Minutes of the NPPA meeting held on 5th February continued on 8th and 12th February, 2018 regarding price fixation of coronary stents

NPPA fixed the ceiling prices of coronary stents vide Gazette notification no: S.O 412(E) dated 13/02/2017. The said order was valid for one year and needed to be revisited before that. The initial prices fixed as above got increased after factoring for WPI and GST and the existing prices are as follows:

a) Bare Metal Stents : Rs: 7400

b) Drug Eluting Stents (including vascular scaffolds) : Rs: 30180

2. In order to make a fair assessment of the issue NPPA collected data of the years 2016 and 2017 from manufacturers, both indigenous and importers on opening stocks, manufacturing and imports and distribution etc. of stents to make an assessment of the actual impact of price ceiling on cardiac healthcare, the status of market of indigenous manufacturing and imports, increased affordability and access to cardiac healthcare etc. Efforts were also made to collect data from some Government and private hospitals on number of angioplasties and the number of stents deployed to see if the incentives of profit oriented unnecessary multiple stenting as alleged by some quartershas reduced. Attempt was also made to collect data from Tourism Ministry on number of medical tourists since an apprehension was raisedby private hospitals and MNC manufacturers and some business associations that stents price cap will have an adverse impact on medical tourists inflow in the country. The overall national data was not available with the Tourism Ministry or Bureau of Immigration for the year 2017 so NPPA collected data with the help of MEA through Indian Mission at Dhaka since Bangladesh is the biggest source of medical tourists visiting India.

While written comments and suggestions were invited by NPPA vide O.M dated 9th November, 2017, stakeholders' consultation with the coronary stent manufacturers (both foreign and indigenous), industry associations, civil society groups, hospital and nursing home associations, and eminent cardiologists both from private and public sectors was done by the Authority members vide O.M. dated 29th January, 2018 on 5th February, 2018. As per the written submissions from some business associations and medical device associations like MTaI and AdvaMed and one Indian manufacturer for a

few of its new stents, the matter of further sub classification of DES was formally referred to Ministry of Health and Family Welfare with a request to convene meeting of the core committee on cardiac stents to re-examine the issue of differentiation in DES. All the representations from stakeholders were listed and presented to the Authority along with issues raised during stakeholders' consultations.

3. During the stakeholders' consultation and also through written representations, following views were expressed:

a) The multinational coronary stent manufacturers and importers especially from USA were not in favor of treating all Drug Eluting Stents (DES) in one bracket and favoreda sub-categorization and differential prices for different categories in order to ensure future innovation and growth in this sector. They also mentioned that if differential prices in DES is not adopted, they may be forced to withdraw their latest generation stents from the market and may not introduce the new generation stents. Argument further emphasized that some of their brands deserve to be treated differently and be given higher prices to make all the choices available for patients who should not be deprived of new generation stents if they are willing to pay for it. They also mentioned that the NLEM Sub-Committee on stents had concluded in its report that if adequate evidence was provided, a differential pricing within the DES could be considered in future and that NLEM committee in general has mentioned in its report that for procurement and pricing purpose 'incremental' innovations may be considered separately.

This group of importers also suggested a matrix of classification based on several features for a corresponding price preference. They further mentioned that proving 'superiority' of their new generation stents as per the requirements of the Ministry of Health & Family Welfare is a long process where adequate clinical data is to be made available which may take years. They insisted on 'generational incremental improvements' within DES and strongly favored differential pricing based on theseincremental innovations for the sake of rewarding investment in R&D and innovation. They also mentioned that the core committee on stents should have been broad based and not just be taking the views of Government sector experts. By and large, three US MNCs supported increase in trade margins over and above 8% but

wanted it to be factored over and above the ceiling price so that their margins are not adversely affected.

On excessive trade margins in the devices out of price control they unanimously supported the Government proposal of rationalization of trade margins in a way that leaves enough profits for all the stakeholders.

(b) The Indian coronary stent manufacturers were opposed to the idea of sub-categorization within the DES and claimed that the India made stents are not inferior in any manner to imported stents and these are also being exported to different countries. They emphasized the fact that the so called new generation DES of MNCs do not have adequate clinical evidence to support their claim of 'superiority' and should not be given preferential price. They also referred to the original deliberations done during the NLEM Sub-Committee meeting on cardiac stents which decided against sub categorization within DES or special category to BVS. Indigenous manufacturers also emphasized that if any differential and higher prices are given to imported stents, it will kill the Indian industry and it will be against the spirit of Government's 'Make in India' policy. Indian manufacturers emphasized that because of price cap, a level playing field has been created after decades and because of that they have been able to compete with the foreign stent manufacturers and been able to capture a larger share of stent market. Indian manufactures favored strict adherence to 8% trade margin which has eliminated the unethical practices from the market and said that any increase will further encourage the same. On being asked why are they against differentiation and want to stay at the level of present technology, they said that they are not against differentiation as such but none of the existing US based stent makers have clinical data to deserve higher prices than the Indian stents. They also said that they have asked ISMA members to further improve the quality of their stents. Indian manufacturers strongly endorsed the decision of the Government for price capping of stents and knee implants and asked for urgent trade margin rationalization in other devices as well.

c) The civil society representatives were, by and large, against the idea of sub categorization of coronary stents in the DES and on this issue they supported the stand of Indian manufacturers. However, a few members suggested that availability of all kinds of stents needs to be ensured so that the people who want to get particular

imported stent and want to pay for that are not deprived of its availability. Most of them emphasized the point that all DES are same and multinational importers are just changing brand names in order to charge higher prices in the name of ill-defined and unverified innovations. They also mentioned that the prices of MNC's stents are much cheaper in countries like Germany, UK, France and Italy than the prices in India after price cap. They suggested that instead of fixing the prices for one year, these should be fixed for longer term, for a period of 3-5 years. They appreciated the efforts of the Government on putting a curb on excessive profiteering and asked for a cap on catheter and balloon as well as hospital procedure cost so that the benefits of cardiac stent prices could reach the patients in real terms.

Civil society members strongly asked for trade margin capping in case of all drugs and devices, inclusion of other medical devices like intra ocular lenses, heart valves, catheter and balloons, cochlear implants, dental implants etc. in NLEM and requested that NPPA should put the trade margins in these devices in public domain and use its extraordinary powers under Para 19 to cap the prices.

c) The Hospital and Nursing Home Association and related institutions claimed that they need to spend huge capital on construction and running of the healthcare facilities and need to realize the money from various services including cardiac procedures and any margin taken by them is a legitimate return on capital deployed. The hospital groups also emphasized that capping the stent prices have forced them to change their business model and they had to make up for losses by increasing the procedure and other charges. They further emphasized that they are providing essential services and taking care of more than 70% burden of healthcare in the country and if any decision adverse to their profitability is taken, it may harm further investments and expansion of private hospitals in Tier Two and Three cities. On the issue of excessive margins on drugs and devices, they said that they are charging as per MRPs. On the issue of trade margin rationalization, they said they will follow the same and they welcomed it.Need for greater transparency in billing was accepted and the idea of transparency in package prices was also welcomed. On the issue of differentiation within DES, they mentioned that they would like to have the latest stents available for patients irrespective of the fact whether it is imported or locally made. They suggested that special features of a DES may be identified which can be assigned a premium. They, by and large, agreed

that some Indian stents are as good as imported ones but there are some stents in the market which they will prefer never use. They appreciated the price cap but asked for differential pricing so that the latest technology is available in the country. Pricing part could be decided by NPPA.

d) During the discussion with cardiac care experts, many eminent intervention cardiologists, including many of those working in private sector, there was a clear division of opinion on the rationale of differentiation in DES. While some supported sub-classification within the DES category and said that it is adequately supported by evidence based on 'user experience' and preferences of cardiac surgeons and that there is a strong case of sub categorization of DES. These experts suggested that there should be a 'matrix' of classification within DES based on added features like thickness of stents, its material composition and its better deploy ability. On the question of recommendations of the NLEM Committee, they expressed that most of the cardiologists in the NLEM Sub-Committee on stents were from Government sector and hence the issue was not properly appreciated. On the contrary, other interventional cardiologists were of the clear view that at present all DES are at par since those which are claiming to have 'superiority' and ask for charging higher have no clinical data on 'superiority'. The cardiologists, except a few exceptions, on being questioned on why they should be worried about pricing part of the stents, said that they would 'like to have latest technology' based stents in order to meet their 'professional requirements' and safety of patients and will not mind if the same could be provided by manufacturers at lower prices but that is practically difficult. All the doctors accepted that number of interventions made by them has increased in the year 2017 over 2016 and that the price reduction has helped to that extant. On how to ascertain the numbers of cardiac interventions there was unanimity for creation of a 'compulsory national registry' supported and sponsored by the Government for fair assessment of numbers, the outcomes and also the relative merits of various technologies. The Cardiology Society of India has a registry but that is voluntary and that is not reflecting the actual numbers of angioplasties performed. The convener of CSI registry present in the meeting mentioned that data for the year 2017 shall be compiled and be made available in May or June 2018. On the question of overall quality of stents, some of them said that they prefer to use US FDA approved stents over less verified and tested India made stents

because both are available at the same price. Some of these doctors also expressed that there is a case for further reduction in prices and totally new stents without much verified clinical evidence which have entered the market after price cap can be placed at lower prices. Their contention was that with a ceiling of 31-32 thousand there is enough scope for some companies to dump their old generation stents at the common ceiling price and make hefty undeserved profits. On the issue of numbers in reduction of bye pass heart surgeries, all the cardiologists agreed that with the increased affordability of cardiac stents, the need for bye pass heart surgery will get reduced because patients can get multiple stents at same or lower prices. They also said that this is a global trend. Almost all cardiologists said that unnecessary multistenting is unethical practice and even if some doctors were indulging into that, the same will be reduced because of price cap. On the issue of use and reuse of catheters, the cardiologists were divided in their opinion. While a few cardiologists supported the idea of legalized re-use of catheters after proper sterilization, others opposed it on the ground that it will open a Pandora box for misuse and may compromise the patient's health safety.

f) The industry associations like CII, ASSOCHAM, FICCI, PHDCC and others emphasized the need for differentiation within DES and asked that the innovative DES should be given differential and higher prices and to achieve this objective, NPPA should develop a matrix which could be transparently implemented. They emphasized the fact that new technologies are coming globally and the Indian consumers should not be deprived of it and that Indian device manufacturing has still not evolved and the price cap will deter the MNCs to make further investment and the commitment in India.

3. On the examination of feedback data form stents manufacturers, the Authority made following observations:

(a) The data showed increased indigenous manufacturing activity and enhanced imports and availability of cardiac stents made in India. In the calendar year 2016 the total production was 539,788 which increased to 567,805 by December 31, 2017. The increase in production companywise was not uniform though. While one company had 90% increase in production there were companies with decrease up to 15%. Data show clear brand wise repositioning of stents by

certain manufacturers where they increased supply of lower import priced brands.

(b) The year 2017 also witnessed an overall marginal increase of 1% in imports in case of US based manufacturers while a much higher percentage increase of 35% is seen in case of non US MNCs. The price cap has adversely affected the share of two US companies but the major US company continued to have its domination in the market without losing ground and in fact its overall market share increased by 2% in spite of withdrawal of one of its top brands.

(c) The year 2017 saw entry of some new companies both from India and abroad like USA, Singapore, Spain, China and UK having its manufacturing primarily in UAE. The reason behind these new entrants is that the existing prices are quite attractive for most of the brands used globally. This fact is proved by the left-over margins of the companies over earlier price to stockists in the market even after price cap. Since manufacturers and importers do not need to pay out more than 8% trade margins all the old and new players have added surplus to their profit margins except for 2-3 brands where the initial import prices were higher.

(d) There was a clear overall 5% growth in case of made in India stents. The 4 to 5% market shift may not sound big enough but it needs to be seen in the light of the fact that MNC stents have had a well-developed market and have been a preferred choice of well off patients and corporate hospitals over India made stents. This also makes it imperative on Indian manufacturers to further improve the quality of their products so as to be able to compete with USFDA, CE approved stents where the quality standards are certainly higher and also because of Indian consumers' general attraction for anything with foreign label is still deep rooted.

(e) The decision of putting only 8% trade margins cap eliminated almost all unethical payment and profiteering in the system and also disrupted the status quo in trade of stents which was based on profiteering at each level. While hospitals pressurized the manufacturers to make up for their losses by any means, manufacturers found it difficult to meet the demands of the hospitals. March – May, 2017 did witness uncertainty and slow down of supplies to some extent. The data shows that about 8.75 lakh stents were supplied in 2017 by all the companies in the market but it cannot be ascertained how much stock

remained in transit lying with the stockists and the hospitals. The number of stents distribution remained almost at par with the year 2016. Some distributors got disrupted because of squeezed trade margins since several manufacturers went for direct supplies to hospitals by sharing 8% trade margins with hospitals in varying degree. In short, the unethical and exploitative system of predominantly distributor based marketing system gave way to direct marketing in most cases but the process itself involved some slowdown in distribution in the transition. The four months, February, March, April and May, in 2017 witnessed some disruption in the market and also affected by the MNCs holding their stocks of their high-priced stents by issuing 'informal instructions' to distributors and hospitals for not using their earlier high priced brands. This explains lack of any substantial hike in the distribution of stents in 2017 over 2016.

(f) The availability of stents in Indian market in the year 2017 was higher by 5% which is a healthy sign. The opening stock for the year 2018 is higher than the year 2017 and 2016 which shows that the number of angioplasties are likely to grow further in coming years in spite of poor passing of benefits of price cap to the patients by the hospitals and other infrastructural handicaps like shortage of Cath labs and trained intervention cardiologists. The Authority also realized that with increased momentum in production there are remote chances of any future shortage of stents in Indian market.

(g) The Authority also took note of the study conducted by IQVIA and sponsored by AdvaMed. Though not an independent study, Authority took note of the facts that there has been an increase in number of angioplasties but not to a very significant level. The prime reason identified by the study and also by several stakeholders has been the resistance at the level of hospitals which did not pass the complete benefits of price cap to patients, limitations of Cath labs and trained intervention cardiologists and lack of awareness on the part of the patients about the disease. The Authority found truth in these assertions but did not agree with the finding of the study that 'cost is not a limiting factor in case of availing angioplasty services'. Apart from other factors, cost does play the most important role in case of large section of population in India consisting of poor farmers, daily wage earners, people below poverty line etc. Even if they

somehow manage funds to get the procedure done, the cost factor shatters their lives and savings of years gets exhausted in the process.

(h) Issue which IQVIA study misses or has consciously left out is the fact that though the stent prices have come down, the cost of cardiac catheters, balloon catheter and the guide wire used in the procedure remains grossly exorbitant and leaves very high margins and scope for profiteering. The Authority took note of the data on cardiac catheters and balloons and found that combined cost of these disposables was even higher than stents itself in some cases. Authority decided to upload the data in public domain.

(i) The Authority had complaints from some health activists and confidential admissions by some intervention cardiologists that many hospitals reuse the catheters/balloons/guide wire after sterilization and charge the patients at the full rate of new catheters/balloons/guide wire or with some 'concession'. Authority also took note of NPPA's request to Ministry of Health & Family Welfare to put these devices under essential category so that its prices could be capped.

(j) Authority also examined the impact of cardiac stent pricing on medical tourist arrivals since voices were raised that non availability of new generation stents will adversely affect the medical tourism business in the country. The data provided by the Indian High Commission in Dhaka, Bangladesh, showed that arrival of medical tourists from Bangladesh increased to 96,849 in 2017 in comparison to 77,405 medical tourists in the year 2016. It is to be noted that Bangladesh sends maximum number of medical tourists to India and though all the medical tourists may not be cardiac patients but the same applies to figures of 2016. This proves the fact that medical tourism will get a boost because of increased affordability of angioplasties in India and that can further be enhanced if private hospitals pass on the complete benefits of price cap to patients.

(k) One of the major collateral benefits of cardiac stent price cap has been the overall switchover from usage of DES in comparison to BMS because of increased affordability of superior quality DES. Based on a rapid data collection by NPPA from 12 metro based hospitals (4 public and 8 private) it was found that there has been a reduction of 31% in the usage of BMS in 2017 over 2016 though the same percentage decrease is not reflected in the total sales figures of BMS where

it shows a decline of 18% (69,769 in 2017 over 85,299 in 2016). This shows that in tier two and three cities where poor or lower middle-class patients avail angioplasties, there is a sizable section of population which cannot afford DES even at present rates. Company wise distribution of BMS shows that one major MNC distributed more number of BMS along with three Indian companies while all other MNCs reduced the distribution of BMS. The opening stocks of BMS as on January 1, 2018 is 9% lower than previous year which indicates towards future trend of higher use of DES. One US, 6 non- US MNCs and 5 Indian companies (total 12), out of total 24 companies in Indian market, did not operate in BMS segment in 2017 and have nil stocks for 2018.

(l) Authority also took note of the entry of new importers and Indian manufacturers in the market and increased push in sales of lower import cost brands by existing importers and took these developments with a note of caution along with the positive note regarding increased competition. The existing prices are quite competitive and attractive for most global brands and about 83% of import is taking place below landing cost of Rs.25,000/-. This, however, requires caution on the part of the CDSCO to apply safety and efficacy criterion on new entrants and also the periodic monitoring of some of the existing manufacturers. Authority also took note of the fact that lots of media reports apprehended influx of Chinese stents in the market. As against it, the total share of Chinese stents remained only 1% of the overall Indian market in 2017.

(m) Authority was fully satisfied with the implementation part of the stent price capping decision and it was found that after initial phase of implementation of two months when about 30 complaints were registered, rest of the year witnessed no fresh complaints of overcharging. Hospital billing pattern changed to write the cost and other details of stents separately and other instructions of the Authority like compliance with 8% trade margin etc. were by and large complied with. One MNC tried to short cut the import channel to offer extra trade margins but the same was scuttled by NPPA in time.

(n) Finally, the Authority came to the conclusion that cardiac healthcare remains an essential element of healthcare in India and it must be kept affordable for masses through all necessary interventions. All other factors like increase in imports, indigenous manufacturing, much higher opening stents stock, increase in

number of players and increase in number of tourist arrivals do make the decision of price capping of stents a big reform in cardiac healthcare sector requiring further strengthening. Benefits of the price cap have not been fully passed on to the patients by hospitals but, once it is known, instead of questioning the very rationale of price cap, as done by some interest groups, there is a need to look at the real causes of it and take necessary follow up steps. Rationalization and standardization of hospital charges and more affordable packages within the new NHPS umbrella by Government is an essential step in this direction. Voluntary rationalization by hospitals may be a welcome step. Further, there is a need to increase number of Cath labs and trained intervention cardiologists and increased screening to identify the deserving patients specially in the 'have nots' sections of the population.

4. In the light of stakeholders' consultation and taking a note of all their concerns and its own findings and observations and all the market data at its disposal, Authority intensively deliberated on all the aspects of the price fixing of coronary stents and took corresponding decisions summarized below:

(a) The Authority took note of a suggestion that since the prices of cardiac stents are to be again revised after factoring the whole sale price index (WPI) for the year 2017 to be applicable from April 1, 2018, whether it should extend the existing prices till 31st March 2018 and do the new pricing exercise before that. In order to examine the suggestion Authority deliberated on the figures of all the probable ceiling prices under various options and found that under all options normally taken into account by Authority under Para 19, a downward correction in the ceiling prices is inevitable. Taking into account the usage of stents in the year and dividing it by number of months multiplied by resultant benefits in case of any of the revised prices of DES and BMS, it was found that there is substantial overall benefits in terms of cost to the patients undergoing angioplasty between 13th February to 31st March, 2018 and it will not be in their interest to deprive them of the said benefit. Accordingly, Authority decided to revise the prices ignoring the fact of another mandatory revision due to WPI before April 1, 2018. The prices shall move upwards from existing level after factoring WPI increase for the year 2017 which is positive so far and shall be notified by Authority in March end, 2018. The Authority also took note of the fact that stent prices were

increased from April 1, 2017 just after one and half month because of mandatory factoring of the positive WPI for the year 2016. The revision to be effective from April 1, 2018 shall be exactly effective after 12 months.

(b) The Authority took note of the fact that cardiac stents is a part of the Schedule I of DPCO, 2013 based on the recommendations of the NLEM, 2015 hence its continuation under price control is a legal requirement as well as a necessity for the safety of public health and especially the cardiac care and prevalent rate of CVD in the country. During price fixation of stents in February, 2017 the Authority was constrained from fixing the ceiling prices of coronary stents under the normal procedure under Para 4 and 5 of DPCO, 2013 like other scheduled drugs. It was also realized that market based pricing system as provided for under DPCO, 2013 as standard procedure had failed to address to the disproportionately high trade margin in case of coronary stents and hence the Authority took a conscious decision that unless reliable data was available, the Authority cannot fix the ceiling prices of coronary stents under Para 4 and 5 of the DPCO, 2013 taking into account the PTRs (Price to Hospitals) in the market. Accordingly, the Authority decided to go ahead for fixing the prices of cardiac stents under Para (19) of DPCO, 2013. Authority meanwhile has collected the data on PTRs, landed costs and PTDs after price cap and it is possible to consider the new prices in a more realistic manner based on options of averaging of PTRs along with earlier method of PTD based pricing and the import price based pricing as done in case of knee implants.

(c) The issue of whether the NPPA should consider a sub classification of Drug Eluting Stents (DES) was intensively deliberated. The NLEM Sub-Committee on cardiac stents which was convened by Ministry of Health and Family Welfare on the request of NPPA suggested vide its letter dated 30.01.2017 that because of lack of adequate clinical evidence, there is no case for sub-classification of DESs in the NLEM, 2015. In the given situation, the Authority after deliberations decided to go ahead with the recommendation of the MoH&FW for same classification as provided under the NLEM 2015 and the amended Schedule I of the DPCO, 2013 as notified by Department of Pharmaceuticals since NPPA does not have the mandate to alter the Schedule I entry. The Authority did realize that some incremental innovations are taking place and incremental benefits may be there in case of a few stents in terms of one or more

parameters but overall 'superiority' is still not established as recognized by Indian regulator or any other global regulator.

(d) On the issue of 'incremental innovations short of superiority' as under Paras 11(3) and (4) of the DPCO, 2013, the Authority took note of the fact that under DPCO, 2013 the Government has provided enabling provision under this Para for rewarding 'special ceiling' or 'special retail' price for manufacturers who are able to prove some kind of incremental benefits and innovation in terms of special therapeutic rationale. Several drugs, injectable and IV fluid manufacturers got benefitted under this provision for incremental innovations. DES was invented in the year 2001 and since then lots of R&D and incremental innovations are being attempted pushing the cost of few of these stents because of R&D expenses both globally and also in India should be factored into some manner. Authority did agree with the contention by some stakeholders that it is difficult and time taking process to establish 'superiority' of any DES, but the existence of incremental innovations already achieved in some cases or likely to happen in future with certain added incremental benefits cannot be ruled out and the windows for future innovations should be kept open. After intensive deliberations over Paras 11(3) and (4) it was found that in the present form of Para 11(3) and (4), which were incorporated for common drugs, it is not possible to legally and technically consider the incremental innovations for preferential pricing in case of stents or any other medical device. Authority, accordingly, decided to refer the issue to Department of Pharmaceuticals to consider modification issue in existing provision under Paras 11(3) and (4) or incorporate a new para, if it deems fit, to meet out the incremental innovation based differential price requirements in case of not only stents but also other medical devices as per the footnote of the NLEM, 2015 and the Schedule1 of DPCO, 2013 which recognizes such incremental innovations for the purpose of separate prices.

(e) It was also decided that if an enabling provision is notified under DPCO, 2013 in order to meet the requirements of future incremental innovations which cannot prove the 'superior efficacy' test of the Ministry of Health & Family Welfare to deserve a separate classification from other DES but at the same time therapeutically helps in any manner, NPPA may be in a position to work out a transparent 'matrix of features' for such incremental innovations supported by adequate clinical evidence through the Sub Committee of Experts of NPPA and with the help of Ministry of Health & Family Welfare

expert bodies. This may take care of the scope for future incremental innovation, R&D and new products development and also the availability of the so called 'cutting edge' products to Indian patients through imports or indigenous production. The said matrix may be finalized after extensive stakeholders consultation and through an absolutely transparent process with the inputs from experts, available medical literature and the global trends.

(f) Authority also took note of the fact that viewing the existing prices at the company level, both Indian manufacturers and the MNCs have enough trade margins left based on the earlier price to stockists. However, in case of the margins with regard to specific brands, two MNCs are left with negative margins because of higher import prices and lower ceiling price during the original process of price fixation in February 2017. The sale of these stents has facedsetbackseither because the manufacturers slowed down its imports (24% and 29%) and supplies because of brand specific 'losses' or the hospitals changed their preferences because of reduced trade margins. These companies have also applied for withdrawal of these two brands along with price increase request under Para 19 of DPCO, 2013 which continues to be pending because of lack of enough evidence in support of 'unviability'. Total of three brands of US MNCs had applied for withdrawal of one of their brands but seem to have held up the process probably waiting to see NPPA's decision on new prices of stents. Out of these three, one major US importer, in spite of application of withdrawal and subsequent approval, witnessed increased sales of the said brand by more than 22%.

(g) The Authority further deliberated on the issue of putting a ban on the withdrawal requests of some MNC brands which was considered necessary after price cap in February 2017 because it could have adversely affected the overall availability of stents for the patients. During one year, stent market has witnessed increase in imports and manufacturing of stents and the increased opening stocks of stents as on January 1, 2018 gives confidence that there will be increased capacity utilization in both imported and indigenously manufactured stents in the Indian market and shortage of stents should not be a concern on withdrawal of a few brands.

(h) Authority extensively deliberated on the issue of the ceiling of 8% trade margin and found that this restriction has helped in cleaning almost all the unethical practices

in the market and all the manufacturers including MNCs had welcomed the decision as a major relief from being exploited in the trade channel. Because of the cap on trade margins the bottom line of stent manufacturers got secured and that is being witnessed in the form of increased imports and indigenous manufacturing. The nature of stent business requires direct link and synergy between manufacturers and the end users like hospitals/doctors and a long term responsible commitment in the Indian market. In the earlier Authority meeting the decision of 8% trade margin cap was taken after detailed analysis of stents market and there is no reason to change the decision. The high cost, low bulk product like stents does not require high spending on supply chain and the 8% margin shared between distributors and hospitals or passed on to one entity is fair enough. Authority also took note of the case of one MNC which started selling its product by appointing several distributors to import directly and probably offer higher margins to hospitals to promote its stents. Over the year the stents market has stabilized along with its trade channel and any alteration in that will give rise to distortions and emergence of unethical practices in the light of intense competition. Accordingly, Authority decided to continue with the existing 8% trade margin restriction.

(i) Authority took a serious note of the existing margins in the cardiac catheters, balloon catheters and guide wire and its increased usage as per the sample data from 8 hospitals and decided that NPPA will intensify monitoring of MRPs not only based on manufacturers' data but also at retail usage end. Accordingly, Authority decided that apart from details of coronary stents all the healthcare institutions performing angioplasty shall also mention billing cost of cardiac catheters, balloon catheter and guide wire along with name of the company, brand name, batch number and specifications in order to bring in greater transparency in the billing and for effective monitoring of the MRPs under Para 20 of the DPCO, 2013 by NPPA.

5. The Authority decided that all other terms and conditions of price compliance as prescribed by the NPPA shall be applicable as per the provisions of DPCO, 2013.

6. Finally, Authority considered various options and consequent figures of new ceiling prices and after a detailed deliberation on this issue, it was unanimously decided to go for the ceiling prices on the basis of the average landed cost of the two categories

of stents. DPCO 1995 provided for a MAPE of upto 50% of the landed cost and this pricing methodology continued from 1995 to 2012 till adoption of DPCO, 2013. Report of the Committee on High Trade Margins has recommended a margin varying from 35% to 50%. The Authority itself has fixed the ceiling prices of knee implants where a margin of 24% to 40% was added to the average landed cost to arrive at the ceiling prices for different types of knee implants. After considering all the options, the Authority approved a margin of 35% over the average landed cost for the purpose of calculation of the ceiling price in the case of DES. Since average landed cost of BMS is much lower, the Authority approved a margin of 50% over the average landed cost which was considered reasonable to arrive at the ceiling price. After adding these margins to the average landed cost and rounding off the numbers, the Authority approved the following new ceiling prices of cardiac stents:

(a) Bare Metal Stents : Rs 7,660

(b) Drug Eluting Stents including Bio-vascular Scaffolds : Rs 27,890

Date: 12/02/2017

Bhupendra Singh

(Chairman, NPPA)