

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

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3<sup>rd</sup>& 5<sup>th</sup> Floor,  
YMCA Cultural Centre Building,  
1, Jai Singh Road, New Delhi - 110 001

Dated, the 25<sup>th</sup> September, 2017

**Office Memorandum**

**Subject: Consideration of request for discontinuation of Xience Alpine brand of coronary stent under Para 21(2) of DPCO, 2013 - regarding.**

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A letter dated 8<sup>th</sup> September, 2017 along with Form IV had been received from M/s. Abbott Healthcare Pvt. Ltd, requesting to consider their request for discontinuation of Xience Alpine stent under para 21(2) of Drugs Prices Control Order (DPCO), 2013 on the ground of 'commercial unviability' post fixation of ceiling price.

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. As per the above provision, the process of withdrawal formally starts with the issue of 'public notice' by the manufacturers. In the present case same has not yet been done by M/s. Abbott Healthcare Pvt. Ltd.


4. The request of M/s. Abbott Healthcare Pvt. Ltd. for discontinuation of Xience Alpine stent was considered in the 49th Authority Meeting held on 19/09/2017. The Authority, after examining the legal status of the application and taking into account the fact that Department of Pharmaceuticals has not accepted the request of NPPA to exercise Government powers under Para (3) of the DPCO, 2013 and extend the restriction on the stent manufacturers from withdrawing, NPPA is left with no option but to allow formal withdrawal as per the provisions of Para 21(2) of DPCO, 2013.

The Authority, accordingly, examined the whole issue and found that the import cost of Alpine brand is less than the ceiling price and adequate margins are there, so the reason of unviability of sales in India is not understandable. It was also found that these brands have a sizable market share and its withdrawal will create sudden shortage of stents which will not be in the interest of public health safety. Considering all the issues and availability of other brands in the country and in order to ensure adequate supplies of life saving medical device like stent, Authority decided to invoke the public interest clause under Para 21(2) to allow the complete withdrawal of Xience Alpine brand by the applicant company in a period of one year from the date of issue of public notice. Accordingly, the Authority issued following directions:

- (i) As per Para 21(2) of DPCO, 2013, M/s. Abbott Healthcare Pvt. Ltd. is directed to issue a public notice intimating about the discontinuation of Xience Alpine stent. The public notice (sample enclosed) to be issued and published in at least two national newspapers (one English and one Hindi) along with its publication on manufacturer's website (for at least six months). The counting of first six months period shall start from the date of publication and submission of copy of the same to NPPA.
- (ii) The company is also directed to continue to maintain uninterrupted supply of Xience Alpine stent for a period of first six months at the level of average of total imports in the last three months (June to August, 2017) from the date of issue of the public notice. From the seventh month, however, the manufacturer may start reducing supplies of stents of this brand @ 15% every month for another five months and at the end of twelfth month, it can withdraw the same by hundred per cent.
- (iii) M/s Abbott Healthcare Pvt Ltd. if want to reconsider their decision of withdrawal, the company shall be required to submit a written request to NPPA within 60 days from the date of issue of this order failing which withdrawal shall be treated as irrevocable and the company shall be required to surrender its licence for export and marketing of the brand with the licencing authority.

- (iv) During the period of this one year as per (ii), the manufacturers will ensure that uninterrupted supplies are made available on demand by the patients/hospitals/ distributors and no artificial barriers are created to hinder availability, supplies and sales in any manner which shall be taken as a very serious violation of law liable to legal action not ruling out even prosecution under Essential Commodities Act.
- (v) The Abbott Healthcare Pvt. Ltd. is also required to submit monthly import, inventory and sales details, by 5<sup>th</sup> date of every month starting from October, 2017.

Encl.: As above

  
(R. Nihal Pedric)  
Deputy Director

The 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 Drug 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: