गोपनीय: Confidential

मिसिलस.- 8(41)/2017/डी.पी/एनपीपीए-डीवी-II

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

कार्यवाहीस. : 173/41/2016/F

Proceeding No : 173/41/2016/F

Minutes of the 173rd and 41st meeting of Authority under DPCO, 2013 held on 13.02.2017 at 11.00 A.M.

I. 1. The 173rd overall meeting of the Authority, which is the 41st under the DPCO, 2013 was held on 13 February, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

(i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
(ii) Shri G.S. Negi, Adviser (Price, Money & Banking Unit), Deptt. of Economic Affairs, Ministry of Finance.
(iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iv) Shri R. Chadrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

1.1 The following officers of NPPA also attended the meeting and assisted the Authority in its deliberations:-

i. Shri Kalyan Nag, Adviser (Cost)
ii. Shri A.K. Khurana, Director (Pricing)
iii. Shri A.P.S. Sawhney, Director (Overcharging)
iv. Shri Baljit Singh, Asstt. Director (Pricing)
v. Shri Prasenjit Das, Asstt. Director (Pricing)
vi. Shri Suneel Chopra, Pr. Legal Consultant

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 41st Meeting held on 13.02.2017.

The Authority confirmed the minutes of the overall 172nd and the 40th Meeting held on 23.01.2017 under DPCO, 2013.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

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3.1 The Authority discussed in detail the data and calculation sheets of 37 formulations at the meeting. The Authority approved the ceiling prices in respect of following 33 formulations. The ceiling price cases in respect of 4 formulations viz. Anti-Rabies Immunoglobulin 150IU/ML, Anti-Rabies Immunoglobulin 300IU/ML, Hepatitis B vaccine and Calamine Lotion (as per IP) have been deferred for further detailed examination.

3.2 The Authority approved the ceiling prices in respect of following 33 formulations:-

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	Dosage From	Unit for Ceiling Price	Approved ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations						
Section 1–Anesthetic agents						
1.1–General Anesthetics and oxygen						
1	1.1.2	Isoflurane	-	Inhalation	Per ML	9.30
1.2–Local anesthetics						
2	1.2.3	Lignocaine (A) + Adrenaline (B)	2% (A) + 1:200000 (5mcg/ml) (B)	Injection	Per ML	0.85
Section 5–Anticonvulsants/ Antiepileptics						
3	5.7	Phenobarbitone	20mg/5ml	Oral Liquid	Per ML	0.35
Section 6.2–Antibacterials						
6.2.1–Beta lactam medicines						
4	6.2.1.9	Cefotaxime	500 mg	Powder for Injection	Each Pack	19.04
5	6.2.1.9	Cefotaxime	250 mg	Powder for Injection	Each Pack	14.47
6.2.2–Other antibacterials						
6	6.2.2.2	Ciprofloxacin	200mg/100ml	Injection	Per ML	0.15659
7	6.2.2.4	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	200mg (A)+40mg (B)	Oral liquid	Per ML	0.20
8	6.2.2.4	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	400mg (A)+80mg (B)	Tablet	Per Tablet	0.48
9	6.2.2.4	Co-trimoxazole (Sulphamethoxazole (A)+Trimethoprim (B)]	800mg (A)+160mg (B)	Tablet	Per Tablet	0.98
10	6.2.2.7	Metronidzole	500mg/100ml	Injection	Per ML	0.12039
6.5.3–Antimalarial medicines						
6.5.3.1–For curative treatment						
11	6.5.3.1.4	Chloroquine	50 mg/5 ml	Oral liquid	Per ML	0.26
12	6.5.3.1.4	Chloroquine	150mg	Tablet	Per Tablet	0.59
Section 8 –Antineoplastic/immunosuppressives and medicines used in palliative care						
8.1–Antineoplastic medicines						
13	8.1.14	Cyosine arabinoside	1000mg	Powder for Injection	Each Pack	953.51
14	8.1.21	Gemcitabine	200mg	Powder for Injection	Each Pack	1069.33
Section 12–Cardiovascular medicines						

12.1–Medicines used in angina						
15	12.1.1	Acetylsalicylic Acid	75 mg	Tablet	Per Tablet	0.28
16	12.1.5	Isosorbide-5-mononitrate	10 mg	Tablet	Per Tablet	1.82
17	12.1.5	Isosorbide-5-mononitrate	20 mg	Tablet	Per Tablet	2.84
Section 12–Cardiovascular medicines						
12.2–Antiarrhythmic medicines						
18	12.2.1	Adenosine	3mg/ml	Injection	Per ML	82.75
19	12.2.2	Amiodarone	50mg/ml	Injection	Per ML	18.19
20	12.2.4	Lignocaine	Injection 2%(Preservative free for IV use)	Injection	Per ML	0.90
Section 14–Dermatological medicines (Topical)						
14.2–Antiinfective medicines						
21	14.2.4	Povidone iodine	10%	Solution	Per ML	0.66
Section 18–Diuretics						
22	18.2	Hydrochlorothiazide	Tablet 50 mg	Tablet	Per Tablet	0.07679
Section 19–Ear, nose and throat medicines						
23	19.2	Ciprofloxacin	0.30%	Drops	Per ML	1.41
Section 20–Gastrointestinal medicines						
20.5–Laxatives						
24	20.5.2	Ispaghula	Ispaghula	Granules/Husk/Powder	Per GM	0.73
Section 21–Hormones, other endocrine medicines and contraceptives						
21.5–Ovulation Inducers						
25	21.5.1	Clomiphene	50mg	Tablet	Per Tablet	6.91
26	21.5.1	Clomiphene	100mg	Tablet	Per Tablet	10.86
Section 29–Solutions correcting water, electrolyte disturbances and acid-base disturbances						
27	29.6	Sodium Bicarbonate	8.40%	Injection	Per ML	1.20
28	29.6	Sodium Bicarbonate	7.50%	Injection	Per ML	1.29
29	29.3.1	Water for Injection	5 ML	Injection	Each Pack	2.09
30	29.3.1	Water for Injection	10 ML	Injection	Each Pack	2.17
Section 28–Medicines acting on the respiratory tract						
28.1–Antiasthmatic medicines						
31	28.1.5	Salbutamol	100mcg/dose	Inhalation (MDI/DPI)	Per MDI	0.37
B. New Formulation						
Section 5–Anticonvulsants/ Antiepileptics						
32	5.8	Phenytoin	30mg/5ml	Oral Liquid	Per ML	0.27
C. Commom (Explanation to Schedule-I) - NIL						
D. New (Explanation to Schedule-I)						
Section 27–Psychotherapeutic medicines						
27.3–Medicines used for Generalized Anxiety and Sleep Disorders						
33	27.3.2	Zolpidem	5 MG	Capsule	Per Capsule	6.83

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4. Agenda Item no. 4: Price fixation of Coronary Stents under DPCO 2013.

4.1 The Authority deliberated this issue in detail. After detailed discussions, the Authority approved the ceiling price of coronary stents invoking Para 19 of DPCO, 2013 as follows:

Coronary Stents	Approved Ceiling Price (Rs.)
Bare Metal Stents (BMS)	7260
Drug Eluting Stents (DES) which include metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable stents	29600

Detailed note in this regard is annexed.

5. Agenda Item no. 5: Review order of DOP in respect of price fixation of Propanolol 40mg tablet for M/s Abbott Healthcare Pvt. Ltd against S.O. no. 1351(E) [corrected SO No. 1951 (E)] dated 02.6.2016 issued under DPCO, 2013.

5.1 This case was discussed in detail and the Authority approved the revised reduced ceiling price of Propanolol 40mg tablet at Rs. 2.56 per tablet (against the existing notified ceiling price of Rs. 2.59 per tablet).

6. Agenda Item no. 4: Retail price fixation of 8 Cyblex brands formulations of M/s Eris Life Sciences Pvt. Ltd. who is manufacturing & marketing without price approval (WPA), under Para 5 of DPCO 2013.

6.1 The Authority discussed the cases in detail and approved the retail prices of M/s Eris Life Sciences Pvt. Ltd. who is manufacturing & marketing without price approval (WPA), under Para 5 of DPCO 2013, in case of following 6 formulations. The proposal for remaining 2 formulations viz. Cyblex MV 40.2 (0.2/500/40) tablet and Cyblex MV 40.3 (0.3/500/40) tablet will be placed before the Standing Committee of Expert under para 15 (i.e. Pharmacoeconomics) in the next meeting for fixing the retail prices. Further, it was decided that the overcharged amount would be recovered from the company, after calculating overcharged amount [i.e. MRP (less local taxes/VAT) – retail price fixed] plus interest plus penalty, as decided in respect of similar cases .

6.2 The 6 cases of retail price fixation of new drugs are as under:-

S. No.	Company name/Product name	Approved Retail Price (Rs.)
6(i)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg (as extended release) + Gliclazide 30mg – (Cyblex M 30 XR tablet).	Rs. 49.60 per 10 tablets
6(ii)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg (as extended release) + Gliclazide 40mg – (Cyblex M 40 tablet).	Rs. 45.40 per 10 tablets
6(iii)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg (as extended release) + Gliclazide 60mg (as extended release)– (Cyblex M 60 XR tablet).	Rs. 79.80 per 10 tablets
6(iv)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg + Gliclazide 80mg– (Cyblex M 80 tablet).	Rs. 50.93 per 10 tablets
6(v)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg + Gliclazide 80mg + Voglibose 0.2mg – (Cyblex MV 80.2 (0.2/500/80 tablet).	Rs. 113.70 per 10 tablets
6(vi)	M/s Eris Life Sciences Pvt. Ltd. (Manufacturer as well as marketing company) – Metformin HCl 500mg + Gliclazide 80mg + Voglibose 0.3mg – (Cyblex MV 80.3 (0.3/500/80 tablet).	Rs. 115.80 per 10 tablets

7. Agenda Item no. 7: Review order of DOP in respect of Retail price fixation of Diclofenac Sodium Injection (Volitra AQ) for M/s Akums Drugs and Pharmaceuticals Ltd and M/s Sun Pharmaceutical Industries Ltd. against S.O. no. 2195(E) dated 23.6.2016 issued under DPCO, 2013.

7.1 This case was deferred.

8. **Agenda Item no. 9: Status of Review orders issued by DOP which are pending with NPPA for implementation.**

8.1 Noted.

9. **Agenda Item no. 10: Fixation of ceiling prices of Schedule-I formulations where market data is not available.**

9.1 This case was deferred.

10. **Agenda Item no. 10: Status of filing of various forms in IPDMS by Pharma Companies.**

10.1 The Authority was informed that an OM dated 01.02.2017 was issued in this regard. The Authority decided that representations submitted by companies in respect of overcharging cases pertaining to Drug (Prices Control) Order, 2013 (DPCO, 2013) will be examined on the basis of forms filed by the company in IPDMS as prescribed under Schedule-II of Drug (Prices Control) Order, 2013 (DPCO, 2013). The submissions made by the company in response to overcharging notices will be summarily rejected in the absence of requisite online submissions through in IPDMS.

10.2 Further for submission of review cases, the representation(s) filed by the company(ies) is (are) to be supported by the requisite forms filed in IPDMS. The pharmaceutical companies may be directed to file the review

application with supporting evidences of requisite forms filed in IPDMS after informing the matter to Department of Pharmaceuticals (DoP).

10.3 It has also been decided that an automated mail system will be awaited for sending all the forms filed by the company in IPDMS as prescribed under Schedule-II of Drug (Prices Control) Order, 2013 (DPCO, 2013) to the State Drug Controllers (SDCs) on real time basis.

11. The meeting ended with a vote of thanks to the Chair.

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(Dr. Sharmila Mary Joseph K)
Member Secretary

Annexure on Agenda Item No. 4 of the Minutes of the 173rd and 41st meeting of the Authority under DPCO, 2013 held on 13.02.2017

Detailed note on ceiling price fixation of Coronary Stents

Ministry of Health and Family Welfare vide Notification No. X.11035/344/2015.DFQC dated 19th July, 2016 notified inclusion of coronary stents in the National List of Essential Medicine, 2015 (NLEM 2015). Subsequently, Department of Pharmaceuticals (DoP) notified coronary stents as part of Schedule I of DPCO, 2013 vide S.O.4100(E) dated 21st December, 2016 and directed National Pharmaceuticals Pricing Authority (NPPA) to take necessary follow up action at the earliest. Under Para 17 of the DPCO, 2013, it is obligatory on the part of NPPA to fix the prices of coronary stents within 60 days from the date of notification (i.e.by 20th February, 2017).

2. After the formal notification of coronary stents as scheduled products, NPPA intensified the exercise of collecting information regarding market data of coronary stents. In order to make a fair assessment of the subject, stakeholders' consultation with coronary stent manufacturers (both foreign and indigenous), industry associations, civil society groups, hospital and nursing home associations, distributors' associations and eminent cardiologists was done by the Authority members on 4th, 5th and 6th January, 2017. NPPA also collected required data from Director Central Government Health Scheme (CGHS), Director General of Commercial Intelligence and Statistics (DGCI&S), Advisor (Cost) Cost Audit Branch (CAB) and Central Drugs Standards Control Organisation (CDSCO) so as to make a fair assessment of Landing cost(LC) (in case of imported stents) and Cost of Production(CoP) (in case of indigenously manufactured stents).

3. It was also realised that as NPPA's official data provider, All India Organisation of Chemists and Druggists (AIOCD-AWACS) (which provides Pharmatrac data) was not capturing data including Price to Retailer (PTR) data on coronary stents, NPPA would have to explore all possible sources of data and work upon diff erent options of price calculations within the overall framework of DPCO, 2013. The Authority also realised that the 'provisional price' of coronary stents could not be ascertained by the NPPA office as per the DoP letter No. 31015/44/2016/PI.1 dated 11th July, 2016, as independent PTRs were not available and the data provided by manufacturers/ importers was proprietary data and submitted with different 'caveats'. It was also realised that uploading of 'provisional prices' was not obligatory

on the part of NPPA under DPCO, 2013. However, in order to give all the stakeholders fair opportunity for representation, it was thought proper, based on DoP's advice, to upload the various options of price calculations and also ask for stakeholders' suggestions which would by and large serve the purpose of transparency and price consultancy. Accordingly, the various options of price calculation likely to be considered by NPPA were uploaded on NPPA's website on 4th January, 2017; draft calculation sheet for the different options was uploaded on NPPA's website on 12th January, 2017 and clarificatory OM regarding the same was uploaded on 13th January, 2017.

4. During the stakeholders' consultation, the following views emerged:

(a) The multinational coronary stent manufacturers and importers were not in favour of treating all Drug Eluting Stents (DES) in one bracket and favoured sub-categorisation and differential prices for different categories of DES in order to ensure future innovation and growth in this sector. They also apprehended that if any unreasonable price cap was imposed, foreign manufacturers might withdraw their 'cutting edge' products from the Indian market and also stop thinking of future investment in the country. They further emphasized that there could be a basic lower price for majority of the DES and rest of the stents may either be kept out of price control or given higher prices to make all choices available for patients who should not be deprived of high end stents, if they are able to afford the same. They also referred to the Report of the Sub-Committee (constituted to examine the issues relating to essentiality of coronary stents) of the Core Committee on NLEM 2015 which had concluded in its Report that if adequate evidence was provided, a differential pricing within the DES could be considered in future. The importers also suggested preparation of a matrix of classification based on several features for a corresponding price preference. The manufacturers were asked to submit such clinical evidence/literature in support. On being enquired about existence of such clinical evidence, they accepted the fact that since the conclusion of the NLEM Sub-Committee report, no new clinical evidence was generated to conclusively prove 'superiority' of Bioresorbable Vascular Scaffold (BVS) or other new generation DES as per Indian or global clinical norms. In spite of this, they referred to generational improvements within DES and strongly favoured differential pricing for the sake of rewarding investment in R&D and future innovation.

(b) The Indian coronary stent manufacturers were by and large opposed to the idea of sub-categorisation within the DES and claimed that the 'Made-in-India' stents are not inferior in

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any manner to imported stents and several indigenous stents are also being exported to different countries. They emphasised the fact that the so called bio-absorbable/biodegradable and high end DES did not have adequate clinical evidence to support their claim of 'superiority' and should not be given preferential price. They also referred to the deliberations done during the NLEM Sub-Committee meeting on coronary stents which decided against categorisation within DES or any special category to BVS. They also referred to the study published in 'Lancet' in 2016 which concluded that the BVS showed an increased risk of 'stent thrombosis'. Indigenous manufacturers also emphasised that if any differential and higher prices were given to imported stents, that would cause a death-blow to the Indian industry and would be against the spirit of Government's 'Make in India' Campaign. They strongly expressed their reservations on some hospitals/doctors giving undue importance to USFDA or European certificates and discriminating against 'Made-in-India' products.

(c) Both the coronary stent importers and manufacturers, however, did emphasise the need for a higher price cap and mentioned that huge margins are paid to distributors and hospitals (including doctors) in the existing business model. Further they needed to work in symbiotic relationship with the doctors for training them, taking product feedback and for making necessary improvements. They also suggested that as the hospitals acted as 'de facto' retailers in case of coronary stents, the Price to Hospitals (PTH) may be taken as PTR for the purpose of price fixation and a reasonable retailer (hospital) margin may be considered in consultation with the hospitals. Both importers and the Indian manufacturers were opposed to taking CGHS price or cost of production or even landed cost as benchmark since, as per their arguments, those prices neither reflected the actual market conditions, nor was such an option provided for, under DPCO, 2013. They unanimously mentioned that stents being provided to CGHS were among the lowest category of DES and many patients had to pay out-of-pocket, if they went for 'higher quality' stents. This practice, as per their view, had been officially provisioned for by CGHS and was a known practice by all hospitals availing CGHS rate contract.

(d) The civil society representatives were clearly against the idea of sub-categorisation of coronary stents in the DES category and on this issue they supported the stand of Indian manufacturers. They emphasised the point that all categories of DES were the same and that multinational importers resorted to the practice of changing brand names and batches in order to charge higher prices in name of ill-defined and clinically 'unverified innovations'.

They also submitted documents with regard to one such company which had accepted this fact in an affidavit filed with DCGI for licensing purpose stating that their new product was similar to an earlier product. They also expressed their views that PTH should not be treated as PTR because PTH data was alarmingly inflated and the data provided by the manufacturers was not 'independent' data and could not be relied upon without independent verification. Moreover, as per these groups, the PTH based option of price fixation would defeat the very purpose of price fixation. Civil society representatives held the view that CGHS rates or the cost of production data could be taken as benchmark for price fixation on which a reasonable margin to distributors and hospitals could be provided for. They also pleaded for CGHS rates on the ground that general public should be given the same benefits of lower prices as Central Government Staff. On the issue of separate categorisation of BVS, they vehemently opposed the suggestion and also referred to the study published in Lancet, which suggested higher risks of thrombosis in case of BVS.

(e) The Hospital and Nursing Home Associations and related institutions claimed that they needed to invest substantially on capital investment - construction and running of the healthcare facilities; hence the need to realise returns for various services including cardiac procedures and any margin taken by them is only 'legitimate returns' just as in the case of any other service industry where huge capital is deployed. They also mentioned that they were not to be equated with other 'retailers' as their job and responsibilities were wider and much more elaborate than just dispensing medicines (stents). Some of them stated that they charged the entire procedure as a 'package' and cost of the stents was not taken separately in real terms. During discussions, they also expressed apprehension that capping of stent prices may not result in passing on of benefits to consumers, as charges of other heads might increase, including multiple 'stenting', prolonged hospitalisation and even angioplasties getting converted to bypass surgeries apart from increased procedure charge etc. This apprehension was expressed by civil society groups as well. The hospital groups also emphasised that capping the stent prices may compromise the standards of services of the hospitals and also have an adverse impact on medical tourism in the country where India has a competitive advantage and has the potential to acquire leadership position in Asia. Healthcare providers, in general, were against the idea of price cap or any cap on the margins to hospitals, or treating them as 'retailers'.

(f) During discussions with cardiac experts, many eminent cardiologists, including many working in private sector, supported sub-classification within the DES category and said that it was adequately supported by evidence based on 'user experience' and 'preferences of cardiac surgeons' and that there was a strong case of sub categorisation of DES and also BVS. These experts suggested that there should be a matrix of classification, although there was no consensus on the number/ parameters of categories to be made. On the contrary, few cardiologists were of the clear view that at present all DES are at par, in view of the fact that those which were claiming to have 'superiority' and charging higher, had no supporting clinical data on 'superiority'. These doctors also expressed doubts whether NPPA had the expertise and legal powers to alter something which was decided by NLEM Core Committee and confirmed by the Department of Pharmaceuticals. On the question of recommendations of the NLEM Sub-Committee, the supporters of sub-classification in DES expressed that most of the cardiologists in the NLEM Sub-Committee on stents were from Government sector and hence the issue was not properly dealt with and remained inconclusive. The cardiologists, except few, on being questioned on their 'concerns' about pricing part of the stents, said that they would 'like to have latest technology' based stents in order to meet their 'professional requirements' for safety of patients and that they would not mind if the same could be provided by manufacturers at lower prices, but that was practically difficult. By and large, cardiac professionals denied the 'general perception' that their choices were governed by monetary considerations rather than purely professional or therapeutic considerations.

(g) The coronary stent distributors pointed out that the distribution network of stents was quite different from that of other drugs because it was dependent on one particular product unlike other distributors or chemists doing business in a plethora of drugs. They emphasised that the distributors needed to invest on an inventory of stents of all makes, prices and specifications and needed to be constantly in touch with hospitals and doctors. The expiry or obsolescence cost is to be borne by the distributors as manufacturers/marketers do not take back the inventory. They also said that they generally got their payments after 2-3 months from hospitals/CGHS stream while they needed to purchase the stents against advance payments from the manufacturers. Informally they suggested that they needed at least 40% margin on the price to distributors (PTD) in order to meet all obligations and to stay in business. Basically they were also opposed to price capping but mainly emphasised ensuring adequate margins to distributors.

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(h) The industry associations like CII, ASSOCHAM, FICCI, AdvaMed, AiMED, MTAI, and others emphasised the need for differentiation within DES and suggested that distinct innovative DES including cutting edge BVS should be kept out of purview of price control, to enable future R&D and growth and also in the interest of patients. Further, this would also enable the Indian devices manufacturing industry to grow at par with foreign manufacturers, and price control was likely to arrest this growth. They, too, like the industry representatives, maintained that CGHS prices or cost of production based or landed cost based pricing should not be made the benchmark for the price fixation exercise as these provisions were not provided for in DPCO,2013. All these associations supported Price to Hospitals (PTH) based pricing with a provision for margins to hospitals based on negotiations with hospital associations. Thus, industry associations basically reflected the views of the manufacturers and importers.

5. In the light of the various points which emerged during stakeholders' consultations and taking a note of all the concerns, the Authority intensively deliberated on all the aspects of price fixation of coronary stents which are summarised as below:

(a) The first and the overall issue was whether the NPPA should consider a sub classification of Drug Eluting Stents (DES) and treat BVS as entirely distinct category, as strongly pleaded by multinational companies and several ca rdiac experts and hospitals & distributors, but vehemently opposed by the Indian manufacturers (except for a few exceptions), few eminent cardiologists and also the civil society and health advocacy groups. The Authority examined the entire report of the Sub-Committee of the NLEM Core Committee (constituted to examine the essentiality of cardiac stents by the Ministry of Health and Family Welfare) where this subject was discussed in great detail by large number of eminent cardiologists and other stakeholders. The NLEM Sub-Committee, after intensive deliberations, had classified cardiac stents in two categories - (i) Bare Metal Stents (BMS) and (ii) Drug Eluting Stents (DES) which included metallic and Bioresorbable Vascular Scaffold (BVS)/Bio-degradable stents. The Authority also took note of the fact that the Department of Pharmaceuticals after detailed analysis of the matter finally notified coronary stents as part of Schedule I of the DPCO, 2013 with the same classification as was done by the Sub Committee of the NLEM Core Committee. During the stakeholders' consultations with the multinational importers of coronary stents they were asked to submit documentary evidence in support of the superiority of BVS/ Biodegradable and other cutting edge DES. However, no such

document was presented to NPPA till the holding of this meeting which could be treated as independent, verifiable and widely accepted evidence of 'superiority' as per Indian or globally accepted clinical norms. The stent importers had, during the stakeholders' consultation, accepted that there was no fresh clinical evidence in support of their 'high end' products to establish 'superiority' of one DES over other. On the contrary, few reports were submitted by civil society groups which reported higher incidence of stent 'thrombosis' with the usage of BVS. The Authority also took note of the fact that in spite of USFDA approval of such BVS stents, the superiority of these stents in terms of 'superior therapeutic rationale', is still being debated in the US and that USFDA ap proval took almost three years to be granted. The Authority also took note of the document submitted by the civil society groups, which related to an affidavit filed by one multinational stent manufacturer/importer that their newer brand of DES was the same as the earlier one.

(a.ii.) In the given situation, the Authority after intensive deliberations decided to consider the same classification as provided in the Report of the Sub-Committee of the Core Committee of NLEM 2015 and the amended Schedule I of the DPCO, 2013 as notified by Department of Pharmaceuticals, as NPPA did not have the mandate to alter the Schedule I entry, unless some special feature or special therapeutic rationale, distinguishable from other similar products was established under Para 11(3)and 11(4) of DPCO, 2013. The Authority did realise that some incremental innovations were taking place and that incremental benefits could be attributed in case of few stents in terms of one or more parameters but overall 'superiority' as recognised by USFDA, European or Indian regulator has still not been established. The Authority also took note of the fact that under DPCO, 2013, the Government had already provided a window for 'special ceiling' or 'special retail' price for manufacturers who are able to prove product 'superiority' in terms of special therapeutic rationale under paras 11(3)&(4) of DPCO, 2013. It was realised that once the uniform ceiling prices are fixed, the importers/manufacturers can apply to NPPA for special prices based on special therapeutic feature claimed, and supported by independent and verifiable evidence and independently examined by the Committee of Experts of NPPA. This will take care of the scope for future innovation, R&D, new product development and also the availability of so called 'cutting edge' products to Indian patients through imports or indigenous production.

(b) On the methodology of price fixation, NPPA collected official data on landed cost and cost of production of indigenous manufacturers etc., but the information on PTD, PTH and

MRP was mostly based on the data provided by importers and manufacturers. The Authority noted that the data provided by manufactur ers was not independent sources of data and unverified by NPPA or any official agency. IMS (Health) or AIOCD-AWACS (Pharmatrac) are independent sources of data. Even though these are private companies, these at least provide data which is more independent than the data from interested parties themselves. It was found that data given by companies, in many cases, was not provided on the format and several manufacturers having substantial market share qualified their information as 'provisional' or 'unverified' or 'representative'. One major manufacturer/importer mentioned that data was 'based on some 'assumptions' and PTH was 'indicative' while others qualified data with observations such as 'based on rate contract between company and the hospitals'. The Authority also found that out of about 13 licensed domestic manufacturers (based on database of Central Drugs Standards Control Organisation), actual data was provided by only 9; and out of 24 companies importing stents, actual data was provided by only 5 companies. It was also realised that the trade channel of coronary stent is unlike that of other drugs as coronary stents are not sold through normal retailers/chemists. Broadly, most of the importers/manufacturers have their distributors/C&F agents who in turn provide the stents to the hospitals/nursing homes and the hospitals seem to operate as retailers, at least in terms of billing to the end user/consumer/patient, but not in the legal framework as licensed retailers, as in the case of other medicines under Drugs & Cosmetics Act. Some companies were found to be in direct link with the hospitals and had rate contracts which varied between hospitals. The hospital associations and other such stakeholders claimed that their role could not be equated with usual retailers, as they did not keep inventories of coronary stents and did much more than simply buying and selling stents implying that hospitals be given adequate margins without being treated as retailers in legal terms. The status of hospitals in the supply chain and the trade channel remained inconclusive as per the provisions of the DPCO,2013.

(c) Analysis of the data also showed that there was huge trade margin involved in the stents' trade channel. The Authority also took note of the minimum and maximum landed cost, PTD, PTH and MRP for BMS and DES, for domestic manufacturers and importers as uploaded on NPPA's website of NPPA on 16th January, 2017. The trade margins confirmed the general perception that the margins were exorbitant and irrational, indicating vulgar 'profiteering' at every level and mostly at the level of hospitals, and that the existing trade channel had failed to eliminate the chances of unethical practices in the context of a

traumatised patient suffering heart ailment and reaching a hospital. The level of average margins ranging between maximum 436% (BMS) to 654% (DES) at the level of hospitals indicated a failed market system where asymmetry of information has resulted in unethical practices and exorbitant prices for coronary stents.. The maximum trade margin of distributors was found to be 194% (BMS) and 196% (DES). In comparison, the margin at the level of manufacturers/importers was modest, in terms of average maximum of 56% (BMS) and 27% (DES). The margins itself proved the existence of a failed market system further aggravated by information asymmetry, providing grounds for unethical practices.

(d) The Authority also took note of the Hon'ble Supreme Court judgment in Glaxo India Limited vs. UOI reported in (2014) 2 SCC 753, which dealt with the implementation of notified prices for the benefit of consumers, and which had referred to the prefatory statement made by the Hon'ble Supreme Court in Cynamide India Limited (1987) 2 SCC 722 as worth noticing, wherein the Court observed:

> *"2. Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining foodstuffs and life-saving drugs is diabolic. It is a menace which has to be fettered and curbed. One of the principal objectives of the Essential Commodities Act, 1955 is precisely that. It must be remembered that Article 39(b) enjoins a duty on the State towards securing 'that the ownership and control of the material resources of the community are so distributed as best to subserve the common good".*

(e) Having considered all the provisional options of price fixation it was realised that given the state of market data and other official as well as company provided data available with the NPPA, the Authority was constrained from fixing the ceiling prices of coronary stents under the normal procedure under paras 4, 5, and 6 of DPCO, 2013 as in the case of other scheduled drugs. It was realised that market based pricing system as provided for under DPCO, 2013 as standard procedure failed to address the disproportionately high trade margins. The Authority observed that considering PTH as PTR will lead to exorbitant ceiling price which would defeat the objective of price capping. In the given scenario, the Authority took a conscious decision that unless reliable PTH data was available, the Authority would not be able to fix the ceiling prices of coronary stents, taking into account (PTH) as demanded by manufacturers/importers because analogy between hospitals and retailers cannot be stretched beyond a point for the purpose of actual ceiling price fixation and further such an exercise would defeat the entire objective of keeping stent prices affordable for the common man. The Authority deliberated that the final ceiling price needed to address the requirement

for a 'fair price' to public and, also not deny the industry, scope for 'fair returns' and adequate margins for future innovation.

(f) The Authority, having considered the fact that ceiling price fixation under standard procedure may not be possible, also realised that NPPA is under statutory obligation under Para 17(1) of DPCO, 2013 to notify the prices of coronary stents within a period of sixty days from the date of notification under Schedule I of DPCO, 2013 (that is, by February 20, 2017). The Authority also realised that it was under legal obligation to comply with the directions of the Hon'ble High Court of Delhi order dated 22.12.2016 in W.P.(C)11085/2016 [Birender Sangwan Vs. Union of India and others] scheduled for hearing on 1st of March, 2017.

6. Apart from the above, the matter is of great significance to public welfare, and concern has been raised on the exorbitant prices being charged to 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 price fixation. The Authority observed that, therefore, extraordinary circumstances did exist, warranting immediate action under Para19 of DPCO, 2013, notwithstanding anything contained in DPCO, 2013, to fix ceiling prices of coronary stents, urgently, in public interest. Accordingly, the Authority decided to determine the prices of coronary stents under Para 19. The expression in the language of para 19, 'notwithstanding anything in this order' provides flexibility to explore all available options and even work out any innovative method of price fixation, provided it is logical, reasonable and takes care of the interest of all the stakeholders.

(a) The Authority also noted that the price fixation notifications issued for certain formulations under paragraph 19 of the DPCO, 2013 by the NPPA on 10th July 2014 have been upheld by the Hon'ble High Court of Bombay in its judgment dated 26thSeptember 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 ofpublic 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...."

The Authority also observed that SLP (C) 30089/2016 filed by Indian Pharmaceutical Alliance was dismissed on 24th October 2016 by the Hon'ble Supreme Court of India.

7. After taking a considered view to proceed under Para 19, the Authority examined the prospective ceiling prices within the types of options which were uploaded vide OM No. 19(837)/2016/DP/NPPA-Div. II dated 4th January, 2017 for stakeholders' feedback and subsequently the calculations on 12th January, 2017 and clarificatory OM dated 13th January, 2017. The Authority also took note of all the representations received on the method of calculation of ceiling prices and the representations of provisional prices based on different options.

8. The Authority deliberated the entire issue of price fixation and worked out several methods of price fixation and corresponding prices.

(a) The Authority unanimously decided that the option of PTH as PTR should not be considered since hospitals are not legal entities as retailers and the margins at the level of PTH are too exorbitant to defeat the basic objective of price capping, along with the fact that this data is neither independently verified nor verifiable. It was also unanimously held that since hospitals are not doing value addition in the supply chain of coronary stents nor having any financial stake in the trade, hospitals need to be dissociated from the trade channel for the fixation of the prices of coronary stents, except for minimal hospital handling charges, which could be reasonably built within the ceiling price. The Authority also decided that the CGHS based pricing method should not be taken as a benchmark because CGHS prices are based on open tenders and based on supply of bulk quantities where the manufacturers normally quote at bottom level. CGHS based prices do not provide scope for margins for future R&D, innovation and growth and may not be good from the public health policy perspective in the long term. Moreover, CGHS prices are meant for reimbursement and may not reflect real price, and despite being official prices, these may not leave margins for future innovation.

(b) The Authority found that the data of price to distributor was a close -to -be -reliable 'market data', apart from landed cost data which certainly was the most reliable data on pricing. The PTD data is provided by the manufacturers based on their actual invoices and not dependent on information from distributors or hospitals. Similarly, the landed cost data has been obtained from official sources, which is verified, and indicated the price range of imported coronary stents in the country. However, the landed cost data does not indicate the fair price of indigenously manufactured coronary stents.

(c) In order to take into consideration the fair prices of domestic manufacturers, the Authority took the cost of production data (as provided by the manufacturers) into consideration, as no official data could be obtained from concerned official agencies. Thus, for the final price calculations, the Authority considered the options of price to distributor (PTD), the landed cost (LC) and the cost of production (COP) data and excluded CGHS and PTH for the reasons discussed earlier. The Authority also took note that price determination based on these parameters (cost of production and landed cost) were legally provided for under cost based pricing system under DPCO 1995 as reasonable methods for fair price fixation of drugs . The Authority was conscious of the fact that CoP and the LC based methods were not provided for under DPCO, 2013 but did not rule out these methods, simply because Govt. switched over to a market based system which was presumably more industry friendly than the cost based system existing under DPCO, 1995. The Authority was aware that even the existing market based system has been challenged in a writ petition by the civil society group viz. AIDAN which had prayed to the Hon'ble Supreme Court to direct the Govt. to adopt the old pricing system i.e. cost based system The Authority was clear about the objective of the exercise of fixation of a reasonable and 'fair for all' price level in a transparent manner. To this end, the Authority looked into the merits of all options. The Authority discussed that a system suitable for DPCO, 1995 could require moderation and flexibility in the present context, for which the Authority decided to keep an open mind. Under Para 19 of DPCO, 2013, the Authority has the flexibility not to restrict the price determination methodology to PTR based pricing, but also has the option to look into other methods of fair price fixation. The price to distributor (PTD) based methodology fitted broadly within the purview of market based price determination method, better than PTH in the given circumstances.

9. The Authority accordingly went ahead to work out prices based on the averages of PTD, LC and CoP, independently, and separately worked out rational price levels based on these broad options as follows: -

(a) DES (including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents)

i) Taking data on price to distributors into account, the Authority took note of the fact that hospitals are not acting as retailers. The Authority discussed that the existing margins in the trade of scheduled drugs, with a separate provisioning of 16% margin over the PTR as retailer margin cannot be and need not be provisioned in case of

coronay stent market, as there are no legally identifiable retailers in the stent trade channel. As per the different business models in coronary stents trade, some companies have direct contracts with the hospitals and no distributor is involved, while some are based exclusively on distributor system; it was also discussed that mostly companies tended to adopt a mix of both the options. The Authority also recognised that in keeping inventory of coronary stents of different companies at different prices and specifications in their stocks, although without deploying any significant capital, the hospitals seemed to spend a fraction of the cost of coronary stents, which could be termed as 'handling charges'. The provisioning of 8% 'overall trade margin' (excluding inbuilt margins of manufacturers/importers) was allowed for price calculation and it was decided that NPPA will leave this margin to be deployed by the manufacturers/ importers as per their discretion in the trade channel according to their business model, provided it is within the ceiling prices fixed and notified by NPPA. The Authority felt that this also adequately covered 'hospital handling charges' (by whatever name called), which did not need to be separately indicated or accounted for. Under this methodology of PTD plus 8% added trade margin, the price of DES was worked out to be Rs.29,600/. The provision of 8% margin for distributors is a long standing accepted norm

ii) The Authority also did the exercise of taking average landed cost which was provided under DPCO, 1995 with a provision for maximum 50% margin (MAPE) over landed cost. In order to take care of future R&D and innovation and also to set rest the apprehensions that the so-called 'high end' products could be withdrawn from Indian markets and may not be imported in future if no differentiation was done within DES, the Authority took the average landed cost based price and added an additional 25% margin over the DPCO, 1995 prescribed margin of maximum 50%. Adding 75% margin to average landed cost of DES incidentally provided the same figure of Rs. 29,600/- for DES.

iii) The exercise based on cost of production based prices took note of 100% margin (MAPE) over cost of production as provided for under DPCO, 1995.The Authority also took note of the fact that in the given situation, unlike LC data, the cost of production data was totally unverified and data on cost of the inputs or packing charges or other ingredients fixed by the Government under DPCO, 1995 was not available in the

existing situation. In respect of data, in some cases, the manufacturers had also stated that the cost included marketing expenses/other expenses etc. Accordingly, the Authority, instead of giving 100% maximum margin on COP as provided for under DPCO,1995, decided to give a reduced margin of 75%, at par with imported stents, and the price arrived under this method was found to be Rs.30,200/- for DES.

iv) After getting the two figures of Rs. 29,600/- and one of Rs. 30,200/- by three different but officially adopted methods of price fixation (under DPCO, 1995 and DPCO, 2013) the Authority felt that the figure of Rs. 29,600/- seemed to be the convergence figure, and in the given situation, it could be taken as a fair and reasonable price for Drug Eluting Stents (DES) taking into account all the market variables and factors and also taking care of all the stakeholders' interests reasonably.

b) Bare Metal Stents (BMS)

For BMS, before applying the same methodology in detail, the Authority consciously took note of the fact that the usage of BMS has been constantly on the decline. This the Authority felt, could perhaps be explained in terms of increasing income and purchasing powers of middle and lower middle classes, enabling them to afford DES; and partly on account of promotional tactics of indigenous manufacturers and importers for promotion of DES. Higher safety results and better therapeutic rationale of DES over BMS were also additional factors prompting a preferential use of DES to BMS. Going by the declining usage of BMS, it was decided not to follow the same provisioning of margins as for DES. The Authority after detailed discussions decided to consider the option of 8% margin over Price to Distributor (PTD) for working out the price of BMS. This worked out to Rs. 7,260/ unit of BMS.

The Authority felt that the above prices were reasonable enough, given that there was no specific retail channel for coronary stents, existence also of direct sales to hospitals and considering the high end value market of coronary stents. Further, ceiling price thus capped would cover margins across the trade channels, working from the level of manufacturer/importer to the end user i.e. consumers/patients.

10. The Authority was conscious of the fact that once the new ceiling prices are notified the existing coronary stent marketing channels will be shaken and the 'old system' will be forced

to restructure and redefine the role of all the stakeholders in the larger interest of public. Ultimately, the new system will provide all stakeholders with an opportunity to reform the entire system, and increase affordability of necessary cardiac interventions for those patients who so far could not opt for angioplasty because of exorbitant costs. For importers, the increased affordability will provide a larger market, and lower trading overheads, which will help bring down the prices of so called 'high end' and 'latest generation stents'. The importers have the scope to benefit immensely from this exercise of NPPA, on account of economy of scales. The landed cost has already factored in manufacturing cost, innovation cost and fair margin before the products landed on Indian shores. It is in fact a kind of transfer pricing. Similarly the rationalised trade structure will stand to the benefit of Indian manufacturers as well, with fixed margins, whereby they can get their products adopted by intervention cardiologists on the basis of pure merit and therapeutic benefits rather than unethical considerations. The flexibility to deploy 8% overall trade margins (excluding manufacturers/importers) level will equally benefit importers and manufacturers, and those having direct contracts could use it for meeting the so-called 'handling charges' etc., to hospitals since there will be no distributors or retailers in between to share the margins. The system of existing distributors will also be redefined as per trade requirements of supply chain and economy of scales in the light of about 6 million CVD patients in India (annually), and will take care of interests of distributors' network.

11. The Authority also deliberated that that price capping of stents should not lead to disruption in supplies, non-essential multi-stenting during angioplasties, increased performance of bypass surgeries, increased cost of cardiac procedures, prolonged (unnecessary) stay in hospitals or increase in doctors' fee or procedure charges. The Authority decided to write to Ministry of Health and Family Welfare, SDCs and State Health Authorities, and the MCI and IMA to be more vigilant and to take preventive and monitoring measures in this regard. The Authority also decided to request the Ministry of Health & Family Welfare to be vigilant about the quality of coronary stents under CGHS, in view of the fact that the manufacturers, hospitals and few other stakeholders did accept that the quality of stents supplied under CGHS rate contract was very 'basic'. If the perception is wrong, the same should be dispelled by random inspections and clinical trials and issue of necessary clarifications to restore the faith of CGHS patients. This monitoring exercise needs to be made regular and stringent, keeping public interest in mind.

12. The Authority also reviewed the status of prices of other devices classified as drugs and decided that NPPA office should make necessary modifications in the IPDMS software to adapt to the reporting necessity of coronary stents and other devices. The Authority decided to take up on priority, monitoring of prices of devices, (which are not under price control), but reporting more than 10% increase in prices, and to take strict action against erring industries. The Authority also expressed that if similar exploitative system prevails in case of other devices, it will not shy away from bringing those devices under price control, exercising its jurisdiction under Para 19 of DPCO, 2013, in public interest.

13. The Authority decided that all other terms and conditions of price compliance as prescribed by the NPPA for scheduled drugs and applicable in case of coronary stents shall be applicable as per the provisions of DPCO, 2013, including separate billing of coronary stents by hospitals to patients and the display of price lists.

Sharmilajoseph

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