Department of Pharmacy GP (Uttawar)

D P C O

Unit 7th
(Pharmaceutical jurisprudence)

INDEX

- What is DPCO
- Objective
- DPCO 2013
- Pricing of SCHEDULE Formulation
- Pricing of NON-SCHEDULE Formulation
- Calculation of retail price of formulation
- Case study of Pricing of Cefixime 200 mg tablet and Ondansetron HCL injection (2mg/ml)

DPCO

- The drug price control order (DPCO) is an order issued by the government under the Essential Commodities Act which enables it to fix the prices of some essential bulk drugs and their formulations.
- The origin of this control dates back to 1970 when for the first time the government placed limits on profitability of pharmaceutical companies.

Objective of DPCO

- To ensure availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality.
- Promoting the rational use of drugs in the country To encourage cost-effective production with economic sizes

DPCO 2013

- The government has notified the DPCO 2013 under the Essential Commodities Act, 1955, which will give power to the NPPA to regulate prices of 348 essential drugs along with their specified strengths and dosages under NLEM 2011.

❖ Main Features of the DPCO 2013

1) The new order will bring 348 drugs & their 652 formulations under price control.
2) The new policy uses a market-based pricing mechanism against the earlier proposed cost-plus method. The ceiling price would be calculated by taking the simple average of prices of all brands of a drug with a market share of 1% or more.

3) Margins of wholesalers & retailers have been cut down to 8% & 16% respectively.

4) Monitoring the M.R.P of Non-Scheduled formulation.

5)Control over Bulk Drug manufacturer.

6) Control over Formulation manufacturer

7)Drug producers will be permitted an annual increase in the retail price in sync with the wholesale price index.

Scheduled Formultion

- Scheduled formulation shall mean Formulation with Same strength and Same dosage form as in the schedule.
- If Dosage Form & Strength of a scheduled formulation are changed, it ceases to be a Scheduled Drugs
- **Example.**
- Amoxicillin Capsules 250mg is covered under schedule
- Amoxicillin Tablet 125mg shall not be called a Scheduled Drug

Non - Scheduled Formulation

- "Non-Scheduled Formulation" means a formulation, containing the molecule, the dosage and strengths of which are not specified in the First Schedule; (Non- NLEM Drug / Formulation)
- **Example**: Aceclofenac,Norfloxocin, Rabeprazole

New Drug / New Formulation

- A). **NLEM (National List of Essential Medicines)** Formulations with same specified dosage and strength as combined with another NLEM Formulations with same specified dosage and strength.
- **Example 1:**
- Paracetamol 500mg Tablet is Scheduled Formulation
- Diclofenac 50mg Tablet is Scheduled Formulation
- New Drug = Paracetamol 500mg + Diclofenac 50mg Tablet is New Drug/Formulation

B) **NLEM** Formulations with same specified dosage and strength as combined with another Non - NLEM Formulations

- **Example 1:**
- Paracetamol 500mg Tablet is Scheduled Formulation
- Aceclofenac 100mg Tablet is Non - Scheduled Formulation
- Paracetamol 500mg + Aceclofenac 100mg Tablet is New Drug

C) NLEM Formulations by changing its strength

- **Example 1**:
- Paracetamole 500mg Tablet is a Scheduled Drug
- Paracetamole 325mg Tablet is a New Drug

D) NLEM Formulations by changing its dosage

- **Example 1**:
- Diclofenac 50mg Tablet is a Scheduled Drug.
- Diclofenac 50mg Ointment is a New Drug.

Not New Drug

- **Example 1**
- Paracetamole 500mg is Scheduled Drug
- Aceclofenac 100mg is not Scheduled Drug
- Paracetamole 325mg + Aceclofenac 100mg is not Scheduled Drug and is not a New Drug under DPCO for price approval

PRICING OF SCHEDULED FORMULATION

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

- *Step1: First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be*

calculated as below:

Average Price to Retailer, P(s) = (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) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

- *Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:*

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

***Margin to retailer**: While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.*

***Maximum retail price*:**

(1)The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Ceiling price + Local Taxes as applicable

(2)The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Retail Price + Local Taxes as applicable

Calculation of retail price of formulation

- The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely:
- **R.P.** = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED. where"R.P." means retail price;
- **"M.C."** means material cost and includes the cost of drugs and other pharmaceutical aids used.
- **"C.C."** means conversion cost worked out in accordance with established procedures

- "P.M." means cost of the packing material used in the packing of formulation, including process loss.
- "P.C." means packing charges worked out in accordance with established procedures of costing.
- "MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;
- "E.D." means excise duty: Provided that in the case of an imported formulation.

CONCLUSION

- The cost of cefixime 200 mg tablet is Rs. 23.84 and if we consider MAPE as 100%,the basic price becomes

Rs. 47.56 + 47.56 X 6.18%(E.D.)= Rs. **50.49**

- AS PER NPPA NOTIFICATION CEFIXIME 200 MG PRICE IS 112.50
- The cost of Ondansetron HCL injection is Rs. 2.13 and if we consider MAPE as 100%,the price becomes

Rs. 4.26 + 4.26 X 6.18% (E.D.)= Rs. **4.52**

- AS PER NPPA NOTIFICATION ONDANSETRON(2MG/ML) 1 ML PRICE IS RS 7.37

Thank You..