

मिसिलस.- 8(27)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(27)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 159/27/2016/F

Proceeding No : 159/27/2016/F

**Minutes of the 159<sup>th</sup> and 27<sup>th</sup> meeting of Authority under DPCO, 2013 held on 29.3.2016 at 11.00 AM.**

- I. 1. The 159<sup>th</sup> overall meeting of the Authority, which is the 27<sup>th</sup> under the DPCO, 2013 was held on 29<sup>th</sup> March, 2016 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 Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iii) Shri R. Chandrashekar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

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 & Admn.)
- (iii) Shri A.P.S. Sawhney, Director (Overcharging)
- (iv) Shri Anand Prakash, Dy. Director (M&E)
- (v) Shri Baljit Singh, 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 26<sup>th</sup> Meeting held on 24.02.2016.**

Since no comments were received on the minutes of 158<sup>th</sup> and the 26<sup>th</sup> Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

**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).**

3.1 The Authority was apprised of the revised Schedule-I of DPCO, 2013 (i.e. NLEM, 2015) in detail and the methodology and quantum of work involved in the price fixation exercise.

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3.2 It was informed that as per plain reading and counting, there are total 875 formulations (approx) in the amended Schedule-I of DPCO, 2013 as per NLEM, 2015. There are 76 duplicate formulations (i.e. which are appearing in more than 1 therapeutic group), 426 common formulations (i.e. which are appearing in NLEM, 2011 as well as NLEM, 2015) and 373 new formulations (i.e. which are added in NLEM, 2015 only, not appearing in NLEM, 2011) in the NLEM, 2015. Keeping in view the explanatory notes and the position explained in the agenda regarding scope/coverage of ceiling prices to be fixed for the medicines mentioned in revised Schedule-I, the list of the new formulations may rise from 373 to 1000-1500 (approx) considering the different variants of 373 formulations. Further, the variants of common 426 formulations may also rise to 1000-1500 (approx). Thus, for approx. 2000-3000 formulations the ceiling prices will require to be fixed/ notified as per revised Schedule-I, under DPCO, 2013.

3.3 Ceiling prices of medicines in revised Schedule-I are being fixed in accordance with the provisions of DPCO, 2013.

3.4 It was observed that para 4 of DPCO 2013 which lays out the methodology for the calculation of ceiling prices of scheduled formulations listed in Schedule-I states thus 'Average Price to Retailer',  $P(s)$  is (the sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover (MAT) of that medicine)/(total number of such brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover for that medicine).

3.5. It was pointed out that the Authority in the First meeting under DPCO, 2013 (held on 12.6.2013), had decided that the MAT value of specific medicines manufactured by the same company in different brand names/generic names, may be clubbed for determining the market share (of more than or equal to 1%) for working out the ceiling prices of medicines included in Schedule-I. However, it is observed that when average PTR is worked out on the basis of the above principled decision taken at the 1<sup>st</sup> Authority meeting, in some cases, the average PTR and hence the ceiling prices work out to be higher than the figure worked out as per para 4 of DPCO, 2013; and lower in some cases. This was deliberated in detail, and it was decided that whenever application of the principle based on the decision of the 1<sup>st</sup> Authority meeting works to the benefit of the consumer resulting in lower PTR and ceiling price, the ceiling price would be worked out accordingly.

3.6 The exercise of fixation of ceiling prices has been done initially in the case of some medicines of certain therapeutic groups for which data was available viz:- Analgesics, antipyretics, non steroidal anti inflammatory medicines; anticonvulsants/antiepileptics; anti infective medicines, antimigraine medicines, antiparkinsonism medicines, medicines affecting blood, cardiovascular medicines, gastrointestinal medicines, hormones, other endocrine medicines; muscle relaxants; vitamins and minerals.

3.7 The PTR and ceiling prices of 103 scheduled medicines in the revised Schedule-I have been worked out accordingly considering the methodology given below:-

(a) The base data considered is data of Pharma Trac August, 2015. Two ceiling prices are fixed i.e. one with immediate effect and another effective from 01.4.2016 (after giving the effect of reduction in WPI @ 2.7015%).

(b) After deliberations, the Authority decided that price fixation of ceiling prices of other Scheduled formulations in amended Schedule-I shall be done on the basis of data for August 2015 in Pharma Trac. In such cases, ceiling price shall be fixed and notified after giving the effect of WPI, which is reduction @ 2.7015% w.e.f. 01.4.2016. The Authority took note of the precedent followed in such price fixations (e.g. S.O. 835(E) dated 25.3.2015 when ceiling price of scheduled formulations was fixed giving the effect

positive WPI). Such principle was followed consistently for fixation of ceiling prices under original Schedule-I of DPCO, 2013. It was decided that this principle will be followed uniformly, while fixing the ceiling prices of scheduled formulations under revised Schedule-I and the ceiling price will be effective from the date of notification.

(c) The lowest average PTR as worked out in accordance with the principles given below will be considered for determining the ceiling prices.

- (i) PTR of all brands and generic versions of medicines with market share (MAT value) equal to or more than 1% (as per para 4 of DPCO, 2013),
- (ii) Even when some brands/generic versions of a medicine of a company have less than 1% market share, the market share of all such versions of that medicine of that company is clubbed for the purpose of determining whether the company's market share is equal to or more than 1%. PTR of all such generic/branded versions are considered for working out average PTR.
- (iii) When some brands of a medicine of a company are sold in different packs and when such packs have less than 1% market share, the market share of such different variants of that medicine of that company is clubbed for the purpose of determining whether the company's market share is equal to or more than 1%. PTR of all such variants are also considered for working out the average PTR.

3.8 In case of common scheduled medicines also in revised Schedule-I, the base data will be considered as per para 9(5) of DPCO, 2013 (i.e. August 2015 data) for fixation of ceiling prices.

3.9 A Table showing the list of 103 scheduled formulations and approved ceiling prices is given below:

| Sl. No. | NLEM Number | Formulation        | Strength         | Unit for ceiling price | Ceiling price with immediate effect | Ceiling price (w.e.f. 01.4.2016) |
|---------|-------------|--------------------|------------------|------------------------|-------------------------------------|----------------------------------|
| 1       | 2.1.5       | Paracetamol        | Tablet 650 mg    | per Tablet             | 1.76                                | 1.71                             |
| 2       | 2.3.1       | Allopurinol        | Tablet 300 mg    | per Tablet             | 7.13                                | 6.94                             |
| 3       | 2.4.2       | Hydroxychloroquine | Tablet 400 mg    | per Tablet             | 11.39                               | 11.08                            |
| 4       | 5.1         | Carbamazepine      | CR Tablet 200 mg | per Tablet             | 1.48                                | 1.44                             |
| 5       | 5.1         | Carbamazepine      | CR Tablet 400 mg | per Tablet             | 2.91                                | 2.83                             |
| 6       | 5.1         | Carbamazepine      | Tablet 400 mg    | per Tablet             | 3.16                                | 3.07                             |
| 7       | 5.2         | Clobazam           | Tablet 5 mg      | per Tablet             | 4.90                                | 4.77                             |
| 8       | 5.2         | Clobazam           | Tablet 10 mg     | per Tablet             | 8.61                                | 8.38                             |
| 9       | 5.4         | Levetiracetam      | Tablet 250 mg    | per Tablet             | 5.58                                | 5.43                             |
| 10      | 5.4         | Levetiracetam      | Tablet 500 mg    | per Tablet             | 11.28                               | 10.97                            |
| 11      | 5.4         | Levetiracetam      | Tablet 750 mg    | per Tablet             | 17.33                               | 16.86                            |
| 12      | 5.4         | Levetiracetam      | ER Tablet 750 mg | per Tablet             | 16.58                               | 16.13                            |
| 13      | 5.5         | Lorazepam          | Tablet 1 mg      | per Tablet             | 1.97                                | 1.92                             |
| 14      | 5.5         | Lorazepam          | Tablet 2 mg      | per Tablet             | 2.39                                | 2.33                             |
| 15      | 5.8         | Phenytoin          | Tablet 300 mg    | per Tablet             | 4.51                                | 4.39                             |
| 16      | 5.8         | Phenytoin          | ER Tablet 300 mg | per Tablet             | 5.54                                | 5.39                             |
| 17      | 5.9         | Sodium valproate   | Tablet 300 mg    | per Tablet             | 3.79                                | 3.69                             |
| 18      | 6.1.1.2     | Mebendazole        | Tablet 100 mg    | per Tablet             | 2.80                                | 2.72                             |
| 19      | 6.1.2.1     | Diethylcarbamazine | Tablet 100 mg    | per Tablet             | 1.30                                | 1.26                             |
| 20      | 6.2.1.6     | Cefadroxil         | Tablet 500 mg    | per Tablet             | 3.85                                | 3.75                             |
| 21      | 6.2.1.8     | Cefixime           | Tablet 400 mg    | per Tablet             | 21.05                               | 20.48                            |
| 22      | 6.2.2.3     | Clarithromycin     | Tablet 250 mg    | per Tablet             | 26.70                               | 25.98                            |
| 23      | 6.2.2.3     | Clarithromycin     | Tablet 500 mg    | per Tablet             | 47.07                               | 45.79                            |
| 24      | 6.2.4.2     | Cycloserine        | Capsule 250 mg   | per Capsule            | 51.78                               | 50.38                            |

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|    |           |   |   |             |        |        |
|----|-----------|---|---|-------------|--------|--------|
| 25 | 6.2.4.4   | <i>Ethionamide</i>                                    | Tablet 250 mg   | per Tablet  | 15.06  | 14.65  |
| 26 | 6.2.4.5   | <i>Isoniazide</i>                                     | Tablet 300 mg   | per Tablet  | 1.91   | 1.86   |
| 27 | 6.2.4.7   | <i>Levofloxacin</i>                                   | Tablet 250 mg   | per Tablet  | 4.20   | 4.09   |
| 28 | 6.2.4.7   | <i>Levofloxacin</i>                                   | Tablet 500 mg   | per Tablet  | 6.40   | 6.23   |
| 29 | 6.2.4.7   | <i>Levofloxacin</i>                                   | Tablet 750 mg   | per Tablet  | 10.42  | 10.14  |
| 30 | 6.2.4.8   | <i>Linezolid</i>                                      | Tablet 600 mg   | per Tablet  | 31.51  | 30.66  |
| 31 | 6.2.4.9   | <i>Moxifloxacin</i>                                   | Tablet 400 mg   | per Tablet  | 24.16  | 23.51  |
| 32 | 6.2.4.13  | <i>Rifampicin</i>                                     | Capsule 600 mg  | per Capsule | 11.07  | 10.77  |
| 33 | 6.3.3     | <i>Fluconazole</i>                                    | Tablet 400 mg   | per Tablet  | 29.80  | 28.99  |
| 34 | 6.4.3.1.1 | <i>Abacavir</i>                                       | Tablet 300 mg   | per Tablet  | 44.98  | 43.76  |
| 35 | 6.4.3.1.2 | <i>Abacavir (A) + Lamivudine (B)</i>                  | Tablet 600 mg (A) + 300 mg (B)                          | per Tablet  | 45.95  | 44.70  |
| 36 | 6.4.3.1.6 | <i>Tenofovir (A) + Lamivudine (B)</i>                 | Tablet 300 mg (A) + 300 mg (B)                          | per Tablet  | 41.05  | 39.94  |
| 37 | 6.4.3.1.7 | <i>Tenofovir (A) + Lamivudine (B) + Efavirenz (C)</i> | Tablet 300 mg (A) + 300 mg (B) + 600 mg (C)             | per Tablet  | 94.27  | 91.71  |
| 38 | 6.4.3.2.2 | <i>Nevirapine</i>                                     | Tablet 200 mg   | per Tablet  | 13.65  | 13.28  |
| 39 | 6.4.3.3.1 | <i>Raltegravir</i>                                    | Tablet 400 mg   | per Tablet  | 143.13 | 139.25 |
| 40 | 6.4.3.4.1 | <i>Atazanavir (A) + Ritonavir (B)</i>                 | Tablet 300 mg (A) + 100 mg (B)                          | per Tablet  | 94.15  | 91.60  |
| 41 | 6.4.3.4.2 | <i>Darunavir</i>                                      | Tablet 600 mg   | per Tablet  | 159.20 | 154.88 |
| 42 | 6.4.3.4.3 | <i>Lopinavir (A) + Ritonavir (B)</i>                  | Tablet 200 mg (A) + 50 mg (B)                           | per Tablet  | 43.47  | 42.29  |
| 43 | 6.4.4.1   | <i>Entecavir</i>                                      | Tablet 0.5 mg   | per Tablet  | 72.98  | 71.00  |
| 44 | 6.4.4.1   | <i>Entecavir</i>                                      | Tablet 1 mg   | per Tablet  | 115.95 | 112.81 |
| 45 | 6.4.4.3   | <i>Ribavirin</i>                                      | Capsule 200 mg  | per Capsule | 76.50  | 74.43  |
| 46 | 6.4.4.4   | <i>Sofosbuvir</i>                                     | Tablet 400 mg   | per Tablet  | 636.56 | 619.31 |
| 47 | 6.4.4.5   | <i>Tenofovir</i>                                      | Tablet 300 mg   | per Tablet  | 45.01  | 43.79  |
| 48 | 6.5.3.1.1 | <i>Artemether (A) + Lumefantrine (B)</i>              | Tablet 20 mg (A) + 120 mg (B)                           | per Tablet  | 11.94  | 11.62  |
| 49 | 6.5.3.1.1 | <i>Artemether (A) + Lumefantrine (B)</i>              | Tablet 40 mg (A) + 240 mg (B)                           | per Tablet  | 15.39  | 14.97  |
| 50 | 6.5.3.1.1 | <i>Artemether (A) + Lumefantrine (B)</i>              | Tablet 80 mg (A) + 480 mg (B)                           | per Tablet  | 22.10  | 21.50  |
| 51 | 6.5.3.1.5 | <i>Clindamycin</i>                                    | Capsule 150 mg  | per Capsule | 13.24  | 12.88  |
| 52 | 6.5.3.1.5 | <i>Clindamycin</i>                                    | Capsule 300 mg  | per Capsule | 21.61  | 21.02  |
| 53 | 7.2.1     | <i>Flunarizine</i>                                    | Tablet 5 mg   | per Tablet  | 2.63   | 2.56   |
| 54 | 7.2.1     | <i>Flunarizine</i>                                    | Tablet 10 mg  | per Tablet  | 4.50   | 4.38   |
| 55 | 7.2.2     | <i>Propranolol</i>                                    | Tablet 80 mg  | per Tablet  | 4.76   | 4.63   |
| 56 | 9.1       | <i>Levodopa (A) + Carbidopa (B)</i>                   | CR Tablet 100 mg (A) + 25 mg (B)                        | per Tablet  | 3.19   | 3.10   |
| 57 | 10.1.6    | <i>Hydroxyurea</i>                                    | Capsule 500 mg  | per Capsule | 11.73  | 11.41  |
| 58 | 10.2.5    | <i>Tranexamic acid</i>                                | Tablet 500 mg   | per Tablet  | 15.89  | 15.46  |
| 59 | 10.2.6    | <i>Warfarin</i>                                       | Tablet 1mg  | per Tablet  | 2.30   | 2.24   |
| 60 | 12.1.1    | <i>Acetylsalicylic acid</i>                           | Effervescent/ Dispersible/ Enteric coated Tablet 75 mg  | per Tablet  | 1.17   | 1.14   |
| 61 | 12.1.1    | <i>Acetylsalicylic acid</i>                           | Tablet 150 mg   | per Tablet  | 0.39   | 0.38   |
| 62 | 12.1.1    | <i>Acetylsalicylic acid</i>                           | Effervescent/ Dispersible/ Enteric coated Tablet 150 mg | per Tablet  | 1.15   | 1.12   |
| 63 | 12.1.3    | <i>Diltiazem</i>                                      | SR Tablet 90 mg   | per Tablet  | 8.90   | 8.66   |
| 64 | 12.1.5    | <i>Isosorbide-5-mononitrate</i>                       | SR Tablet 30 mg   | per Tablet  | 4.67   | 4.54   |
| 65 | 12.1.5    | <i>Isosorbide-5-mononitrate</i>                       | SR Tablet 60 mg   | per Tablet  | 6.09   | 5.92   |
| 66 | 12.1.6    | <i>Isosorbide dinitrate</i>                           | Tablet 5 mg   | per Tablet  | 0.73   | 0.71   |

|     |          |                      |  |            |       |       |
|-----|----------|----------------------|--|------------|-------|-------|
| 68  | 12.1.6   | Isosorbide dinitrate | Tablet 10 mg                           | per Tablet | 0.71  | 0.69  |
| 69  | 12.1.7   | Metoprolol           | SR Tablet 25 mg                        | per Tablet | 3.85  | 3.75  |
| 70  | 12.1.7   | Metoprolol           | SR Tablet 50 mg                        | per Tablet | 5.50  | 5.35  |
| 71  | 12.3.1   | Amlodipine           | Tablet 10 mg                           | per Tablet | 4.84  | 4.71  |
| 72  | 12.3.7   | Ramipril             | Tablet 2.5 mg                          | per Tablet | 4.74  | 4.61  |
| 73  | 12.3.7   | Ramipril             | Tablet 5 mg                            | per Tablet | 7.48  | 7.28  |
| 74  | 12.3.9   | Telmisartan          | Tablet 20 mg                           | per Tablet | 3.47  | 3.38  |
| 75  | 12.3.9   | Telmisartan          | Tablet 40 mg                           | per Tablet | 6.29  | 6.12  |
| 76  | 12.3.9   | Telmisartan          | Tablet 80 mg                           | per Tablet | 9.59  | 9.33  |
| 77  | 12.6.1   | Atorvastatin         | Tablet 10 mg                           | per Tablet | 5.23  | 5.09  |
| 78  | 12.6.1   | Atorvastatin         | Tablet 20 mg                           | per Tablet | 12.68 | 12.34 |
| 79  | 12.6.1   | Atorvastatin         | Tablet 40 mg                           | per Tablet | 18.41 | 17.91 |
| 80  | 13.1     | Donepezil            | Tablet 5 mg                            | per Tablet | 10.72 | 10.43 |
| 81  | 13.1     | Donepezil            | Tablet 10 mg                           | per Tablet | 15.30 | 14.89 |
| 82  | 20.1.3   | Ranitidine           | Tablet 150 mg                          | per Tablet | 0.71  | 0.69  |
| 83  | 21.1.4   | Methylprednisolone   | Tablet 8 mg                            | per Tablet | 4.87  | 4.74  |
| 84  | 21.1.4   | Methylprednisolone   | Tablet 16 mg                           | per Tablet | 8.51  | 8.28  |
| 85  | 21.4.1.1 | Glimepiride          | Tablet 1 mg                            | per Tablet | 3.42  | 3.33  |
| 86  | 21.4.1.1 | Glimepiride          | Tablet 2 mg                            | per Tablet | 5.44  | 5.29  |
| 87  | 21.4.1.4 | Metformin            | Tablet 500 mg<br>(controlled release)  | per Tablet | 1.82  | 1.77  |
| 88  | 21.4.1.4 | Metformin            | Tablet 1000 mg<br>(controlled release) | per Tablet | 3.47  | 3.38  |
| 89  | 21.4.1.4 | Metformin            | Tablet 1000 mg<br>(Immediate release)  | per Tablet | 3.43  | 3.34  |
| 90  | 21.7.2   | Levothyroxine        | Tablet 12.5 mcg                        | per Tablet | 1.30  | 1.26  |
| 91  | 21.7.2   | Levothyroxine        | Tablet 25 mcg                          | per Tablet | 1.25  | 1.22  |
| 92  | 21.7.2   | Levothyroxine        | Tablet 50 mcg                          | per Tablet | 0.94  | 0.91  |
| 93  | 21.7.2   | Levothyroxine        | Tablet 75 mcg                          | per Tablet | 1.24  | 1.21  |
| 94  | 21.7.2   | Levothyroxine        | Tablet 88 mcg                          | per Tablet | 1.46  | 1.42  |
| 95  | 21.7.2   | Levothyroxine        | Tablet 100 mcg                         | per Tablet | 1.14  | 1.11  |
| 96  | 21.7.2   | Levothyroxine        | Tablet 125 mcg                         | per Tablet | 1.46  | 1.42  |
| 97  | 21.7.2   | Levothyroxine        | Tablet 150mcg                          | per Tablet | 1.47  | 1.43  |
| 98  | 23.2     | Baclofen             | Tablet 5 mg                            | per Tablet | 5.07  | 4.93  |
| 99  | 23.2     | Baclofen             | Tablet 10 mg                           | per Tablet | 9.83  | 9.56  |
| 100 | 23.2     | Baclofen             | Tablet 20 mg                           | per Tablet | 13.54 | 13.17 |
| 101 | 26.1.4   | Misoprostol          | Tablet 200 mcg                         | per Tablet | 15.92 | 15.49 |
| 102 | 30.4     | Cholecalciferol      | Tablet 1000 IU                         | per Tablet | 3.58  | 3.48  |
| 103 | 30.4     | Cholecalciferol      | Tablet 60000 IU                        | per Tablet | 23.87 | 23.22 |
| 104 | 30.6     | Pyridoxine           | Tablet 100 mg                          | per Tablet | 5.34  | 5.20  |

4. Agenda Item no. 4: Price fixation cases of new drugs which were launched in the market without applying for price approval under Para 5 of DPCO, 2013 from NPPA- (i) Hyoscine Butylbromide 10mg + Paracetamol 325mg Tablet manufactured by M/s Acme Pharmaceuticals and marketed by M/s German Remedies (A division of M/s Cadila Healthcare i.e. Zydus Cadila) and (ii) Methyldopa 500mg tablet manufactured by M/s Medibios Lab. Pvt. Ltd. and marketed by M/s Wockhardt Ltd.

4.1 The Authority discussed the case in detail and approved the retail price of Rs. 3.76/tablet for the tablet manufactured by M/s Acme Pharmaceuticals and marketed by M/s German Remedies (a division of M/s Cadila Healthcare i.e. Zydus Cadila).

4.2 The Authority discussed the case in detail and approved the retail price of Rs. 4.46/tablet for the tablet manufactured by M/s Medibios Lab. Pvt. Ltd. and marketed by M/s Wockhardt Ltd.

*Sharmilay Joseph*

**5. Agenda Item no. 5: Overcharging on Without Price Approval (WPA) case- Buscogast Plus Tablet.**

5.1 The issue was discussed in detail. 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. After deliberations, it was decided that as the company had filed application in Form – I for price approval, penalty need not be levied from the company.

**6. Agenda Item no.6: Guidelines regarding identification & initiating action for recovery in cases of Overcharging by companies under DPCO, 2013.**

6.1 The Agenda was discussed in detail. The Authority approved the draft guidelines with the following modifications in the guidelines as detailed below:-

5 (c) If the company has not responded to the show cause notice, NPPA after issuing one reminder giving another 15 days shall fix the price of such medicine and calculate the overcharged amount based on the differences between the prices. A penalty amount not less than 100% of the principal amount shall necessarily be imposed in such cases and demand notice be issued, giving 30 days time to deposit the money.

5 (d) However, if the company had applied to NPPA as prescribed and the price fixation was pending at NPPA, a lower penalty or its waiver may be considered on case to case basis.

5(e) If the company fails to deposit the money within the stipulated time and does not respond to NPPA, a recovery certificate to concerned Collector will be issued; and NPPA will start prosecution of the company under section 7 of the E.C. Act, after issuing a pre-prosecution notice giving 15 days' time to the company to respond.

6(c) In all test sample purchase cases, NPPA shall also take action against concerned retailer under para 26 or 27, as the case may be, for over- pricing.

**7. Agenda Item no.7: Any other item with the permission of Chair.**

**(a) Shortage of Human Albumin**

Major pharmaceutical companies producing human albumin had earlier raised issue regarding non-availability of plasma at the prescribed rates resulting in decreased production of human albumin. It was decided that Ministry of Health and Family Welfare (MoHFW) may be requested to issue necessary instructions to blood banks for ensuring availability of plasma at reasonable rates.

It was also decided that M/o Health & Family Welfare/M/o Commerce may be requested to initiate suitable steps for stopping the export of human albumin till such time the issue of shortage of human albumin is addressed.

**(b) Shifting of Scheduled formulations to Non-scheduled formulations due to amendment of Schedule-I of the DPCO, 2013**

(i) The Authority took note of S.O. 644(E) dated 02.3.2016 whereby NPPA notified the revised ceiling prices of 530 scheduled formulations, after applying WPI of (-) 2.7105%; and (ii) notification no. S.O. 701(E) dated 10.3.2016 of Department of Pharmaceuticals (DOP) whereby the Schedule-I of DPCO 2013, has been revised.

*Shamulay Joseph*

The Authority, after detailed discussions took the following decisions in respect of the new non-scheduled formulations:-

- a. Reference date for price revision for any non-scheduled formulation is the date succeeding twelve months of last notified ceiling price or last revised MRP (in case of those formulations being sold at sub-ceiling prices), as the case may be.
- b. Reference date of transition from scheduled to non-scheduled category in respect of these formulations is 10.3.2016. Last ceiling price as notified on 02.3.2016 for such formulations (or sub-ceiling price with corresponding reduction due to decline in WPI, as per paragraph 16(4) of DPCO, 2013), shall be kept frozen and maintained as MRP for twelve months from 01.4.2016 by the manufacturers of such formulations; and thereafter increase upto ten percent in MRP will be allowed as per paragraph 20 of DPCO, 2013.

  
(Dr. Sharmila Mary Joseph K)  
Member Secretary