


सत्यमेव जयते

भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 2674]

नई दिल्ली, मंगलवार, अगस्त 13, 2019/श्रावण 22, 1941

No. 2674]

NEW DELHI, TUESDAY, AUGUST 13, 2019/SHRAVANA 22, 1941

रसायन और उर्वरक मंत्रालय

(औषध विभाग)

(राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण)

आदेश

नई दिल्ली, 13 अगस्त, 2019

का.आ. 2934(अ).—डीपीसीओ, 2013 के पैरा 19 के अंतर्गत जारी ओर्थोपेडिक घुटना प्रत्यारोपण के अधिकतम मूल्य को नियत करने से संबंधित दिनांक 16 अगस्त, 2017 के का.आ. 2668 (अ) और दिनांक 13 अगस्त, 2018 के का.आ. 3987 (अ) के माध्यम से राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण, औषध विभाग, रसायन एवं उर्वरक मंत्रालय द्वारा जारी अधिसूचनाओं के अनुसरण में, इस बात का निर्णय लिया गया कि डीपीसीओ, 2013 के पैराग्राफ 20 (I) के प्रावधानों के अनुसार इनकी निगरानी की जाए। यह आदेश, जब तक कि अन्य अधिसूचना द्वारा संशोधित न हो, 16 अगस्त, 2019 से (अर्थात् 15 अगस्त, 2020 तक) एक वर्ष की अवधि के लिए लागू किया जाएगा।

2. ओर्थोपेडिक घुटना प्रत्यारोपण के अधिकतम मूल्य की एक वर्ष की अवधि के बाद समीक्षा की जाएगी।
3. दिनांक 16 अगस्त, 2017 के का.आ. 2668 (अ) की टिप्पणियां (ख) से (न) तक इस आदेश के जारी होने की अवधि के दौरान लागू की जाएंगी।

[पी.एन./201/69/2019/एफ/फा. सं० 8(69)/2019/डिपी/एनपीपीए/डिवी.11]

प्रकाश हेमानी, सहायक निदेशक

MINISTRY OF CHEMICALS AND FERTILIZERS

(Department of Pharmaceuticals)

(NATIONAL PHARMACEUTICAL PRICING AUTHORITY)

ORDER

New Delhi, the 13th August, 2019

S.O. 2934(E).— In continuation to the notifications issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical and Fertilizers vide S.O. 2668(E) dated 16th August, 2017 and

S.O. 3987(E) dated 13th August, 2018 regarding fixation of ceiling price of the orthopaedic Knee Implants issued under Para 19 of the DPCO, 2013, it has been decided that the same may be monitored as per the provisions of Paragraph 20(1) of the DPCO, 2013. This order shall be applicable for the period of one year from 16th August, 2019 (i.e. up to 15th August, 2020), unless revised by another notification.

2. The ceiling prices for orthopaedic Knee Implants will be reviewed after a period of one year.
3. The notes (b) to (t) of the Notification S.O. 2668(E) dated 16th August, 2017 shall remain in force during the currency of this order.

[PN/201/69/2019/F/F. No. 8(69)/2019/DP/NPPA/Div.II]

PRAKASH HEMANI, Asstt. Director

NPPA issues notification to extend ceiling price on knee implants by one year; puts cap of 10% annual increase in prices

Friday, August 16, 2019, 08:00 Hrs [IST]

The national drug pricing regulator, National Pharmaceutical Pricing Authority (NPPA) has notified that ceiling price of orthopaedic knee implants should not be increased beyond 10 per cent in a given year. Orthopaedic knee implants were brought under price control two years ago to make it affordable to the common man.

As per the data analysis of NPPA, price control was required as there was huge margin in trade of orthopaedic knee implants which led to unreasonable and unethical profiteering.

“This is in continuation to the notifications issued by NPPA dated August 16, 2017 and dated August 13, 2018 regarding fixation of ceiling price of orthopaedic knee implants issued under Para 19 of the Drug Price Control Order (DPCO-2013),” as per the NPPA notification issued recently.

NPPA in its recent meeting reviewed the matter of price monitoring of knee implants and found that knee implants have become affordable because of price capping exercise as per DPCO-2013. As per the data submitted by manufacturers and importers there has been an increase of 30 per cent in the sales of knee implants during July, 2018 to June, 2019 due to price control.

As per the notification, NPPA stated that ceiling price of orthopaedic knee implants will be monitored as per the provisions of Paragraph 20(1) of the DPCO- 2013. This will be applicable for a period of one year from August 16, 2019 till August 15, 2020 unless revised by another notification.

With this notification, NPPA also further extended the ceiling prices for orthopaedic knee implants for a period of another one year till August 15, 2020.

According to NPPA, with this exercise the cost of knee implants have been reduced upto 69 per cent resulting in a notional saving of Rs. 1,500 crore per annum to the consumers.

The knee implant is a non-scheduled medical device or drug for which DPCO, 2013 allows an annual increase upto 10 per cent of MRP. However, this was not permitted in 2018.

Though the industry has requested for a 20 per cent (10 per cent for the year 2018 and 10 per cent for the year 2019) increase in the price of knee implants, it was decided to further monitor the price increase of knee implants as per DPCO, 2013 that restricts price increase beyond 10 per cent in a given year. This shall be subject to a review after one year.

NPPA notification has categorized knee implants into two major categories - Primary Knee

Replacement Systems and Revision Knee Replacement Systems. In each category, there are four sub-categories - Femoral Component, Tibial Component or Tibial Tray, Articulating Surface or Insert and Patella.

Under four sub-categories, there are super-sub-categories distinguishable on the basis of feature or material such as titanium alloy, oxidized zirconium, Hi-flex, cobalt chromium, polyethene etc. The ceiling prices have been prescribed for the super-sub-categories.

NPPA, while fixing the ceiling prices, has kept all the new technology implants in mind and prices have been fixed accordingly.

New ceiling price and MRP of Cobalt Chromium, which is most widely used knee implant has seen a reduction of 65 per cent from Rs. 1,58,324 to Rs. 54,720. Special Metal like Titanium & Oxidized Zirconium has seen a reduction of 69 per cent from Rs. 2,49,251 to Rs. 76,600. High Flexibility Implant has seen a reduction of 69 per cent from Rs. 1,81,728 to Rs. 56,490 and Revision Implants has seen a reduction of 59% from Rs. 2,76,869 to Rs. 1,13,950. Companies will print the MRP by adding GST on these ceiling prices.

It is estimated by World Health Organization (WHO) that by 2020, osteoarthritis is going to be the fourth largest cause of immobility in the world. India has about 1.2 to 1.5 crore orthopaedic patients who require orthopaedic implant surgery.