

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,
I, Jai Singh Road, New Delhi – 110 001
Dated: 27th December, 2017

Office memorandum

Subject: Consideration of request for discontinuation of Endeavour Sprint RX Zotarolimus Eluting Coronary Stent System(Coronary Stent) under Para 21(2) of DPCO, 2013 due to stoppage of manufacturing of the product globally – regarding.

A letter dated 10th October, 2017 with Form- IV and further letter dated 1st December, 2017 submitting required documents had been received from M/s India Medtronic Pvt. Ltd. requesting to consider their request for discontinuation of Endeavor Sprint RX Zotarolimus Eluting Coronary Stent 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 read 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 indented 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 the 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 India Medtronic Pvt. Ltd for discontinuation of Endeavor Sprint RX Zotarolimus Eluting Coronary Stent has been considered by NPPA based on unavailability because of stoppage of its production globally and noted in the Authority meeting No 51 held on 15/12/2017.

4. 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.

Ray

(Jay Prakash Ray)
Assistant Director (M)

✓ The Managing Director/CEO,
M/s India Medtronic Pvt Ltd.,
201-202, IInd Floor, Plot No-14,
Local Shopping Complex,
Kalkaji, New Delhi-110 019
Email: sanjeev.minhas@medtronic.com

Copt to-

1. Secretary, department of pharmaceuticals
2. Secretary, Ministry of health & Family Welfare.
3. Drug Controller General of India

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: