

औषधि नियंत्रण संगठन स्वास्थ्य भवन, तिलक मार्ग, जयपुर राजस्थान

क्रमांक: डीसी/डी-२/२०१७/१६

दिनांक: १३/०२/२०१७

:--परिपत्र:--

"अति-आवश्यक"

भारत सरकार द्वारा कोरोनरी स्टेन्ट (Coronary Stent) को Notification No. X-11035/344/2015-DFQC दिनांक 19.07.2016 द्वारा National List of Essential Medicines 2015 (NLEM 2015) में सम्मिलित किया गया है। इसी क्रम में भारत सरकार के Notification No. S.O. 4100(E) दिनांक 21.12.2016 द्वारा Coronary Stent को Drug Price Control Order 2013 (DPCO 2013) की अनुसूची-1 में क. सं. 31 में सम्मिलित किया गया, इस कारण कोरोनरी स्टेन्ट DPCO 2013 के प्रावधानों के तहत "Scheduled Formulations" है।

वर्तमान में विभिन्न प्रकार के Coronary Stent के मूल्य को भारत सरकार (NPPA) के असाधारण राजपत्र के Notification S.O. 412(E) दिनांक 13.02.2017 के द्वारा निम्नानुसार अधिसूचित किया गया है:-

S. No.	Coronary Stent (Sl. 31 in Schedule I of DPCO 2013)	Unit (in Number)	Ceiling Price (in Rs.)
1	2	3	4
1	Bare Metal Stent	1	7260
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/Biodegradable Stents.	1	29600

Note:-

- The ceiling prices specified in column (4) of the above table shall be applicable from 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.
- All manufacturers of Coronary Stents, selling branded or non-branded or both versions of stents 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 stents downward not exceeding the ceiling price specified in column (4) in the above table, plus local taxes as applicable and paid, if any.
- 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.
- The manufacturers 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.
- 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.
- 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.
- As per paragraph 24(4) of DPCO 2013, every retailer and dealer 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 in a manner so as to be easily accessible to any person wishing to consult the same.
- 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.
- Institutions such as hospitals/nursing homes/clinics utilizing Coronary Stents shall specifically and separately mention the cost of the coronary stent 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.


P.T.O.


- (j) 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.
- (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.

- The ceiling price fixed hereinabove shall be maintained for a period of one year from the 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-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 till clearance from the Government.

अतः भारत सरकार द्वारा जारी अधिसूचना केन्द्र सरकार की वेब साईट (<http://www.nppaindia.nic.in/>) पर उपलब्ध है। अतः अधिसूचना की अक्षरशः पालना किया जाना सुनिश्चित किया जावे।

संलग्न:- Notification की प्रति (05 पृष्ठ)

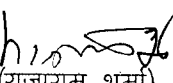

(राजाराम शर्मा)
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राज० जयपुर।

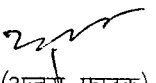

(अजय फाटक)
औषधि नियंत्रक-प्रथम
राज० जयपुर।

क्रमांक: डीसी/डी-२/2017/ 16

प्रतिलिपि:- निम्न को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित है:-

1. विशिष्ट सचिव, माननीय चिकित्सा स्वास्थ्य एवं परिवार कल्याण व आयुर्वेद मंत्री महोदय, राजस्थान सरकार, जयपुर।
2. निजि सचिव, प्रमुख शासन सचिव, चिकित्सा, स्वास्थ्य एवं परिवार कल्याण विभाग, शासन सचिवालय, जयपुर।
3. निजी सचिव, प्रमुख शासन सचिव, चिकित्सा शिक्षा विभाग, शासन सचिवालय, जयपुर।
4. निजी सचिव, मिशन निदेशक, एन एच एम, राजस्थान, जयपुर।
5. निजी सचिव, प्रबन्ध निदेशक, आर एम एस सी एल, जयपुर।
6. औषधि महानियंत्रक (भारत), सी एच ईबी कॉम्प्लेक्स, कोटला रोड, नई दिल्ली।
7. सदस्य सचिव, एन पी पी ए, भारत सरकार नई दिल्ली।
8. समस्त जिला कलेक्टर, राजस्थान।
9. उप औषधि नियंत्रक, सीडीएससीओ (नॉर्थ जोन), नेहरू कमला नगर, सी जी ओ कॉम्प्लेक्स, गाजियाबाद (यूपी)।
10. शासन उप सचिव, चिकित्सा एवं स्वास्थ्य (ग्रुप-1)/(ग्रुप-2) विभाग, शासन सचिवालय, जयपुर।
11. प्रधानाचार्य व नियंत्रक, मेडीकल कॉलेज (जयपुर/बीकानेर/जोधपुर/कोटा/अजमेर/उदयपुर), राजस्थान।
12. निदेशक (जन स्वा./पं.क/आई.ई.सी./ईएसआई/एमएसयू) चिकित्सा एवं स्वास्थ्य सेवार्य, राजस्थान जयपुर।
13. संयुक्त निदेशक, चिकित्सा एवं स्वास्थ्य सेवार्य, जोन-जयपुर/बीकानेर/कोटा/अजमेर/उदयपुर/जोधपुर/भरतपुर
14. अधीक्षक, सामूहिक चिकित्सालय संघ (जयपुर/बीकानेर/जोधपुर/कोटा/अजमेर/उदयपुर), मेडिकल कॉलेज सम्बद्ध अस्पताल।
15. समस्त सीएमएचओ/पीएमओ, राजस्थान।
16. राजस्थान मेडीकल कॉउन्सिल, पटेल मार्ग सी-स्कीम, जयपुर।
17. समस्त सहायक औषधि नियंत्रक/समस्त औषधि नियंत्रण अधिकारी को भेजकर निर्देशित किया जाता है कि अपने-अपने क्षेत्राधिकार में उपरोक्त के संबंध में DPCO 2013 के प्रावधानों की पालना सुनिश्चितता करावें।
18. अध्यक्ष, प्राईवेट अस्पताल संघ, राजस्थान जयपुर।
19. अध्यक्ष, प्राईवेट प्रेक्टीशनर चिकित्सक संघ, जयपुर।
20. अध्यक्ष, राजस्थान फार्मास्यूटिकल मैन्यूफेक्चरिंग एसोशिएशन, जयपुर।
21. अध्यक्ष, राजस्थान केमिस्ट एसोशिएशन, जयपुर।
22. समस्त अध्यक्ष जिला केमिस्ट संघ, राजस्थान।
23. ✓ प्रभारी सर्वर रूम, वि. एव स्वा. सेवार्य को प्रेषित कर लेख है कि कृपया परिपत्र को उक्त सभी को ईमेल एवं औषधि नियंत्रण संगठन के वेब पेज पर प्रदर्शित करावें।
24. रक्षित/कार्यालय प्रति।


(राजाराम शर्मा)
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राज० जयपुर।


(अजय फाटक)
औषधि नियंत्रक-प्रथम
राज० जयपुर।

दिनांक: 13/02/2017

(Published in Part II, Section 3, Sub Section (ii) of the
Gazette of India Extraordinary)

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

New Delhi, the 13th February 2017

ORDER

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 Stents 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 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 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 DPCO, 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.II/DP/NPPA dated 23rd December 2016; and whereas NPPA considered all available information and data on prices of Coronary Stents in its 40th 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 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. 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, 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.

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 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.

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

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	7260
2.	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents	1	29600

Note:

- (a) The ceiling prices specified in column (4) of the above table shall be applicable from 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) All manufacturers of Coronary Stents, selling branded or non-branded or both versions of stents 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 stents 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 manufacturers 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 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.
- (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 supplementary 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 the coronary stent 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.
- (j) 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.
- (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 the 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-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 till clearance from the Government.

PN/173/41/2017

F.No 8(41)/2017/DP/NPPA/Div II

(Dr. Sharmila Mary Joseph K)
Member Secretary
National Pharmaceutical Pricing Authority