null and void. Covering letter cannot replace the mandatory Form IV. Consequently, the request as such cannot be considered as a withdrawal request under Para 21(2) of DPCO, 2013.
3. The Authority also took note of the Government Order No.31026/05/2017-Pricing dated 21.02.2017 addressed to M/s. Abbott Healthcare Pvt. Ltd., where the Government has invoked its powers under Para 3 of the Drugs Prices Control Order, 2013 and directed the company to maintain uninterrupted supplies of all its coronary stents (including BVS) for six months from the date of the order. The company has also been placed under obligation to provide weekly report on coronary stents produced and distributed in the country alongwith weekly production plan to NPPA. Status check from the Monitoring and Enforcement Division reveals that Abbott Healthcare Pvt. Ltd. has not been complying with the directions of the Government.

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 the 'Absorb BVS' with "immediate" effect. There is no provision under DPCO, 2013 under which such withdrawal is permissible.

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

- a) M/s. Abbott Healthcare Pvt. Ltd. shall be free to resubmit its request two weeks before the expiry of the orders of the Government under Para 3 of DPCO, 2013.
- b) However, if M/s. Abbott Healthcare India Ltd. finds that 'Absorb BVS' cannot address the 'safety concerns' already raised by USFDA, EU, TGA-Government of Australia, CDSCO and others, the company can approach NPPA any time before the period mentioned in 5(a) above, clearly stating the reasons for withdrawal to be 'safety concerns'.
- c) 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).
- d) The Authority also decided to advise M/s. Abbott Healthcare Pvt. Ltd. to be more cautious and responsible in 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