

## **NPPA Stent Notification**

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Government of India

Ministry of Chemicals and Fertilizers

Department of Pharmaceuticals

National Pharmaceuticals Pricing Authority

New Delhi. The 13. February 2017

S.O. 412(E) Whereas the Government of India in the Ministry of Health and Family Welfare included Coronary Stents in the National List of Essential Medicines. 2015 (NLEM, 2015) by notification No. X-11035/344/2015-DFQC dated 19th July 2016.

2. And whereas the Government of India in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, by notification No. S.O. 4100 (E) dated 21st December 2016 has incorporated Coronary Stents at serial no. 31 of Schedule I of the Drug Prices Control Order, 2013 (DPCO, 2013) and therefore, Coronary Stems are 'scheduled formulations under the provisions of the DPCO, 2013.

3. And whereas the National Pharmaceutical Pricing Authority (NPPA) was established by Resolution No. 33/7/97-PI.I dated 29. August 1997 of the Government of India in the Ministry of Chemicals and Fertilizers to fix/revise, monitor prices of drugs/formulations and oversee the implementation of the DPCO; and whereas the Government of India by S.O. 1349(E) dated 30th May 2013 in exercise of the powers conferred by Section 3 and 5 of the Essential Commodities Act, 1955 (10 of 1955) has delegated the powers in respect of paragraphs 4, 5, 6, 7, 8, 9,10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 29,30 and 32 of the DPCO, 2013 to the NPPA to exercise the functions of the Central Government.

4. And whereas the aim of the DPC. 2013 issued under section 3 of Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices. Whereas the Hon'ble Supreme Court of India by order dated 12th November 2002 in SLP no. 3668/2003 (Union of India vs. K.S. Gopinath & others) directed the Government to ensure that life saving drugs do not fall out of price control.

5. And whereas the Core Committee which examined the issues relating to the essentiality of Coronary Stents in its report to the Government in April 2016 observed that there is very high incidence of coronary artery disease (CAD) in India associated with high morbidity and mortality; and that CAD has become a major public health problem; and that Percutaneous Coronary Intervention (PCI) procedure requiring coronary stent implantation is an important treatment modality for the management of CAD, and hence coronary stents are 'essential' for public health.

6. And whereas NPPA carried out an exhaustive exercise of consultation with stakeholders for fixing the ceiling price of Coronary Stents on 4th January 2017, 5th January 2017 and 6th January 2017, as per office memorandum no. 19(837)/2016/Div.11/DP/NPPA dated 23<sup>rd</sup> December 2016; and whereas NPPA considered all available information and data on prices

of Coronary Stents in its 40<sup>th</sup> Authority Meeting held on 23rd January 2017. During deliberations, it was found that huge unethical markups are charged at each stage in the supply chain of Coronary Stents resulting in irrational, restrictive and exorbitant prices in a failed market system driven by information asymmetry between the patient and doctors pushing patients to financial misery; and whereas under such extraordinary circumstances, there is an urgent necessity, in public interest, to fix ceiling price of Coronary Stents to bring respite to patients.

7. And whereas the Hon'ble Supreme Court of India in its judgment in Glaxo India Limited vs UOI reported in (2014)2 SCC 753, while dealing with the implementation of notified prices for the benefit of consumers, referred to the prefatory statement made by the Hon'ble Supreme Court in Cynamide India Limited (1987) 2 SCC 722 as worth noticing, wherein the Court observed:

*"2. Profiteering by itself. is evil Profiteering in the scares resources of the community, much needed life-sustaining foodstuffs and life-saving drugs is diabolic It is a menace which has to be fettered and curbed. One of the principal objectives of the Essential Commodities Act. 1955 is precisely that. It must be remembered that Article 39(b), enjoins a duty on the State towards securing 'that the ownership and control of the material resources of the community are so distributed as best to subserve the common good"*.

8. And whereas the Government is under constitutional obligation to provide fair, reasonable and affordable price for Coronary Stents and therefore its immediate intervention is imperative to check unethical profiteering and exploitive pricing; and whereas Paragraph 19 of the DPCO, 2013 inter- alia authorises the Government, extraordinary circumstances, if it considers necessary so to do in public interest, to fix the ceiling price or retail price of any drug for such period, as it deems fit.

9. And whereas price fixation notifications issued for certain formulations under paragraph 19 of the DPCO, 2013 by the NPPA on 10th July 2014 have been upheld by the Hon'ble High Court of Bombay in its judgment dated 26th September 2016 in W.P.(C) No. 2700 of 2014 (Indian Pharmaceutical Alliance vs. Union of India) wherein the Hon'ble High Court. inter-alia, observed:

*"20..... when such failure is considered in the context of role the pharmaceuticals play in the area of public health, which is a social right, the Government intervention becomes necessary especially when exploitive pricing makes medicines tin-affordable and beyond the reach of most and also puts huge financial burden in terms of out of pocket expenditure on healthcare...."* and whereas SLP (C) 30089/2016 filed by Indian Pharmaceutical Alliance has been dismissed on 24th October 2016 by the Hon'ble Supreme Court of India.

10. And whereas W.P.(C) 1772/2015 (PIL) and W.P. (C)11085/2016 have been filed in nature of Public Interest Litigation (PIL) including Cont. Case (C.) 815/2015 before the Hon'ble High Court of Delhi seeking directions to the Respondents (Union of India) to include Coronary Stents in the National List of Essential Medicines (NLEM) and thereby control the sale price of Coronary Stents.

11. And whereas, the NPPA in its Authority Meeting held on 13th February 2017, after duly examining in detail and considering all available information/data and all relevant options for price fixation of Coronary Stents, under present extraordinary circumstances of a failed and exploitative market system has decided that it is immediately necessary to fix ceiling prices of Coronary stents in order to protect public interest.

12. Now, therefore, in the exercise of the powers delegated by Government of India in the Ministry of Chemicals and Fertilizers under paragraph 19 of the Drugs (Prices Control) Order, 2013 by S.O. No. 1394(E) dated 30th May 2013, the Government having been satisfied in view of extraordinary circumstances as explained above, that it is necessary to do in public interest, hereby fixes and notifies the ceiling prices, exclusive of local tax applicable, if any, in respect of Coronary Stents, as specified below:

**TABLE**

<b>Sl. No.</b>	<b>Coronary Stents (Sl. 31 in Schedule I of DPCO, 2013)</b>	<b>Unit (In Number)</b>	<b>Ceiling Price (In Rs.)</b>
<b>(1)</b>	<b>(2)</b>	<b>(3)</b>	<b>(4)</b>
<b>1.</b>	<b>Bare Metal Stents</b>	<b>1</b>	<b>7260</b>
<b>2.</b>	Drug Eluting Dents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BSV), Biodegradable Stents	<b>1</b>	<b>29600</b>

Note:

(a) The ceiling prices specified in column (4) of the above table shall be applicable from the date of publication of notification in the Gazette of India Extraordinary and shall also be applicable to all the stocks of Coronary Stents available for sale in the trade channel.

(b) All manufacturers of Coronary stents, selling branded or non-branded or both versions of gents at prices higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the price of all such stems downward not exceeding the ceiling price specified in column (4) in the above table, plus local taxes as applicable and paid, if any

(c) All manufacturers/marketers of Coronary Stents having MRP lower than the ceiling price specified in column (4) in the above table plus local taxes as applicable and paid, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(d) The manufactures may add local taxes/VAT and no other charges in the calculation of MRP if they have actually paid such taxes or if it is payable to the Government on the ceiling price specified in column (4) of the above said table in paragraph (12) of this order.

(e) The ceiling price for a pack of coronary stent shall be arrived at by concerned manufacturer/importer in accordance with the ceiling price specified in column (4) of the above table as per the provisions under DPCO, 2013.

(f) The manufacturers under Paragraph 24 of DPCO, 2013 shall issue price list in Form—V as prescribed in Schedule II of the DPCO, 2013 to the NPPA online through Integrated Pharmaceutical Database Management System (IPDMS) and submit a copy to all State Drug Controllers and all distributors/dealers/ retailers. They shall also furnish quarterly return to the NPPA, in respect of production / import and sale of Coronary Stents in Form - III as prescribed in Schedule-II of the DPCO, 2013 through IPDMS.

(g) As per paragraph 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplement, price list, if any, as furnished by the manufacturer/importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(h) Wherever institutions such as hospitals/nursing homes/clinics performing cardiac procedures using Coronary Stents are billing directly to the patients, they shall be required to comply with the ceiling prices notified hereinabove and follow the applicable provisions of the DPCO, 2013 including(g) above.

(i) Institutions such as hospitals/nursing homes/clinics utilizing Coronary Stents shall specifically and separately mention the cost of coronary gent along with its brand name, name of the manufacturer/importer/batch no. and other details, if any, in their billing to the patients or their representatives.

4) The ‘manufacturer’ for the purpose of this order means person who manufactures or imports or markets Coronary Stents for distribution or sale in the country.

(k) Any manufacturer or institution or person not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order. 2013 read with Essential Commodities Act, 1955.

13. The ceiling price fixed hereinabove shall be maintained for a period of one year from date of this notification, unless revised by another gazette notification.

14. Any manufacturer intending to discontinue production or import of Coronary Stents shall furnish information to the NPPA, in respect of discontinuation of production and /or import in Form-1V of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation as prescribed under paragraph 21(2) of the DPCO, 2013 and follow the ceiling price till clearance from the Government.

PN/I73/41/2017

F.No.8 (4I)/2017/DP/NPPA/Div II  
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