

(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 16th, August 2017

ORDER

S.O..... 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 Drugs (Prices Control) Order (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;

02. 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 lifesaving drugs do not fall out of price control;

03. 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 of drugs 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’”

04. And whereas Ministry of Health and Family Welfare vide its S.O. 1468 dated 6th October 2005, has notified the orthopedic implants as ‘drugs’, the DPCO, 2013, is applicable to all notified drugs (including notified devices) and NPPA is mandated to monitor the prices of these drugs under paragraph 20, so as to ensure availability of such drugs (i.e. notified devices) and also ensure that no unethical profiteering is happening in case of any drugs (i.e. notified devices) at the cost of patients. It is noticed that orthopedic-knee implants are having unjustified, unreasonable and irrational high trade margins leading to their exorbitant prices which affects the out of pocket expenses of patients and lakhs of patients are not able to pay for arthroplasty procedures because of these exorbitant prices and suffering in pain; and whereas the estimates of such patients requiring arthroplasty intervention, both diagnosed and undiagnosed, is about 1.5 to 2 crores out of which only about 1 lakh plus well off patients are in a position to pay for it every year and whereas **‘osteoarthritis is likely to become fourth leading cause of disability by year 2020’** as per the *W.H.O Bulletin, 2003, 81, (9)* and India is likely to be one of the leading countries of such immobilized citizens in terms of numbers; and whereas preventing such a scenario is essential in individual as well as national interest;

05. And whereas the Government is under constitutional obligation to provide fair, reasonable and affordable price for orthopedic implants and therefore its immediate intervention is imperative to check unethical profiteering and exploitive pricing at the cost of the patients in an unregulated market; and whereas Paragraph 19 of the DPCO, 2013 inter-alia authorizes 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 (i.e. notified devices) for such period, as it deems fit; and whereas based on the above assessment the extraordinary situation in the case of knee implants does exist;

06. And whereas price fixation notifications issued for certain drugs 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 and order 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 challenging the aforesaid judgment and order has been dismissed on 24th October 2016 by the Hon’ble Supreme Court of India;

07. And whereas NPPA carried out an exhaustive stakeholder’s consultation on the issue of exorbitant cost of orthopedic knee implants and excessive trade margins and analysis of

‘trade margins’ in the market of knee implants was uploaded in public domain for the sake of transparency and in the spirit of people’s right to information.

08. Whereas, the NPPA in its Authority meeting held on August 10 2017 which continued on August 14, 2017 after duly examining in detail, deliberating and considering all available information/data/viewpoints and all relevant options for price fixation of orthopedic knee implants, under present extraordinary circumstances of a failed and exploitative market because of information asymmetry between the patient and healthcare delivery system has decided that it is necessary to control the excessive trade margins for fixing ceiling price of orthopedic knee implants which is fair and reasonable based on its intrinsic value of the implants with rational margins to protect public interest.

9. 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 DPCO, 2013 by S.O. No. 1394(E) dated 30th May 2013, the NPPA, having been satisfied that in view of extraordinary circumstances as explained above, finds that it is urgently necessary to do so in public interest, hereby fixes and notifies the ceiling prices of orthopedic knee implants for knee replacement system, along with the notes, as specified herein below to be effective from August 16, 2017, the date of its gazette notification:

TABLE

Sl. No.	Orthopedic knee Implant system	Component	Feature/Material of the knee implant	Units (In Number)	Ceiling Price (In Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	<u>PRIMARY</u>				
1.	Primary knee replacement system	Femoral component by whatsoever name/specification	Titanium alloy (all variants) coated	1	38,740
2.	Primary knee replacement system	Femoral component by whatsoever name/specification	Oxidized zirconium (OxZr) alloy (all variants)	1	38,740
3	Primary knee replacement system	Femoral component by whatsoever name/specification	Hi-flex	1	25,860
4	Primary Knee replacement system	Femoral component by whatsoever name/specification	Cobalt chromium (CoCr) alloy (all variants)& other than at serial no 1,2 and 3	1	24,090
5	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Titanium alloy (& it’s all variants) coated	1	24,280
6	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Oxidized zirconium (OxZr) alloy	1	24,280

7	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Cobalt chromium (CoCr) alloy & other than at Serial no 5 and 6	1	16,990
8	Primary knee replacement system	Articulating surface or Insert by whatsoever name/specification	Any Material	1	9,550
9	Primary knee replacement system	Patella by whatsoever name/specification	Any Material	1	4,090
10	Primary knee replacement system	Component having Tibial tray and Insert combined as single unit by whatsoever name/specification	Polyethylene or crosslinked polyethylene or highly crosslinked polyethylene or any other material	1	12,960
11	Primary knee replacement system	Components having Tibial Tray and Insert combined as single unit by whatsoever name called	Tibial: Metallic Insert: Polyethylene or Polyethylene or Cross-linked polyethylene or highly cross-linked Polyethylene or any other material	1	26,546
	<u>REVISION</u>				
12	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	62,770
13	Revision Knee Replacement system	Tibial component or Tibial Tray by whatsoever name/specification	Any material	1	31,220
14	Revision Knee Replacement system	Articulating surface or Insert by whatsoever name/specification	Any material	1	15,870
15	Revision Knee Replacement system	Patella by whatsoever name/specification	Any material	1	4,090

Note:

- a) The ceiling prices specified in column (6) 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 knee implants available for sale in the trade channel.
- b) All manufacturers shall comply and implement the ceiling prices mentioned hereinabove under the applicable category and serial number irrespective of being cementable, uncementable, gender specific or unisex. The manufacturer of uncemented implants, however, may approach NPPA with supporting documents, for fixation of separate ceiling price or retail price.

- c) Special orthopedic knee implants for cancer/tumor etc will follow the prices of revision surgery. However, if the import prices are higher than the ceiling price of such implants, manufacturers may add a total margin of maximum 30 percent over the import price of the first batch of such implant launched in India as the ceiling price for 45 days from the issue of this notification and apply to NPPA for a retail price notification at the earliest.
- d) All manufacturers of knee Implants, selling branded or non-branded or both versions of implants 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 implants downward not exceeding the ceiling price specified in column (6) in the above Table, plus goods and services tax as applicable and paid, if any.
- e) All manufacturers/marketers of knee implants having MRP lower than the ceiling price specified in column (6) 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.
- f) 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 (6) of the above said Table in paragraph (9) of this order.
- g) The ceiling price for a pack of implant shall be arrived at by the concerned manufacturer/importer in accordance with the ceiling price specified in column (6) of the above Table as per the provisions under DPCO, 2013.
- h) The Ceiling prices mentioned in Table hereinabove are all components and consumables, which are used in the knee implant procedure and remain in the body of the patient
- i) 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) along with a hard copy and submit a copy immediately to all State Drug Controllers and all its distributors/dealers/orthopedic healthcare institutions.
- j) 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 in a manner so as to be easily accessible to any person wishing to consult the same.
- k) Wherever institutions such as hospitals/nursing homes/clinics performing orthopedic surgical procedures using knee implants 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 (j) herein above.
- l) No healthcare institutions such as hospitals/nursing-homes/clinics performing orthopedic surgical procedures using knee implants shall solicit any patient to

purchase knee implants from it, in case, the patient is interested in procuring such implant from any other third-party sources.

- m) All the manufacturers will continue to ensure the availability of all the brands of implants and ensure that no disruption is caused in the supply chain because of printing new MRPs
- n) Institutions such as hospitals/nursing homes/clinics utilizing knee implants shall specifically and separately mention the cost of the knee implant component-wise along with its 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.
- o) The 'manufacturer' for the purpose of this order means any person who manufactures or imports or market drugs i.e. notified devices such as knee implants for distribution or sale in the country.
- p) Any person who imports knee implants 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. Such distributors will need to approach NPPA to get special ceiling price before the product launch in India.
- q) 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.
- r) The ceiling prices as specified in para 9 of the order are inclusive of 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 maximum trade margin permissible for distributor/stockist and hospitals/nursing homes/clinics is 16 percent and 8 percent of ceiling price respectively for primary knee replacement system at serial no 4,7,8, 9, 10 and 11 of the Table. The maximum trade margin permissible for distributor/stockist and hospitals/nursing homes/clinics is 12 percent and 4 percent of ceiling price respectively for primary knee replacement system and revision knee replacement system at serial no 1,2,3,5,6,12,13,14 and 15 of Table. The maximum trade margin permissible for distributor/stockist and hospitals/nursing homes/clinics is 16 percent and 8 percent of computed ceiling price respectively for Special orthopedic knee implants for cancer/tumor whose ceiling price has been computed as per note (c) considering import price plus 30 percent.
- s) Where, the manufacturer supply/sell knee implant directly to the orthopedic healthcare institutions, without involvement of any distributor, then the maximum trade margin for hospitals/nursing homes/clinics shall be restricted at 16 percent.

t) Trade margin in excess of specified in note (r) and (s), 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.

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

PN/180/48/2017

F.No 8(48)/2017/DP/NPPA/Div II

(Bhupendra Singh)
Chairman
National Pharmaceutical Pricing Authority