

(To be Published in Gazette of India Extraordinary on February 12, 2018)

Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
National Pharmaceuticals Pricing Authority

New Delhi, the 12th February 2018

S.O. 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; 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 Stents are 'scheduled formulations' under the provisions of the DPCO, 2013.

2. 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.

3. And whereas the National Pharmaceutical Pricing Authority (NPPA) has been established by Resolution No. 33/7/97-PI.I dated 29th 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 to exercise the functions of the Central Government in terms of fixing ceiling prices of all essential drugs included in the Schedule I of DPCO, 2013.

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

5. 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 case reported in (1987) 2 SCC 722 as worth noticing, wherein the Court observed:

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"2. Profiteering, by itself, is evil. Profiteering in the scarce 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".

6. And whereas the Government is under constitutional obligation to provide fair, reasonable and affordable price for Coronary Stents and therefore its continued intervention is imperative to check unethical profiteering and exploitive pricing; and whereas Paragraph 19 of the DPCO, 2013 inter- alia authorises the Government, in 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.

7. 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 un-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.

8. And whereas, the NPPA in its Authority Meeting held on 13th February 2017, after duly examining in detail and considering all available information/data of coronary stents supply chain and all relevant options for price fixation of Coronary Stents, under the prevailing extraordinary circumstances of a failed and exploitive market system characterized by exorbitant, irrational and restrictive trade margins had decided that it was immediately necessary to fix ceiling prices of Coronary Stents, in order to protect public interest;

9. And whereas the National Pharmaceuticals Pricing Authority fixed the ceiling prices of coronary stents and notified the same through publication in Gazette of India Extraordinary Part II, Section 3, Sub Section(ii) vide SO 412 (E) dated February 13, 2017 under paragraph 19 of the DPCO,2013 read with S.O. 1029(E) dated 31st March 2017, S.O. 1041(E) dated 1st April 2017, S.O. 2063(E) dated 30th June 2017 and S.O. 2466(E) dated 3rd August 2017 and whereas the validity of the said notification was till February 12, 2018 requiring a revalidation of the said order with or without modification;

10. And whereas NPPA had invited views and suggestions of all concerned and organised stakeholders' meet vide OM dated 9th November 2017 and OM 20(8)/2018/Div. III dated 29th January 2018 for identifying the issues raised by the stakeholders; and whereas several

representations and suggestions both for and against the issues of sub-classification of drug eluting stents (DES), rewarding incremental innovation, an upward revision or no change in the ceiling price in ceiling prices, increase in trade margins and freedom to withdraw unviable brands from Indian market were flagged and placed before the Authority during its meeting on dated 05th January 2018 and continued on 8th February 2018 and finally concluded on February 12, 2018;

11. Whereas the issue of further sub classification of drug eluting stents was referred to the Ministry of Health and Family Welfare for ascertaining the expert views of the NLEM core committee on cardiac stents and whereas the Ministry of Health and Family welfare vide its letter dated 31st Jan 2018 has communicated the findings of the expert committee which after giving opportunity of representation to concerned stakeholders with due consideration has decided that there is no case for sub classification of DES in the light of lack of enough clinical evidence to support superiority of one DES or other; and as a result there has been no change in classification of coronary stents in Schedule I of the DPCO, 2013;

12. And whereas Authority in its extended meeting held on February 12, 2018 after intensive deliberations on all the issues and available information/market statistics at its disposal, was of the unanimous view that cardiac stents being an essential drug under Schedule I of DPCO, 2013 and part of NLEM, 2015 having paramount importance on public health needs to continue to be kept under price regulation in larger public interest till the country is under acute and emergent threat of cardiovascular diseases requiring PTC interventions and to prevent the cardiac stents market falling back to its old archaic state characterized by exorbitant margins leading to exploitative pricing, unethical profiteering and an extraordinary failed market system causing unwarranted and unreasonable economic burden on out of pocket expenses of hapless patients and their families;

13. 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, NPPA having been satisfied in view of extraordinary circumstances and reasons as explained herein above, that it is necessary to do in public interest, hereby fixes and notifies the revised ceiling prices, exclusive of goods and services tax applicable, if any, in respect of Coronary Stents, as specified below:

TABLE

Sl No	Coronary Stents (Sl 31 in Schedule I of DPCO 2013)	Unit (in Number)	Ceiling Price (in Rs.)
(1)	(2)	(3)	(4)
1	Bare Metal Stents	1	7,660
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents	1	27,890

Notes:

- a) The ceiling prices specified in column (4) of the above table shall be applicable from February 13, 2018, the date of publication of this 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) The ceiling prices specified in Para 13 of this order shall also apply to 'Covered Coronary Stents'.
- c) All manufacturers of coronary stents, selling branded or non-branded of both BMS and DES versions at prices higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the price of all such stents downward not exceeding the ceiling price specified in column (4) in the above Table, plus goods and services tax as applicable and paid, if any.
- d) All manufacturers/marketers of above coronary stents having MRP lower than the ceiling price specified in column (4) in the above Table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.
- e) The manufacturers may add goods and services tax 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 (13) of this order.
- f) The ceiling price for a pack of coronary stent shall be arrived at by the concerned manufacturer/importer in accordance with the ceiling price specified in column (4) of the above Table as per the provisions under DPCO, 2013.
- g) 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 through online Integrated Pharmaceutical Database Management System (IPDMS) along with a certified hard copy and submit a copy of the same immediately to all the State Drug Controllers and all its distributors/dealers/cardiac healthcare institutions performing angioplasties.
- h) In accordance with paragraph 24(4) of DPCO 2013, every distributor, dealer and institution shall display price list and the supplementary price list, if any, as furnished by the manufacturer/importer, on a conspicuous part of the premises where he carries on business including its publication on its website in a manner so as to be easily accessible to any person wishing to consult the same.
- i) Wherever institutions such as hospitals/nursing homes/clinics performing angioplasty 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.
- j) No healthcare institutions such as hospitals/nursing-homes/clinics performing angioplasty procedures coronary stents shall solicit any patient to purchase coronary

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- stents from it, in case, the patient is interested in procuring such stents from any other third-party sources.
- k) All the manufacturers will continue to ensure the availability of all the brands of coronary stents and ensure that no disruption is caused in the supply chain because of printing new MRPs and compliance with para(f) above shall be taken as discharge of responsibility on the part of the manufacturers.
 - l) Institutions such as hospitals/nursing homes/clinics utilizing coronary stents shall specifically and separately mention the cost of the coronary stents, its category like BMS or DES, brand name, name of the manufacturer/importer/batch no./specifications and other details, if any, in their Estimate/Performa invoice/Final-billing, etc. to the patients or their representatives.
 - m) Since cardiac catheters are necessarily used during angioplasties and are integrated part of the angioplasty package by healthcare institutions which are performing angioplasty and billing the patients shall also mention cost of cardiac catheters, balloon catheter and guide wire separately along with their respective brand name, if any, name of the company, batch number and specifications in order to bring in greater transparency in the billing and monitoring of compliance with the MRPs by the NPPA under Para 20 of DPCO, 2013.
 - n) The 'manufacturer' for the purpose of this order means any person who manufactures or imports or markets coronary stents for distribution or sale in the country.
 - o) Any person who imports coronary stents directly without having registration certificate (RC) in Form 41 issued under Drugs and Cosmetics Act, 1945 and Rules, thereunder in its own name and does it under Form 10 license issued on the undertaking given in Form 9 by another person having RC in Form 41, issued under Drugs and Cosmetics Act, 1945 and Rules, thereunder, shall be construed as 'distributor' for the purpose of this order under the DPCO, 2013.
 - p) 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.
 - q) The ceiling prices as specified in para 13 of the order are inclusive of 8% maximum permissible trade margin which is sacrosanct and no additional charge, whatsoever, over and above the ceiling price specified hereinabove, in the price notification shall be charged from the consumer/patient except applicable goods and services tax, if any, paid or payable. The inter-se distribution of above-said 8% trade margin could be decided by the stent manufacturers/importers, as the case may be, depending upon their business model.
 - r) Trade margin in excess of 8% specified above, in whatsoever form, shall be construed as 'violation' by the 'person/ institutions/ manufacturers/ importers/ distributors/ hospitals' involved in the transactions, jointly and severally, and shall be liable to appropriate action including prosecution, for violation of the provisions of the DPCO, 2013 under the Essential Commodities Act, 1955.

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- s) Trade margin in excess of 8% specified hereinabove, in whatsoever form, if any involved in the transactions between such distributors, as stated in aforesaid para (q) of this order with any other 'person/institution/hospitals' up to consumer/patient, shall be liable to be deposited, jointly or severally, by the concerned along with interest payable from the date of transaction under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.
- t) Any manufacturer intending to discontinue production or import of any Coronary Stent shall furnish information to the NPPA, in respect of discontinuation of production and / or import in Form-IV 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 in such manner and till such a time prescribed by the Government.

14. The ceiling price fixed hereinabove under Para 13 shall be applicable till March, 31, 2019 unless revised by another notification.

PN/186/54/2018

F.No 8(54)/2018/DP/NPPA/DivdII

(Rakesh Ranjan)

Member Secretary

National Pharmaceutical Pricing Authority