

**Record of the discussions of the Authority on ceiling
price fixation of knee Implants**
(48th meeting of NPPA concluded on August 14, 2017)

Ministry of Health and Family Welfare (M/o H&FW) vide Notification S.O. 1468E dated 06.10.2005 notified “orthopaedic implants” as drugs. Drug Prices Control Order, 2013, is applicable to all notified drugs (including notified devices) and NPPA is supposed to monitor the prices of these non-scheduled drugs under Para 20 so as to ensure that the prices of these drugs/devices do not increase beyond 10 percent in a year. However, NPPA is also responsible to keep a watch on the market to ensure availability of these drugs and devices and also that no unethical profiteering at the cost of patients is happening in case of any drug/device. Such profiteering happens because of information asymmetry between patient and the doctor and the healthcare system as a whole. NPPA, working on behalf of the government, is also conscious of its obligation to ensure affordable health care to people as enshrined in the Constitution of India.

2. In the course of monitoring the prices of different medical devices, NPPA found that the expenditure on musculoskeletal conditions are a major burden on individuals, health systems and social care systems with significant cost factor. This burden had been recognised by the United Nations and the WHO by endorsing the ‘International Bone and Joint Decade 2000-2010’ in the past. It has also been found that Osteoarthritis which is characterised by loss of joint cartilage that leads to pain and loss of friction primarily in the knees and hips, globally affects 9.61% of men and 18% of women > 60 years. ***“Increase in life expectancy and expanding aging population is expected to make Osteoarthritis the fourth leading cause of disability by year 2020.”*** (Anthony D. Woolf & Bruce Pflieger- Bulletin of the WHO, 2003, 81(9).

As per a rough estimate about 1.00 lakh knee surgeries were performed in the year 2014 (Indian Orthopaedic Association) which has been corroborated by the industry sources and other research estimates. There is no universal and compulsory registry of orthopaedic surgeries in India, like

UK which could provide the details on actual number of arthroplasties. Going by the growing numbers of voluntary registries managed by the 'Indian Society of Hip and Knee Surgeons', India is witnessing a fast growth in this segment ranging from 20-25% per year. Based on that it can be estimated that in the year 2016, about 1.50 lakh total/partial/and revision knee replacements might have been performed. With increasing incidences of diabetes osteoporosis, osteoarthritis, obesity and increased awareness of benefits of arthroplasty, it is estimated that India is likely to witness an average 15-20% growth in this segment till 2030. Presently, it is estimated that there may be about 1.5 to 2 crore Indians who may require orthopaedic surgery interventions but remain largely either undiagnosed or are diagnosed but cannot afford the high cost of implants and the knee surgery and leading a life of low mobility and productivity. In comparison to India, USA with a much lesser population has well recorded about 600000 arthroplasties way back in the year 2010. In the 2016, the numbers are likely to be above 7 lakhs by very conservative estimates.

Based on the increasing significance of orthopaedic care in India, NPPA started studying the market of knee and hip implants and started collecting the requisite data from Central Drugs Standards Control Organisation (CDSCO), Central Board of Excise & Customs (CBEC), Director CGHS, and Amrit database so as to make a fair assessment of the market. On the analysis of the data it was found that there is disproportionately high trade margins in case of certain orthopaedic devices especially knee and hip replacement implants. It is estimated that in comparison to knee, hip replacement surgeries are relatively lesser in number, about 60-70 thousand per year. Accordingly NPPA focused on knee replacement implants to start with further trade analysis.

Since many companies did not submit price to retailer (PTR) data as per format based on the presumption that hospitals are not retailer in the supply chain, the margins of stockists and hospitals had to be clubbed and separate margins could not be ascertained. The matter was not pursued further since from consumer's point of view it did not matter much and the issue was found

to be extraordinarily urgent in public interest and collection of further data would have delayed the exercise.

3. In the light of this background and to make a fair assessment of the subject, stakeholders' consultations with orthopaedic devices manufacturers (both foreign and indigenous), medical devices and orthopaedic industry associations, orthopaedic surgeons and civil society groups, was done by the NPPA on 28, 29th June, 2017 and with industry associations again on 25th July, 2017 and on August 09, 2017. Separate consultation with the distributors was not done since it was realised that industry represents the interest of the distributors and as such there is no recognised association of distributors in case of orthopaedic devices. Consultation with few reputed and conscientious orthopaedic surgeons was particularly done which provided feedback on the operational procedure of the orthopaedic care system at hospital level and the real benefits of different types of implants, different technologies and its respective merits & demerits.

(a) The multinational orthopaedic device manufacturers (overseas) which control about 85%-90% of the orthopaedic devices market in the country held that the prices are not unreasonable in the light of the present 'market structure' in India and that the 'latest technology' comes at a cost. They also apprehended that if any price cap was imposed, foreign manufacturers will not import new generation implants and might withdraw their 'cutting edge' products from the Indian market and Indian patient's might be deprived of the 'latest generation' implants. The concerns of MNCs was also expressed through various representations given by different associations and industry bodies from time to time. The Indian orthopaedic device manufacturers also said that indigenous orthopaedic implants manufacturing units are nascent and if adequate incentives are not provided, the industry will die in the very beginning. Both the orthopaedic implant importers and Indian manufacturers emphasised the need for higher prices and mentioned that huge margins are to be paid to distributors and hospitals (including doctors) in the existing business model. Further, industry needed to work in symbiotic relationship with the doctors for training them into their equipments, taking product

feedback and for making necessary improvements. On being questioned why companies were offering huge margins in trade which could be passed on to consumers, all of them expressed that if they do not pay these margins, distributors and hospitals will not buy their product and rivals will benefit. When asked what stops them to act as a group since all MNCs put together have about monopoly market control and reduce MRPs and each industry plays fair, their response was that they have been trying it but not succeeding and that the hospitals are to be brought on the board which is difficult at their level.

(b) The industry associations like CII, ASSOCHAM, FICCI, AdvaMed, AiMED, MTAI, and others emphasised the need for letting the market go on with its own momentum and structures because it is a nascent industry which should not be put under any price cap in the interest of future investment, R&D and growth and also in the interest of patients who can afford higher priced latest generation implants. Further, this would also enable the Indian devices manufacturing industry to grow at par with foreign manufacturers, and price control will discourage this growth. Issue of adverse impact on medical tourism was also mentioned and flight of new technology were also underlined. Associations also raised the point that price capping of only the devices shall not make the orthopaedic procedure affordable since the hospitals will increase the cost of procedure and other overheads and make for the losses of any trade margin share. This argument was made by almost every industry.

(c) During discussions with few eminent and conscientious orthopaedic surgeons they did not rule out the existence of unscrupulous hospitals and surgeons especially in private sector who are unduly benefiting from the existing market system. They, however, also said that imported orthopaedic devices are as of now superior to Indian counterparts and highlighted that unfortunately in India, there is no reputed test lab to evaluate such devices at par with imported devices which are tested on stringent quality standards. These surgeons also explained the relative merit and demerits of different technologies and its respective usage in the market and expressed

reservations about the actual clinical benefits of the several so called 'new generation' technologies. NPPA also had discussions with these surgeons on various studies on the health technology assessment of orthopaedic devices done globally and consulted by it.

(d) Meeting with Indian Orthopaedic Association (IOA) along with Association of Healthcare Providers (India) followed a joint representation by both the organisations which summarised their views as follows 'trying to achieve the goal of affordability should not be counterproductive to the other equally important goals of availability, quality, production of R&D, efforts on Make in India, Start up India and *the physician and the patient's choice.*' They also suggested alternative measures like **“(i) transparency in manufacturers/distributors billing and (ii) making it mandatory for the hospitals to share with the patient, their procurement price from distributors or companies.”** IOA and AHPI further also suggested that hospitals should have some 'margins' since it provides sterilization facilities and does provide space for storage of disposable.

(e) The civil society representatives unanimously pointed out towards the fact that there is a huge gap between the cost of the devices and the MRPs. Some of them provided invoices of hospital procurements and other data procured from a private websites on international trade while others quoted the inspection reports of some State FDAs. The civil society groups thanked the Government for capping the prices of coronary stents and requested that same should be done in case of orthopaedic and other devices where exploitative prices are prevailing. Some of the civil society members themselves are professional doctors who want to clean the medical profession.

4. Discussion with the industry and orthopaedic surgeons and also based on NPPA's own literature based research, it was found that in case of orthopaedic implants, NPPA does need to examine various types of implants based on their construction material and applications and other technological aspects. Authority was aware that in case of fixing ceiling prices, industry,

hospitals and surgeons will raise the issue of new 'generation technology' hence Authority needed to be thorough with the technological status of the knee implants and take it into account.

(a) On this issue Authority, took note of the study on 'Health Technology Assessment on Orthopaedic Implants' by National Health Systems Resource Centre (NHSRC), Ministry of Health & Family Welfare, but more specifically the in depth study ***"Appraisal of Evidence base for Introduction of New Implants in Hip and Knee Replacement: a Systematic Review of Five Widely used Device Technologies"*** cited in *British Medical Journal (BMJ)*, 2014 which evaluated medical devices technologies, in total knee and hip replacement. Out of these, first two technologies are being used in case of knee implants.

- (i) High flexion knee replacement
- (ii) Gender specific knee replacement
- (iii) Ceramic-on-ceramic bearings (hip replacement)
- (iv) Modular Femoral necks (hip replacement)
- (v) Uncemented monobloc cups (hip replacement)

The data in this study was collected from pre-market application and mandated post market studies at USFDA. The study concluded that ***"none of the five devices innovations was found to improve functional or patient reported outcomes"***. It further noted ***"We did not find convincing high quality evidence supporting the use of five substantial well known and already implemented device innovations in orthopaedics. Moreover, existing devices may be safer to use in total hip or knee replacement. Improved regulation and professional society oversight are necessary to prevent patients from being further exposed to these and future innovations introduced without proper evidence of improved clinical efficacy and safety."*** Marc Nieuwenhuijse, Research Fellow ICOR & FDA, R.G.H.H Nelissen, Professor, JW Schoones, A Sedrakyan).

These inferences were further validated in several other independent studies referred by NPPA. The technology of high flexion implants was

invented in 1997 and since then several improvements have been done in USA and other developed countries and the same technology was introduced in India since last 2-3 years while gender specific implants has been introduced very recently. In order to make a fair assessment of these technologies NPPA did extensive examination of all possible relevant independent studies on net and consulted various reputed international journals. The findings of this material research are summarised as follows:

(a) The '**high flexion knee**' implants are now being used in the country with lots of 'hype' by companies and hospitals. These implants are being imported at much higher prices based on its publicised benefits without disclosing the limitations in the technology as proved in the above quoted and several other independent studies. Companies in India are promoting these products on the basis benefits of its claimed 'higher flexibility' in day to day active life along with added sitting postures required for performing several religious and cultural sitting practices.

*In this regard, NPPA referred the study published in Bone and Joint Journal "**Does the new generation of high-flex knee prostheses improve the post-operative range of movement?**" A meta-analysis by R. Mehin R. S. Burnett P. M. A. Brasher from Canada and published in 'The Journal of Bone & Joint Surgery'. The study noted "**Analysis of these trials suggested that no clinically relevant or statistically significant improvement was obtained in flexion with the "high flex prostheses."** In another study "Results of Prospective, Randomized Clinical Trials Comparing Standard and High Flexion Posterior-Stabilized TKA: A Focused Review" by William G. Hamilton, SupatraSritulanondha, MPH, C. Anderson Engh Jr, MD. The study summarised as "**Based on currently available literature, high flexion cruciate substituting TKAs do not appear to provide increased flexion in the short term. The downside of these designs such as increased cost, increased bone resection and early femoral loosening, need to be weighed against the potential long term improvement in polyethylene wear due to increased conformity in high flexion.**"*

These high flexions are being sold in India at a premium in spite of the fact that its clinical long term superiority is not yet established even after a period of 20 years. There are innumerable independent studies on this issue available in public domain.

(b) The '**gender specific knee implants**' are having very limited sale in India and some MNCs have mentioned it in their product profile and uploaded on their website. This technology also is being tried for improvements but outcomes are still very much short of being even close to being superior over existing gender neutral technology. Since not much data was provided by companies, it was decided that whenever such implants are introduced, and some company claims it to be superior, it will approach NPPA for separate price fixation.

(c) The Authority found that now the oldest and the most widely used and clinically proven material technology is the implants made from alloy of Cobalt Chromium (CoCr) which is adequately hard, corrosion resistant and bio compatible. The use of stainless steel has almost been abandoned because of its limited ability to withstand corrosion in the human body in the long term. Steel is more suited as temporary implant such as fracture plates and screws which is taken out after some time.

There is extensive clinical evidence available on the overall merits of CoCr alloy over stainless steel and other metals in the use of implants and that is the reason why it is still the most widely used knee and hip implant material. CoCr does have a limitation since it is found to release tiny particles (metal ions) in the body and which may cause allergic reactions in some individuals especially if they are allergic to metal like nickel. Material scientists have been working since decades to improve upon CoCr option and the two most widely used metal alloys after CoCr are alloys of Titanium and Zirconium. The main concern in the research for an 'ideal alloy' is focused on the limitations of ultralight molecular weight polyethylene (UHMWPE) wear at weight bearing surface in total knee and hip replacement arthroplasties and the clinical life of these implants cannot be over emphasized. Authority,

however, examined several important independent studies on the clinical benefits of these two metal based alloys since the data submitted by the companies did have implants of these alloys.

(d) **Titanium and Titanium alloys** (having part vanadium and aluminium) has been used because of its inert nature, great corrosion resistance, bio compatibility and elasticity and titanium implants act more like natural joint which in turn also has the drawback of complications like bone resorption and reduced atrophy and wear and tear because of lower molecular weight. The most widely used titanium alloy has been Ti6Al4V. Pure titanium has been used where strength is not necessary.

The Authority studied the clinical research literature on titanium alloys and referred studies like “Titanium alloys in total joint replacement – a materials science perspective Marc Long, H. J Rack Biomaterials Volume 19 (18), September 1998, Pages 1621-1639 which noted in its abstract ***“Increased use of titanium alloys as biomaterials is occurring due to their lower modulus, superior biocompatibility and enhanced corrosion resistance when compared to more conventional stainless steels and cobalt-based alloys. These attractive properties were a driving force for the early introduction of α (cpTi) and $\alpha+\beta$ (Ti-6Al-4V) alloys as well as for the more recent development of new Ti-alloy compositions and orthopaedic metastable β titanium alloys. The latter possess enhanced biocompatibility, reduced elastic modulus, and superior strain-controlled and notch fatigue resistance. However, the poor shear strength and wear resistance of titanium alloys have nevertheless limited their biomedical use.”***

In another independent study ‘Titanium-Nitride Coating of orthopaedic Implants: A Review of the literature’ by Ruud P van Hove & others; Bio Medical Research International, Volume 2015, (2015), Article ID 485975; this study notes in its abstract as: ***“In a review of English medical literature, the effect of TiN-coating on orthopaedic implant material in preclinical studies clinical were identified and the influence of these effects on the clinical outcome of the TiN coated orthopaedic implants was explored. The TiN coating has a positive impact on the biocompatibility and***

tribological properties of implant surface; however, there are reports of third body wear due to delamination, increased ultralight molecular weight polyethylene wear, and cohesive failure of TiN coating.”

There are numerous other independent studies to support the above contention referred by NPPA but not being mentioned because of paucity of space.

(e) The other metal based technology is the usage of **oxidised zirconium** alloy implants which is used as an alloy consisting of 97.5% zirconium and 2.5% niobium (Zr-2.5Nb). Oxidation of this alloy under intense heat allows oxygen to be absorbed into the zirconium metal. When oxygen saturates the metal surface, it converts into a 5 micron thick ceramic layer created over the metal core. In lab (in-vitro) studies, Oxinium is shown to have lesser wear and tear relative to the widely used Cobalt Chromium alloy.

NPPA examined several independent studies on the subject and found that this oxidized Zirconium alloy technology too is not yet proven for its claimed benefits. The one of the latest study available is ***“Twelve Year Outcome of an Oxinium Total Knee Replacement Compared with the Same Cobalt Chromium Design: An Analysis of 17,577 Prostheses from Australian Orthopaedic Association National Joint Replacement Registry”***(Vertullo CJ et al, J Bone Joint Surg Am.2017). It concluded with finding that ***“Oxinium femoral component did not reduce revision rates for all causes, loosening or lysis, or when infection as a cause of revision was removed compared with Cobalt Chromium (CoCr) femoral component across all age groups including patients who were <55 years old. The cumulative percent revision was greater for the Oxinium components rather than for the CoCr components.”***

In another independent study conducted by researchers in Australia it has been found that in-vivo studies have failed to show any significant difference in the polyethylene wear between Oxinium and Cobalt-Chromium. Total 26 pairs of PE component were retrieved from patients who had undergone bilateral knee replacement with one leg having Oxinium and the

other having Cobalt-Chromium. ***‘On analysis, all in-vivo components displayed the in-vivo damages such as grooving, indentation and pitting regardless of the implant type.’*** The other studies referred by NPPA also suggested the similar conclusion that there was no difference in the in-vivo PE component wear and tear between Oxinium and CoCr implants [***“Five Year Comparison of Oxidized Zirconium and Cobalt-Chromium Femoral Components in Total Knee Arthroplasty – A Randomized Controlled Trial”*** (Hui, Catherine, & others: *Journal of Bone and Joint Surgery*, Volume 93(7):624 - April 6, 2011). and (2). ***“In-vivo Wear Performance of Cobalt-Chromium Vs. Oxidized Zirconium Femoral Total Knee Replacement”*** – by Gascoyne Trevor C; Tuter Matthew G; Guenther, Leah E, Burnell, Colin D, Bohm, Eric R. in *The Journal of Arthroplasty*, Volume 31(1), Jan 2016.)The studies concluded ***‘that there is need to sensitize patients about limitations of these hyped technologies and their uncontrolled prices needs to be moderated more strictly than well-established lower cost technologies.’***

(d) In another independent study ***“Do Premium Joint Implant Add Value? Analysis of High Cost Joint Implants in a Community Registry”*** by Terence J Gioe, MD Amit Sharma MD, Penny Tatman MD MPH, and Susan Mehle BS, all based in USA; Springer journal, PMID:PMC3008865. The study evaluated registry survival of higher cost “premium” knee and hip replacement implants compared to lower cost standard components. The premium TKA components were defined as mobile bearing design, high flexion design, oxidised zirconium design, those including moderately crosslinked polyethylene inserts in case of knee implants. The comparison was done between 3462 standard TKAs 2806 premium TKAs. There was no difference in the cumulative revision rate at 7-8 years between premium and standard TKAs. The study concluded: ***“In this time frame premium implants did not demonstrate better survival than standard implants. Revision indications for TKA did not differ and instability remained contributors”***.

(e) Though there was no price data submitted by any manufacturer, the Authority took note of the fact that there is price variation in case of ***cemented and un-cemented implants***, globallythe latter is said to be about

twice the cost. However, there was not much data on un-cemented implants which is rarely being used in India primarily because of cost factor and also because the relative clinical benefits in comparison to cemented implants. Un-cemented implants are still in stage of improvement and development. Authority also noted the well cited study 'Survival and Clinical function of cemented and un-cemented prostheses in total knee replacement meta-Analysis ~ R. Gandhi, D. Tsvetkov, J.R. Davey, N.N. Mahomed from the University of Toronto, Canada. The study titled 'Survival and Clinical function' of cemented and un-cemented prostheses in total knee replacement based on randomised controlled trials in 15 studies. The study concluded **"there was improved survival of cemented compared to un-cemented implants with no strategically significant difference in the mean Knee Society score between groups for all pooled data"**. It further noted, **"the result of our study suggests that cemented fixation in TRK offers equivalent clinical outcomes and at least as good as, if not better survival than un-cemented fixation at medium term follow up. Considering the higher cost of the un-cemented components the cemented components offer an economic advantage with comparable clinical outcomes."**

The Authority also took note of the study **"Joints"** published in SIGA COST official journal published on Jan 8, 2014 by F.MATASSI, C.CARULLI, R. CIVINNI and M. INNOCENTI which concluded **"There is no evidence in the current literature to support the use of one method of fixation. The extensive clinical experience with cemented implants gathered over the years, justifies their widespread use. New randomized trials are necessary to compare cement less fixation based on the new ingrowth surfaces with standard cemented implants.** Based on examination of various other studies and consultation with eminent surgeons it was found that though clinical edge of un-cemented implants is not yet established, its ceiling prices need to be dealt separately on case to case basis and as and when some company decides to launch this technology in India, it will need to get specific price approval from NPPA supported with relevant data.

(f) The other issue relates to implants used in **revision surgery**, the Authority found that the import cost of revision surgery implants is almost double the prices of primary knee replacement. Apart from higher cost of implants, the cost of surgery also gets enhanced since it is supposed to require greater skill on the part of the surgeons. The Authority on internet querying the 'cost estimates' from different reputed hospitals did notice that hospitals do not normally provide the package cost on their website directly in case of any surgery. It was also noted that most of the cost is built in the price of implants used and not on the cost of surgical processes which inflated the cost of the surgery package. The industry did try to justify the higher prices of revision implants based on its design, additional consumption of implant material and structure and accordingly it was decided to fix separate ceiling price for revision implants taking into account the global price trends in the market. It was also found that about 2% patients in India are undergoing revision and globally the average is below 10%.

(g) Authority also took note of a few implants which were carrying highest prices and were imported and sold at higher prices based on its claim of the suitable option for tumour and cancer cases in the knee area. The total margins in these implants was found to be more than 400% on the landed price. Accordingly Authority decided that these implants are to be given separate retail price and decided not to club with other implants. For such retail price, the manufacturer/importer will need to apply to NPPA after the price notification and NPPA will fix the retail price in such cases. In order to not let the supplies of such critical implants getting disrupted, the Authority decided that for time being instead of fixing a ceiling by the Authority, the manufacturer shall add maximum 30% of total margin over the import price of the first batch of such implant in India and shall be free to sell it at this ceiling price thus derived along with specified trade margin for a period of maximum 45 days from the date of price notification and apply for retail price at the earliest.

4. After completing the stakeholders' consultation and its own study and consultation on various technologies and analysing the data, Authority

decided to put the market status in the public domain and the same was uploaded on NPPA website on August 04, 2017 followed by revision implant data on August 09, 2017. Subsequent to it the Authority intensively deliberated on all the aspects of the issue of knee implants during its meeting on 10th August, 2017 which was extended for continued discussions on 14th August, 2017 the salient points of which are summarised as below:

(a) The first and the foremost issue was whether the NPPA should consider intervention in the market since orthopaedic devices are not included in the National List of Essential Medicines (NLEM), 2015 drawn by Ministry of Health & Family Welfare and under the general scheme of things NPPA goes for price capping only when a particular drug or device is included in the Schedule I of the Drug Prices Control Order, 2013. Analysis of the data, however, showed that there are huge trade margins involved in the market of orthopaedic devices and more specifically in the case of knee implants. The Authority also took note of the minimum and maximum landed cost, price to distributors (PTD)/stockists, and maximum retail price (MRPs). The trade margins confirmed the general perception that the margins were exorbitant and irrational, indicating unethical 'profiteering' at every level and mostly at the level of distributors and hospitals. It also proved that the existing trade channel has failed to eliminate the chances of unfair trade practices. NPPA found a clear indication towards a failed market system where asymmetry of information between patient and the doctor has resulted into unethical practices and exorbitant profiteering. Much of these trade margins were not being appropriated by manufacturers in product development or investing in research and development but only sustaining a system based on 'commissions' in order to promote sales. Authority also realised that the argument by manufacturers and more specifically MNCs that capping the prices will adversely affect the development of new technology and will harm the interests of the company does not hold much substance since the import prices include all these expenditures.

(b) Authority deliberated on the concerns of the industry extensively but could find no justification for such huge margins being paid in trade. All the

talks of 'self-regulation' by industry itself has not happened in spite of the fact that everything is in the knowledge of the industry. Sometime in the past, President of Orthopaedic Association, as reported in press, had mentioned to bring down the cost of orthopaedic surgery in consultation with the industry but there was no follow up. The orthopaedic manufacturers, too, have been occasionally mentioning the issue since last 5-6 months but without any tangible outcome. Authority did realise that with about 90% of the market in hand, MNC importers could have rationalised the margins and local manufacturers would have followed but there was no sign of it actually happening. Finally, Authority felt that since most of the margins are being passed off in the trade, restraining the same will not adversely affect industry margins nor will it deprive and innovation or R&D as claimed by industry since import prices already include the R&D cost along with sufficient margins. Price capping will make the marketing of knee implants a fair system based on selection of device on its intrinsic value supported by clinical data and not based on margins to distributors, hospitals or orthopaedic surgeons. In the context of rapidly increasing usage of knee replacement kits and the growing market of orthopedic devices more and more people are opting for orthopedic procedures in order to lead a more productive life. The price cap will increase the affordability and companies will benefit from a fair margin because of economy of scales.

5. The Authority also recollected and took note of the **Hon'ble Supreme Court judgment in Glaxo India Limited vs. UOI reported in (2014) 2 SCC 753** which had referred to the prefatory statement made by the **Hon'ble Supreme Court in Cynamide India Limited (1987) 2 SCC 722** as worth remembering, wherein the Court observed:

"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".

Further, in Cynamide case supra page 763 the Hon'ble Supreme Court ruled as follows: "The right of the citizen to obtain essential articles at fair prices and the duty of the State to provide them are transformed into the power of the State to fix prices and the obligation of the producer to charge no more than the price fixed."

(b) Having considered all the facts on record and recalling the commitment of the Government and the Hon'ble Prime Minister himself towards providing affordable healthcare to people, the Authority decided to intervene in the market of knee implants in public interest. Based on the data analysis there was no doubt that market based pricing system as provided for under DPCO, 2013 as standard procedure has failed to address the disproportionately high trade margins and profiteering at the cost of the patients in knee implants business. The Authority observed that waiting for knee implants to be formally notified as 'essential' under NLEM will be as bad as allowing an exploitative system to continue in spite of NPPA being given jurisdiction and corresponding responsibility under Para 19 of DPCO, 2013 delegated to it by the Government. The attention of the Authority was also drawn towards the judgement of the **Hon'ble Supreme Court in M/s. Prag Rice & Oil Mills &Anr. Vs. Union of India (1978)3, SCC, 459 dealing with the E.C. Act** which noted:

"The dominant purpose of these provisions (E.C.Act) is to ensure the availability of essential commodities to the consumers at a fair price. And although patent injustice to the producer is not to be encouraged, a reasonable return on investment or a reasonable rate of profit is not the sine qua non of the validity of action taken in furtherance of the power conferred by section 3(1) and section 3(2) (C) of the consumer has to be kept in the forefront and the prime consideration that an essential commodity ought to be made available to the common man at a fair price must rank in priority over every other consideration."

NPPA also took note that under similar situation 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.

The Authority accordingly unanimously decided that in the light of excessive profiteering at the cost of patients taking place in case of orthopaedic implants, the interest of the consumers' needs to be kept in the forefront and in order to ensure that, NPPA must move urgently under Para (19) of DPCO, 2013 to correct the distortions in the existing market for eliminating profiteering and ensuring fair prices to people. Apart from the above, the matter was found to be of great significance to public welfare, and enough public concerns have been raised on the exorbitant prices being charged from patients in a non-regulated market. Any further delay in price fixation will deprive the patients of likely savings and defeat the very purpose of DPCO, 2013. The Authority observed that, therefore, extraordinary circumstances do exist, warranting immediate action under Para 19 of DPCO, 2013 to fix a ceiling price on knee implants, urgently in public interest. Accordingly, the Authority decided to put a ceiling on prices of knee implants by invoking its powers under Para 19 of DPCO, 2013.

8. On the methodology of price fixation, NPPA collected official data on landed cost of imported implants and the cost of production of indigenous manufacturers etc., but the information on PTD & MRP was based on the data provided by importers and Indian manufacturers. Meagre data on cost of

production received from the Department of Customs & Excise was not specific and clear enough on different technological parameters hence the Authority decided to take the landed cost data as the basis for ceiling price consideration. Since the knee implant market is dominated by overseas manufacturers, (85% to 90%) a ceiling price based on import prices can be taken as a benchmark which will take care of the production cost of Indian manufacturers very well. Authority also realised that the trade channel of orthopaedic implants is unlike that of other drugs since orthopaedic implants are not sold through normal retailers/chemists. Broadly, most of the importers/manufacturers have their distributors/stockists which in turn provide the implants to the hospitals. Hospitals get these implants on substantially reduced prices from companies or distributors while their billing to patients is based on printed MRP which is hugely inflated. Further, unlike coronary stents, the role of distributors in orthopaedic implants was found to be more intensive because they handled and managed equipment which are bulky in weight involving cost on transformation keeping and rotating inventories and some of them providing sterilization facilities. Thus, the distributors played the role of essential link between companies and the hospitals. As per the feedback from companies, marketing of knee implants is almost indispensable without the help of distributors.

9. The Authority deliberated the entire issue of ceiling price fixation and worked on several methods of price fixation, its justification and rationale and corresponding prices. It was held that though hospitals are not doing any value addition in the supply chain of orthopaedic implants nor have any direct legal financial stakes in the trade, they are said to be providing sterilization facilities and storage of equipment in some cases. Further, involvement of hospitals and the doctors was found to be the biggest reason for price distortion and the root cause of unethical practices in the system of orthopaedic health care. This was clearly stated by the industry representatives but feared to go public. Based on the feedback from industries in case of coronary stents it was decided that some specified trade margin sharing could be considered for hospitals as 'handling charges'. In case of coronary stents in spite of 8% fixed trade margins, companies were being

put under pressure by hospitals for sharing the entire margins and several distributors went out of business of stents. It was easier for the manufacturers to do direct supply of stents to hospital but in orthopaedic implants it does not seem to be feasible.

The Authority also considered the prices of knee implants under CGHS and Amrit scheme of Central Government and decided that these prices serve as an index for comparing ceiling prices decided by NPPA but not beyond that since the tender process in Amrit does not eliminate the possible inflation in the prices. For the final price calculations, the Authority considered the option of landed cost (LC) to be the acceptable official data which needed to be analysed in the context of MRPs. It was rightly presumed that the difference between the landed cost and MRP was being appropriated by the manufacturers, the distributors and the hospitals along with the fact that hospitals are the biggest 'beneficiaries' of these extra margins followed by distributors (based on industry feedback). The option of price to distributors (PTD) was ruled out since MRPs of the implants got inflated at the very level of stockists/distributors itself. Authority also did not rule out the possibility that the price to stockists have got inflated after the price fixation of cardiac stents where Authority had fixed the prices based on price to distributors plus 8% trade margin. This trend could be possible in case of other implants as well.

The Authority also took note that in the price determination based on Para 19 of DPCO, 2013, the Authority has the flexibility not to restrict the price determination methodology as per Para 4 & 5 of DPCO, 2013 and has the option to look into other methods of fair price fixation. Moreover, a price based on landed price is actually a kind of 'market based' pricing system in conformity to the Government's Pharmaceutical Pricing Policy since, 2012 since landed cost is a 'transfer price' which companies decide based on local market conditions and NPPA will not be looking into the actual cost of production. It was an accepted principle of price fixation of imported drugs under DPCO, 1995 where a margin of maximum 50% over import price was stipulated as a fair ceiling price. Landed or import price includes production

cost, R&D cost, profits of the parent company and also the overheads of the Indian office and its margins as well. The landed prices also take note of the prevailing 'market system', the trade strategy and all other trade related issues in the host country. The Authority was also conscious, of the fact that in case of orthopaedic implants it is almost a monopoly situation in the hand of MNCs and a very firm control on the market might create disruption and MNCs might like to withdraw their products from India under margin pressures.

10. The Authority accordingly after intensive deliberation decided that:

- a) For the standard cobalt-chromium knee implants in both partial and total knee surgery as well as revision surgery implants (both partial and full), a total margin of 40% over average landed cost of such implants will be a fair ceiling price keeping all the factors in mind. In case of drugs in the Pharma sector, an overall trade margin of 35% is the norm while in practice trade runs at the rate of 40% trade margin. Devices sector is a nascent sector and for promotion of the sector and keeping the incentives for future growth and R&D, 40% margin was found to be the right level. These ceiling prices based on average landed prices with fair trade margins will sustain the market of this most widely and clinically established (CoCr) knee implants with all its potential of future growth both for importers and Indian manufacturers.

- b) Considering the fact that the technology of titanium alloy coated implants, oxidised zirconium (OxZr) and the so called 'high flex' implants is in the stage of evolution and experimentation and have not developed any superiority over CoCr, Authority decided to allow a lower total margins of 30% for knee implants for partial and total as well as for primary and revision knee replacement and also with a lower trade margin in order to discourage indiscriminate 'hype' based promotion of these clinically unproven implants. Authority consciously felt the need for discouraging such 'hype' based practices from the sector which is the major cause of unethical practices.

- c) The new ceiling prices shall be applicable as per the prices of particular components for partial knee replacements or total knee replacement (TKR), and partial as well as full revision knee replacement. In case of partial knee replacement, both under primary and revision arthroplasty, the patient shall be charged only for the implants which have been placed in the body and with no extra charges since cost of all consumables has been factored in fair ceiling prices.
- d) In order to establish an orderly and ethical market, trade margins in case of these implants shall be restricted to maximum 24% in case of standard CoCr total and partial as well as revision knee implant components with a provision for 16% for the stockists/distributors and not more than 8% for the hospitals as handling charges. This will leave enough margins for industry in its business in India and act as an incentive to make a long term commitment with the Indian growth story. These trade margins shall be sacrosanct and NPPA will closely monitor and take legal action in case of its violation. Fixing the margins for distributors and hospitals will also shield the industry from pressure by these stakeholders and the market will behave in an orderly manner.
- e) In case of 'titanium', 'oxidised zirconium' and 'high flex' implants, the Authority decided to provide lower trade margins for stockists and hospitals because even globally these technologies have failed to establish its superiority over standard CoCr implants in spite of the fact of being tried for more than a decade. Now these products are being 'pushed' in India through excessive trade margins based incentive. Accordingly, Authority decided to keep the trade margins in such category of implants in sub para (b) at 12% to stockists and 4% to hospitals. This was found necessary to remove the technological 'hype' from the market.
- f) The implants manufacturers (both importers & local), will fix the MRPs as per new ceiling prices making provisions for applicable GST. Since

the trade margins are built in the ceiling prices, the invoicing by companies to stockists will keep the maximum trade margins provisioning @ 24% and 16% in mind as applicable and shall be responsible for the same. Similarly, the stockists shall be responsible for correct invoicing to hospitals @ 8% and 4% as applicable.

- g) The Authority also decided that in case some innovative product by an overseas or and Indian manufacturers is to be launched, which does not fall in any of the prescribed category or it has some 'superiority' over the existing implants, the companies will have option to explore the window provided under Para 11(3) & (4) of DPCO, 2013 for fixing a separate ceiling or retail price as the case may be.
- h) Since no data on un-cemented, gender specific or 'specialized' for particular 'left' or 'right' knee implants was available, the Authority decided that if any company is already selling or plans such implants it will approach NPPA to get separate ceiling/retail price fixed for the same and till then it will follow the prices fixed for standard CoCr implants.
- i) The Authority also decided 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.
- j) Since hospitals are acting as a de facto retailer in the existing trade of knee implant while providing estimates or doing final billing to the patients, hospitals will separately mention the cost of the implants, name of the manufacturer, brand name, batch number and all other

hospital charges shall be clearly segregated and mentioned. All the provisions applicable for retailers under DPCO, 2013 shall be applicable in case of all the hospitals which are selling and billing the patients for arthroplasty implants.

- k) No hospital shall force the patients to buy implants from it and patients shall be free to procure it from third party sources including Amrit outlets and in such cases the hospitals shall bill the patient only for the procedure and the hospital charges.
- l) All the hospitals shall display price lists of implants and the total package cost separately at prominent place in respective healthcare facilities along with its permanent and continuous publication on hospital websites and in the hospital price list for the arthroplasty procedure.
- m) The Authority also decided that all other terms and conditions of price compliance as prescribed by the NPPA for scheduled drugs shall be applicable as per the provisions of DPCO, 2013 in case of new ceiling prices to each stakeholder in the trade as the case may be.

11. The Authority was conscious of the fact that once the new ceiling prices are notified increased affordability of necessary orthopaedic interventions for the patients who so far could not support knee implants because of exorbitant cost will fuel the growth in the sector and for importers & local manufacturers the increased affordability will provide larger market, lesser trading overheads, bring down the prices of so called 'high end' and 'latest generation implants' in the reach of the common man and all companies will benefit from the economy of scales. The rationalised trade structure will stand to the benefit of Indian manufacturers as well with fixed margins where they can get their products adopted by orthopaedic surgeons based on pure merit and therapeutic benefits rather than other unethical considerations. The new prices will encourage MNCs to make long term commitment in India which is

going to be the future market for implants based on the huge numbers of unserved patients who could not afford high cost of arthroplasty.

12. Based on the extensive examination on the subject by NPPA, the Authority decided that it should request CDSCO to develop some kind of uniformity in its description of orthopaedic and may be other implants while issuing the licences of production or import for sale in India. It was found that in the case knee implants, there was no uniform pattern in the description of implant. This allows companies to get the product approval based on existing product specifications and subsequently promote the same product as 'new generation' and with added 'benefits' at inflated MRPs without any undergoing any corresponding clinical evaluation.

13. The Authority also decided to request Ministry of Health & Family Welfare to promote the registry of all knee and hip arthroplasties so as to create a robust data on the clinical aspects of different technologies and also keep a tab on its numbers and clinical outcomes. If a Government sponsored registry is not possible, it should assist the registry developed by the 'Indian Society of Hip and Knee Surgeons'.

Also, seeing the large number of patients fit for arthroplasty the existing number of orthopaedic surgeons in India may face shortage. The new affordability in arthroplasty procedure shall push the demand and the country will require increased numbers of arthroplasty facilities and orthopaedic surgeons. MoH&FW and the State Health Ministries need to address to this issue.

Issue of quality standards of the existing Indian companies in the sector was flagged by all the surgeons NPPA interacted with and NPPA did find substance in it. Accordingly it was decided that the issue needs to be flagged with a request to CDSCO and MoH&FW to strengthen the quality norms of licencing and follow standards close to global norms.

Finally, based on the experience of the market behaviour in case of coronary stents, the Ministry of Health & Family Welfare should use its good offices to ensure that benefits of reduction in the implants is passed on to the patients. After a lapse of six months, all cardiac care hospitals have gradually increased price. Mere enforcement of 'display' of actual procedure cost by hospital on its website can help in transparency and go a long way in increasing affordability.

14. Authority decided that the pricing division of NPPA should follow of pursuing the price to retailer (PTR) data collection in case of knee implants and the PTR should be taken as synonymous to price to hospitals. Same practice should be adopted for all notified devices which are not being retailed through chemists.

15. The Authority decided to request the Indian Orthopaedic Association(IOA), Indian Medical Association(IMA) and the Association of Healthcare Providers (India), AHPI to sensitize the orthopaedic surgeons not to push the so called 'new technologies' which are in no way 'new' and with unproven overall clinical benefits of superiority over standard implants and advise the patients appropriately. There are patients who can pay extra cost in the name of getting these 'latest' and do not mind the cost. Such patients should be clearly briefed about the benefits as well as limitations of this technology in comparison to existing well accepted technology.

16. The Authority also decided to request the Department of Pharmaceutical to invoke its powers under Para 3 of the DPCO, 2013 so that the manufacturers are not allowed to withdraw their products out of Indian market for at least a period of six months. Since, the Authority has addressed all the concerns raised by the industry in a fair manner and very fair ceiling prices are being fixed there is no reason for any manufacturer to withdraw any product from the market. On the contrary this is the time to 'Make in India', bring down the manufacturing cost and benefit from the economy of scale.

17. The Authority decided to appeal to all the orthopaedic healthcare providers through AHPI to pass on the price reduction benefits to patients and bring down the prices of their arthroplasty packages correspondingly and not to inflate it in future as is being noticed in case of coronary stents. Last but not least the Authority decide to appeal to the entire orthopaedic healthcare stakeholders including manufacturers, stockists, hospitals, surgeons, IHA, IOA and IMA to cooperate in the Government's efforts to increase affordability of the orthopaedic implants and follow the best tradition of keeping the patient's welfare first and make their contribution in making the "New India".

18. Based on above, the Authority fixes the following as ceiling prices of knee implants to be notified under Para 19 of DPCO, 2013.

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 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

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Date: 14.08.2017