

## PROCEDURE FOR PRICE FIXATION / REVISION OF BULK DRUGS

- As per DPCO, 1995 prices of scheduled bulk drugs are fixed by the NPPA.
- Following steps are involved in fixation/revision of bulk drug prices

:Step1: Identification of bulk drugs

Drug taken up for study on the basis of:-

- Validity period
- Concerned manufacturer/company
- Drug produced in the country for which no price has been notified under DPCO,1995

16

Step 2:Collection of data

- Data is collected by issuing questionnaire/Form I of DPCO, 1995/cost-audit report etc. and verification by plant visits, if required.

Step 3 : Preparation of actual cost statement

- Prepare on basis of data submitted / collected & verified during plant visit.

Step 4 : Preparation of Technical Parameters

- Technical parameters are prepared based on data submitted and collected.
- Plant capacity is assessed considering 330 working days for normal operation of plant leaving 35 days for scheduled maintenance of plant.
- The achievable production level is considered at 90% utilization of assessed capacity allowing 10% production loss on account of unforeseen break down.

17

#### Step 5 : Preparation of Estimated Cost

- The estimated cost for the pricing period are then prepared based on actual cost & the technical parameters.
- While projecting the future cost, an increment is recognized at 5% per annum in respect of salaries & wages. The customs duty and other taxes as per the current budget are considered.

#### Step 6 : Calculation of Fair price of bulk drug

- Fair price is calculated by providing returns as specified in sub Para (2), Para 3 of DPCO, 1995.

#### Step 7 : Fixation of maximum sale price of the drug

When the number of manufacturers of the said drug is more than one, the maximum sale price is fixed at 2/3rd cut off level or weighted average price, depending upon the situation.

#### Step 8 : Notification of bulk drug price in official Gazette

18

### 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.)*

19

- Step2.
- Thereafter, the ceiling price of the scheduled formulation i.e.  $P(c)$  shall be calculated as below:
- $P(c) = P(s) \cdot (1 + M/100)$ , 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

20

- *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

21