Consumer Awareness, Publicity and Price Monitoring (CAPPM)

1. Introduction

1(i) Pharmaceutical Industry is a knowledge based and dynamic industry. It has grown many folds in the recent past. With announcement of new National Pharmaceutical Pricing Policy (NPPA), 2012 and the DPCO, 2013, there has been a shift of regulation of prices from economic and cost based criteria to essentiality and market based criteria which entails enormous task of creating and maintaining data base and strengthening the existing monitoring system of NPPA. Further, NPPA does not have its own field units to forge linkages with the activities of the State Drug Controllers (SDCs) and State Drug Inspectors and it is also not equipped with adequate officers for conducting field investigation and inquiries for strict implementation/enforcement of its mandate.

1(ii) Pronab Sen Task Force (2005) set up by the M/o Chemicals and Fertilizers has strongly recommended for establishment of a live linkage of NPPA with the SDCs through a dedicated Price Monitoring Cell which should be fully funded by Central Government for a period of at least five years.

1(iii) Parliamentary Standing Committee on Chemicals and Fertilizers has time and again recommended for strengthening the existing monitoring and enforcement system as well creation of NPPA cells at the States/Uts level in order to carry out the mandate of NPPA in an effective manner. The Committee in its 38th Report has specifically stated that the relevance of strengthening the existing monitoring and enforcement system as well creation of NPPA cells at the State/UTs level should be re-examined again in the backdrop of the new Drug Price Control Order (DPCO), 2013.

1(iv) Keeping in view the changing scenario in the pharma sector and the recommendations of various Committees, NPPA has revised with the approval of Department of Pharmaceuticals revise/modify the existing scheme and also by renaming it as Consumer Awareness, Publicity and Price Monitoring.

1(v) The revised/modified scheme i.e. Scheme of Consumer Awareness & Publicity and Price Monitoring will be implemented at the Central level by the National Pharmaceutical Pricing Authority (NPPA) and at the State level by the registered societies of Price Monitoring and Resource Units (PMRUs).

1(vi) Accordingly, the Government has initiated a new component i.e setting up Price Monitoring And Resource Units (PMRUs) at the State/Union Territories under Central Sector Scheme of Consumer Awareness, Publicity and Price Monitoring that would provide all necessary support to the State Drug Controllers and NPPA. Each Unit will function under the direct supervision of the concerned State Drug Controller. PMRUs will be key collaborating partners of NPPA with information gathering mechanism at the grassroots level. PMRUs will also ensure that the benefits of the DPCO (revised from time to time) trickle down at the grassroots level.

1(vii) The National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals implements the Scheme named “Consumer Awareness, Publicity and Price Monitoring (CAPPM)” Scheme. The Scheme has two components viz., (a) National

component and (b) State component. The national component covers the expenditure for publicity through print and electronic media, organizing seminars for consumer awareness, purchase of samples etc.

1(viii) Under the State Component of the Scheme, it is planned to set up Price Monitoring and Resource Units (PMRUs) in the States. PMRU is a registered society under the Chairmanship of the State Drug Controller. The representatives of NPPA/State Health Department, civil societies and other stakeholders are members of the PMRU.

1(ix) The scheme Consumer Awareness, Publicity and Price Monitoring (CAPPM) was approved by the Standing Finance Committee (SFC) in its meeting held on 29/10/2015 wherein it was decided that: "The scheme initially, at the pilot stage, will be implemented in the States of Maharashtra, Gujarat, Odisha, Haryana, Kerala, Assam and Manipur. Subsequently, the scheme will be followed up for implementation in other States also".

1(x) However, as per 2nd meeting of SFC held on 26.10.2016, it was decided that: "The scheme will be implemented in phases and the States to be covered are to be decided by the NPPA".

2. Aims and Objectives of the Scheme:

2.1 The objectives of the above project are to disseminate message to the consumers and general public about-

(i) Ceiling prices of scheduled medicines notified by the Government;
(ii) Permissible price increase for scheduled and non-scheduled medicines;
(iii) Availability of medicines at reasonable prices and promotion of generic medicines;
(iv) Precautions to be taken while purchasing medicines from chemists/retailers such as checking the MRP (which includes all taxes), manufacturing and expiry dates, price list of medicines, obtaining bill for the medicines bought, etc;
(v) Requirement for prescription of medicines by their generic names also;
(vi) Price control and monitoring and enforcement activities of NPPA;
(vii) Lodging complaints to NPPA for any violation including violation of DPCO, 2013 as well as unethical practices in the Pharma sector.

3. Part A- Activities to be undertaken by NPPA:

(i) Awareness Creation: Creation of general awareness about the availability of medicines, ceiling prices of medicines fixed by the Government, precautions to be taken while purchasing medicines and about the functioning of NPPA. This will be done through issue of advertisements in the print media and through radio jingles and tele-films.

(ii) Organizing Conferences/ Seminars/ Workshops: It is proposed to organize national and State level Conferences/Seminars/Workshops with stakeholders.

(iii) Purchase of test samples by NPPA: NPPA does not have separate fund for purchase of test samples of medicines for its price monitoring activities and to ensure compliance of notified ceiling prices. It is mainly dependent on various complaints received from the State Drug Controllers and individuals for monitoring price compliance. In order to effectively carry out the monitoring the enforcement activities, it has been, therefore, proposed to strengthen the enforcement activities by

way of wide geographical coverage for purchase of test samples of medicines.

3.1 The Scheme is expected to create general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the Government, precaution to be taken while purchasing medicines and about the functioning of NPPA. This will improve the accessibility of quality medicines at a reasonable price to the common people of the country and facilitate both clinically effective and cost effective treatment.

Guidelines for Setting up Price Monitoring and Resource Units (PMRUs) at the State / Union Territories under the Central Sector Scheme of Consumer Awareness, Publicity and Price Monitoring

1. Introduction:

The National Pharmaceutical Pricing Authority (NPPA), constituted vide Gazette notification dated 29.08.1997 [Resolution No.159 (No.33/7/97-PI.I)], has been entrusted with the task of (i) price fixation/ revision of prices of scheduled formulations [as listed in Schedule I of the Drug (Prices Control) Order DPCO] as revised by the Government from time to time, (ii) monitoring and enforcement of the notified prices, (iii) providing inputs to the Government for policy formulation and on other specific issues pertaining to availability, accessibility and affordability of medicine for all.

1.1 The National Pharmaceutical Pricing Policy 2012, implementing authority for the policy inter-alia, provides that NPPA would be provided required organizational and financial support so as to enable it to implement the various provisions of the policy as well as the DPCO, 2013 in a speedy, effective and transparent manner.

1.2 The DPCO, 2013 also provides for monitoring the production and availability of scheduled formulations, active pharmaceutical ingredients contained in the scheduled formulation and the manufacturer of scheduled formulations.

1.3 Such jobs, particularly relating to collection, compilation / creation and analysis of "market based data" were hitherto not undertaken by NPPA. These have now become an integral part of the working of the NPPA under the NPPP, 2012 and DPCO, 2013 regime on a continual basis. The attainment of such task by NPPA would be possible only with necessary support from the States / UTs through the Price Monitoring and Resource Units (PMRUs).

2. Objective of setting up the PMRUs:

2.1 The objectives of setting up the PMRUs are to provide necessary technical assistance to the State Drug Controllers and NPPA towards:

i. Monitoring the notified prices of medicines, detection of violation of the provisions of DPCO (revised from time to time), pricing compliance and ensuring availability of medicines;

ii. Monitoring the price movement of scheduled and non-scheduled formulations based on periodical returns filed by the industry, revision of price of scheduled formulations by the manufacturer based on the annual increase in Wholesale Price Index (WPI) as

per provisions contained in the DPCO, oversee the price of non-scheduled formulations so that the prices of such formulations are not increased beyond 10% annually;

iii. Collection and compilation of market based data of scheduled as well as non-scheduled formulations and analyse them.

iv. Collect test samples of medicines at the retailed market whenever required;

v. Conduct training, seminars and workshops at the State and District levels for consumer awareness and publicity covering aspects relating to the role and functions of NPPA, availability of scheduled and non-scheduled medicines at reasonable prices and care to be taken while purchasing the medicines from the chemists/ retailers and availability of alternative cheaper medicines. The resource persons for the training will be provided by the State Drug Controller and by the NPPA, whenever required; and

vi. Any other related works as assigned to them by the NPPA from time to time.

2.2 The above task requires constant interaction with various stakeholders viz. concerned State Government Departments, State Drug Controllers, consumer groups, etc. for forging linkages. Thus, the PMRUs will be the key collaborating partners of NPPA at the State / UT level for forging linkages with various stakeholders. While the PMRUs will render necessary technical assistance to the State Drug Controllers and NPPA, the Units will, however, have no authority to reach out, communicate and interact with any of the pharma industry.

3. Activities to be undertaken by PMRUs:

3.1 PMRUs will be registered societies of atleast seven members under the Chairmanship of the State Drug Controller and representatives of NPPA/State Health Department, civil societies and other stakeholders. PMRUs will be the key collaborating partners of NPPA with information gathering mechanism at the grass roots levels. They will create public awareness so that benefits of the DPCO (revised from time to time) trickle down to the grassroots levels. Their activities will include market-based data collection, compilation; analysing and management of scheduled/non-scheduled formulations; Monitoring of price movement of scheduled/non-scheduled formulations; Collection/purchase of test samples of medicines; Advertisement and publication of newsletter, etc; conducting Training, seminars and workshops at the State and District levels for consumer awareness and publicity.

3.2 Purchase of samples by PMRUs/States/UTs: The States/UTs will be given grants to purchase samples of medicines to monitor the prices of drugs. The basic purpose is to ensure that the benefits of the DPCO trickle down to the grassroots levels. Samples purchased, along with cash memos/vouchers, will be sent to NPPA so that NPPA can take further action as per provisions of DPCO.

4. Categories of States/ UTs for setting up the PMRU:

4.1 For the purpose of staffing and providing the required infrastructure to the PMRU, States / UTs have been categorised as follows:

Category I - States/ UTs having population of more than 3% of total population;

Category II - States/ UTs having population of less than 3% but more than 1% of total population; and

Category III - States/ UTs having population of less than 1% of total population.

Category I	Category II	Category III
1. Andhra Pradesh	1. Assam	1. Andaman & Nicobar Islands
2. Bihar	2. Chhattisgarh	2. Arunachal Pradesh
3. Gujarat	3. Delhi	3. Chandigarh
4. Karnataka	4. Haryana	4. Dadra & Nagar Haveli
5. Madhya Pradesh	5. Jammu & Kashmir	5. Daman & Diu
6. Maharashtra	6. Jharkhand	6. Goa
7. Odisha	7. Kerala	7. Himachal Pradesh
8. Rajasthan	8. Punjab	8. Lakshadweep
9. Tamil Nadu	9. Telangana	9. Manipur
10. Uttar Pradesh		10. Meghalaya
11. West Bengal		11. Mizoram
		12. Nagaland
		13. Puducherry
		14. Sikkim
		15. Tripura
		16. Uttarakhand

4.2 The above categorisation has been made for the purpose of staffing and infrastructure as detailed in para 5and 6 below.

5. Administrative Structure of PMRUs:

5.1 The PMRUs will function under the direct supervision of the concerned State Drug Controller as per the duties assigned to it. The strength of the PMRUs and its structure will be as under:

Category I	Category II	Category III
State Drug Controller		
1. Project Coordinator	1. Project Coordinator 2. Two (2)Field	1. Project Coordinator 2. One (1)Field

2. Three (3) Field Investigators 3. Three (3) Data Entry Operators	Investigators 3. Two (2) Data Entry Operators	Investigator 3. One (1) Data Entry Operator

6. Proposed Expenditure per PMRU:

A. One-time Non-Recurring Expenditure:

6.1 The scale of expenditure under the Non-Recurring grants would be as under:

States/ UTs Category	**One time expenditure per PMRU (Rs in Lakh)**
Category I (i) 7 Computers (Hardware and Software) (ii) 7 Office Tables (iii) 7 Chairs (iv) 7 Almirahs (v) 1 Air Conditioner (vi) Internet Connectivity	7.00
Category II (i) 5 Computers (Hardware and Software) (ii) 5 Office Tables (iii) 5 Chairs (iv) 5 Almirahs (v) 1 Air Conditioner (vi) Internet Connectivity	5.00
Category III (i) 3 Computers (Hardware and Software) (ii) 3 Office Tables (iii) 3 Chairs (iv) 3 Almirahs (v) 1 Air Conditioner (vi) Internet Connectivity	3.00

6.2 Any expenditure over and above the grant provided for under the nonrecurring expenditure will have to be borne by the respective State/ UT.

B. Recurring Expenditure:

6.3 The scale of expenditure under recurring grants per annum would be:

Category I – Rs. 55 lakh
Category II – Rs. 49 lakh
Category III – Rs. 42 lakh

6.4 The provisioning for recurring grants per PMRU has been worked out as under:

(i) Salary/ Honorarium of Staff

States/ UTs Category	**Designation**	**Salary/ Honorarium per annum (Rs.)**
Category I	Project Coordinator	45,000X1X12=5,40,000
	Field Investigators	25,000X3X12=9,00,000
	Data Entry Operators	15,000X3X12=5,40,000
	Total	**19,80,000**
Category II	Project Coordinator	45,000X1X12=5,40,000
	Field Investigators	25,000X2X12=6,00,000
	Data Entry Operators	15,000X2X12=3,60,000
	Total	**15,00,000**
Category III	Project Coordinator	45,000X1X12=5,40,000
	Field Investigator	25,000X1X12=3,00,000
	Data Entry Operator	15,000X1X12=1,80,000
	Total	**10,20,000**

(ii) Market Based Data collection, compilation, analysis and management of scheduled/ non-scheduled formulations; Monitoring of price movement of scheduled/ non-scheduled formulations; Collection/ purchase of test samples of medicines; Advertisement and Publication of Newsletter, etc.

States/ UTs Category	**Expenditure per PMRU per annum (Rs in Lakh)**
Category I	11.20
Category II	10.00

Category III	7.80

(iii) Conducting Training, Seminars and Workshops at the State and District levels for Consumer Awareness and Publicity

Items	Expenditure per PMRU per annum (Rs in Lakh)
a) Conduct training, seminars and workshops at the State level for consumer awareness and publicity (**One programme every year**)	4.00
b) Conducting training, seminars and workshops at the District levels for consumer awareness and publicity (**Ten programmes every year**)	20.00

6.5 Any expenditure over and above the grant provided for under the recurring expenditure will have to be borne by the respective State/ UT.

7. Method for Releasing Funds:

7.1 In the first year, 90% of the non-recurring expenses and six months advance for recurring expenses would be released as first instalment to the selected States / UTs. The remaining non-recurring expenses and recurring expenses for the next six months will be released as second instalment on the basis of actual expenditure of first six months of funds received as first instalment.

7.2 From the second year onwards, recurring grants will be released in two instalments. 50% recurring grants would be released as first instalment at the beginning of the year after going through the performance, actual expenditure and availability of utilisation certificate of funds received in the previous year. Second instalment during the year will be released on receipt of the actual expenditure.

7.3 Release of further grants will depend upon the performance, actual expenditure and production of utilisation certificate of funds received (duly signed by SDC/FDA in the format prescribed by Government of India under **GFR 12- C,** Rule **212 (1)** for this purpose **(Annexure-IV))** in the previous year.

8. Method of Recruitment of Staff:

8.1 The project staff i.e. Project Coordinator, Field Investigator and Data Entry Operator will be recruited through an outsourcing agency on a contract basis as per the prevailing practice followed by the concerned State Government. The Recruitment Committee will comprise of the following:

1. Principal Secretary/ Secretary (Health) or Chairman

representative nominated for the purpose

2.	State Drug Controller	Convenor
3.	One State Government official concerned with Health & Drug Administration (to be co-opted by the Chairman)	Member

9. Educational Qualifications:

9.1 The educational qualifications and experience requirement for the various project staff will be as under:

1. Project Coordinator: Bachelor degree in Pharma with at least 2 years experience in the pharma sector. Candidates who possess Master Degree in Pharma shall be given preference.

2. Field Investigator: Bachelor degree in Pharma. Candidates who have practical experience in pharma sector shall be given preference.

3. Data Entry Operator: Graduate or equivalent having good knowledge of computer viz. windows, MS office, internet, etc.

10. Orientation programme for the Staff of the PMRU:

10.1 The project staff of each PMRU will have to undergo orientation training programme in NPPA at least twice every year in order to update themselves on the recent development on various issues related to DPCO, 2013.

11. Office Space for the PMRUs:

11.1 The concerned State Government / UT Administration will have to provide the required office space for the PMRU free of cost. All other expenses (both nonrecurring and recurring expenses) will be met under the Scheme. Any expenditure incurred over and above the grant provided for under the recurring and nonrecurring expenditure will have to be borne by the respective State/ UT.

12. Review of Performance of PMRUs:

12.1 Member Secretary (NPPA) and the Director in charge of Monitoring & Enforcement Division will oversee the implementation of the project. At the Central level, the progress of the Scheme will be monitored by the Director of Monitoring & Enforcement Division on monthly basis. At the state level, the monitoring of the progress of PMRUs to be monitored by the concerned State Drugs Controller. The State Drugs Controller has to convene meeting of the PMRU Society every month by 10^{th} to monitor the progress of the scheme. A monthly report, clearly indicating the targets and other pre-determined parameters vis-a-vis achievements in this regard, will be sent to NPPA by 20^{th} of every month.

13. Auditing of the PMRUs:

13.1 Each PMRU will be required to get the audit done annually by 30th September and audit report submitted to NPPA in due course. Release of further grants will depend upon the performance, actual expenditure and production of utilisation certificate of funds received (duly signed by SDC in the format prescribed by Government of India for this purpose) in the previous year.

14. Impact assessment and further release of grant to the PMRUs:

14.1 Based on the monthly performance furnished by the State Level Committee, the NPPA would then make an impact assessment. The impact assessment along with the utilization certificate for funds (duly signed by SDC in the format prescribed by Government of India for this purpose) would form the basis for further release of funds.

15. Period of Implementation

15.1 As of now, the revised/ modified scheme is proposed to be implemented in two years from the financial year 2018-19 to 2019-20. The scheme may be reviewed for extension thereafter.