No. 31A(1)/Stent/2017/Div.III/NPPA
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceuticals Pricing Authority

3rd & 5th Floor,
YMCA Cultural Centre Building,
No.1, Jain Singh Road, New Delhi – 110 001
21st September, 2017

Office Memorandum

Subject: Consideration of request for discontinuation of Absorb and Absorb GT1 brands of Bioresorbable Vascular Scaffold under para 21(2) of DPCO, 2013 due to stoppage of manufacturing of this product globally - regarding.

A letter dated 8th September, 2017 along with Form IV had been received by the Authority from M/s Abbott Healthcare Pvt. Ltd, requesting to consider their request for discontinuation of Absorb and Absorb GT1 brands of Bioresorbable Vascular Scaffold (coronary stents) under para 21(2) of Drugs Prices Control Order (DPCO), 2013 on the ground of stoppage of manufacturing of these stent brands globally.

2. Para 21(2) of the DPCO, 2013 reads as follows :-

21. Monitoring the availability of scheduled formulations.–

(1) .....

(2) Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of schedule-II of this order in this regard at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation.

3. The request of M/s Abbott Healthcare Pvt. Ltd for discontinuation of Absorb and Absorb GT1 brands of Bioresorbable Vascular Scaffold was considered in the Authority Meeting No.49 held on 19/09/2017. The Authority took note of the company's assertion that it is stopping the manufacturing and doing global withdrawal of these brands based on "low commercial uptake". This was being reflected in the sale figures of these brands in India.

The Authority, however, taking more specific note of the issue of global safety concerns of 'enhanced adverse cardiac activity including increased level of thrombosis'already raised by USFDA, EU, TGA-Government of Australia and also in India in this regard decided to approve and allowimmediate withdrawal of Absorb and Absorb GT1 brands of coronary stents of the companyunder exceptional circumstances and by relaxing the mandatory period of six months prior intimation under Para 21(2) of DPCO, 2013 in public interest. The Authority took note of the fact that the safety 'concerns' is the prime reason behind low commercial global sales of these brands.

4. The Authority also directs Abbott to continue to follow up implanted patients in existing Absorb clinical trials and attend to all follow up issues arising in the cases under trial and others who have got the device implanted in India in the same manner it has been asked to do by US and European Federal Drug Regulators apart from instructions by DCGI.

5. In order to formally 'complete' the process of 'withdrawal' the company will issue a public notice in the prescribed format (copy enclosed) in at least two national newspapers (one English and one in Hindi) and also publish the same on their website and send a copy of the same to NPPA.

(R. Nihal Pedric)
Deputy Director

Managing Director/CEO,
M/s Abbott Healthcare Pvt. Ltd.,
Floor 18, Godrej BKC,
Near MCA Club, Bandra East,
Mumbai – 400 051

Copy to : -

1. Secretary, Department of Pharmaceuticals.
2. Secretary, Ministry of Health & Family Welfare.
3. Drug Controller General of India.
4. All State Drugs Controllers

Public Notice

(Under paragraph 21(2) of the Drugs Price Control Order, 2013)

Name of the company
Registered office Address of the company
with their contact details

CIN no.
Website:
E-mail:
Phone no:

Attention of general public is drawn to the fact that (name of company) having registered office at aforesaid address is manufacturing / marketing scheduled formulations namely (brand name) with (composition and strength / dosage) (hereinafter referred to as medicine).(Name of company wants to discontinue and stop the manufacture / marketing of the above said product after a period of six / twelve months from the date of this notice.

After discontinuation of the above medicine, the same may not be available in the market. Therefore, patients using such medicine may consult their doctor for prescribing alternate medicine. All the doctors / Medical Personals may also make note of this.

<Name of the company Secretary/Authorised person>
Designation
Name of the company

Date:
Place: