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INTERNAL GUIDLINE NO 3/2012

National pharmaceuticals Pricing Authority
Salient Features of Guidelines for Price Fixation/Revision of Bulk Drugs under DPCO,1995

S.No	Item	Particulars
1	**Introduction**	The Bulk Drug Division of NPPA is entrusted with the task of processing the proposals for fixing / revising the price of bulk drug under para 3(1) based on the Cost Price Study, after collecting data and visiting the plant of company and revising the price under para 3(5) based on the Adjustment Formula given in the CPS Report which covers raw materials and utilities. In addition to above, prices of bulk drugs are also fixed on suo-moto basis under para 11 of DPCO, 1995. These prices are fixed from time to time by notification in the official gazette.
2	**Collection of Data**	A letter to companies for collection of data in prescribed format is required to be issued at least before six months of expiry of the validity period of the existing price. The data/ information shall be collected by issuing questionnaire and company shall be asked to submit the information required in the questionnaire alongwith Form I of DPCO, 1995 and cost-audit report, annual report etc. Study shall be completed on the basis of available information, where no data/information received from the concerned manufacturers.
3	**Verification of Data by plant visits**	Plant visits to be made for verification of data and collection of additional data, understanding product, process etc. and holding discussions with the officials of the company. The additional information/ data required for CPS shall be communicated in advance to the company before undertaking the visit. In respect of this, the following guidelines may be considered. (i) If a single unit produces 90% or more of the total production in the country, the data of other unit(s) need not be studied in detail i.e. data of unit(s) producing 10% or less of the total production may not be considered for the purpose of price fixation provided that cost of production claimed by the unit(s) producing 10% or less of the production is higher than the cost of production of the major producer. (ii) If there are more than three producers of the bulk drug and a single producer holds 80% or more share of total production, the data relating to the remaining 20% of the total production may preliminarily be scrutinized. If the second unit producing more than 10% then this unit may also be studied for the purpose of price fixation. In case the third unit/company producing 10% or less is cost efficient, then this unit may also be studied. In case 70% of the total production is manufactured by one producer and balance 30% is produced by the second producer, both the units should be studied. If the balance 30% production is shared by two units equally, the data of these units may be scrutinized and the cost efficient unit out of the all may be taken up for detailed study.

4	**Preparation of Actual Cost**	Preparation of actual cost statement
5	**Discussion of Actual Cost of bulk drug with management of the companies**	Actual cost and the details of the bulk drug worked out on the basis of above to be shared and discussed with the management of the companies manufacturing the bulk drug.
6	**Preparation of Technical Parameters**	(i) Yields- The yield of bulk drug under study based on the major input materials is worked out keeping in view the theoretical requirement of input for the unit production of bulk drug. The yields achieved by the company during at least last 3 years are computed, yields adopted in previous study and current 15 consecutive batches are looked into to see the scope of improvement in future. The logical reason for decline/increase in the yields is discussed during the plant visit to units while opting the yield to be achieved by the company in future for working out fair price of the bulk drug. (ii) Capacity Assessment- In order to work out optimum level of production in the plant, the plant capacity is assessed considering the yield and their occupancy hours at each stage of production in terms of finished product. In the case where the production is carried out in dedicated plant, annual installed capacity is worked out based on the working pattern of the plant in i.e. daily number of shifts and number of days in a week. In the case of multipurpose plants, i.e. where production of more than one drug is carried out, the daily installed capacity is worked out and number of days in a year is allocated for the production of said drug keeping in view the past utilisation pattern. For assessing achievable production level, 330 number of days or average of actual working days for the last three years whichever is higher to be taken into the consideration. Designed capacity of the plant of bulk drug may also be kept into consideration while assessing the production capacity of plant. (iii) Schedule Maintenance of Plant & Machinery- Any chemical plant for effective operation requires proper maintenance of plant & machinery. 35 days in a year or average of last three years actual days utilized for scheduled maintenance of plant and machinery whichever is lower be considered while working out annual installed capacity. Apart from scheduled maintenance of plant and meeting another 10% loss of production is considered due to unscheduled maintenance of plant and machinery and other unforeseen break down/reason. In view of the above, the production levels adopted for working out fair price is always worked out at 90% of plant capacity utilisation. (iv) Norms of Raw Materials & Utilities- The norms of raw materials and utilities are worked out after considering the past performance atleast for last 3 years, norms adopted in previous study and analysing scope of improvement in recent 15 consecutive batches. (v) Research & Development- The Research & Development (R&D) activities of the company are looked into pertaining to production activity and bulk drug under study.

		(vi) Effluent Treatment Facilities- The details of effluent treatment facilities created by the company to treat the effluent before discharge is looked into in relation to parameters specified by respective State Pollution Control Authorities. (vii) Additions/Replacement to Plant & Machinery- The future additions/replacements to plant & machinery are considered for normal operation of plant and further improvement in capacity, if any. The value of such additions/replacements is allowed while working out fair prices of bulk drugs.
7	**Preparation of Estimated Cost**	a) Raw Materials- (i) Norms of consumption of raw materials are provided through the Technical Study/Assessment. (ii) The latest six month's rate of individual raw materials collected during the spot visit. The average purchase price of the latest six months after taking into account necessary adjustment of duties and taxes and the price trend of the raw materials, whichever is lower, shall also be considered. Inter firm comparison shall be made and justifications for rates adopted for the raw materials considered be explained. (iii) Appropriate treatment shall be given for taxes, duties, Cenvat / Modvat etc., The exchange rate for imported materials shall be adopted as per the existing practice followed in NPPA. (iv) Where there is sudden spurt in price of raw materials during latest six months period as compared to costed period, such abnormal increase are not to be recognised b) Utilities & Services- (i) Norms of consumption of utilities and services are provided through the Technical Study/Assessment to be considered. (ii) For rates of utilities and services the average of latest six months purchase rates and price trend, whichever is lower, shall be adopted for the purpose of determining normated cost of utilities and services. Inter firm comparison shall be made and reasons for rates adopted for the raw materials to be explained c) Conversion Cost/Overheads- While projecting the future cost of salaries & wages, an increment is recognised at 5% per annum. Wage agreement, if any, which has been finalized and signed is also recognised while preparing the estimates. In respect of other overheads of fixed/semi variable nature, increase at 2.5% per annum is made to cover the normal incremental effects. d) Depreciation- Depreciation is required to be projected for the pricing period. Keeping in view the depreciation rates, gross fixed assets and net fixed assets, depreciation for the future period i.e., pricing period is determined. Thereafter, depreciation and average net fixed assets for every year of the pricing period is determined and from this average depreciation for the product is arrived at for the pricing period. The future additions/replacements to plant & machinery are considered as per Technical Assessment. e) Packing Expenses- Packing material costs are determined with reference to consumption and rates of packing materials, net of MODVAT. In addition, labour or overhead expenses, utilities and services are used for packing should be taken after normation. f) Selling and Distribution Expenses- The incidence of selling and distribution expenses is calculated after taking into an increase at 2.5% per annum to cover the normal incremental effects, and after adjusting for

		fixed and variable nature of expense .
8	**Fixation of Fair Price of Bulk Drug**	Fixation of Fair Price of bulk drug:- Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995 as opted by the individual manufacturer a) Determination of Net Fixed Assets:- Fair price determined for a product should include a reasonable return on the funds employed. Funds are employed on fixed assets and working capital in any business. Fixed assets consist of land, building, machinery, furniture and fixture, etc. Net fixed assets for the product under study are directly identified and average net fixed assets for the pricing period are determined after taking into consideration the proposed additions in the plant & Machinery, ETP etc, as assessed by technical study. Where net fixed assets is not directly identifiable, then the net fixed assets shall be allocated to the bulk drug under study on a appropriate basis following the general costing principle and practice. Similarly, other common assets is also taken into consideration and allocated on appropriate basis. While considering additions/replacements to assets, their effect on capacity, processes, etc. are also considered. Revaluation of fixed assets and intangible assets is not to be considered for CPS. The assessed capacity as at para 9(ii) and 9(iii) above shall be considered for deriving the estimated production and for arriving at the per unit incidence of net fixed assets for the pricing period. b) Working Capital:- Working Capital equal to four months cost of sales minus depreciation or average working capital requirement based on last three years annual accounts or actual requirement as assessed for the product, whichever is lower shall be adopted for allowing return. Fixed Deposit and Inter Corporate Deposit shall not be considered as a part of working capital. c) Return:- Return would be provided as per 3(2) of DPCO, 1995.
9	**Price of bulk drug/ Industry**	Price of the Bulk Drug:- (i) In case of a single producer; price determined on the basis of above guideline would be the price of the bulk drug/industry. (ii) If there are more than one manufacturer producing the same bulk drug and inter se variation in estimated fair selling price of their product is not more than 10%, then in such case the price determined for individual manufacturers are arranged in the ascending order of prices. The price of the manufacturer at 2/3rd cut off level of total estimated production so worked out is compared with the weighted average price of the units undertaken for the study and the lower of the two i.e. the price at 2/3rd cut off level or weighted average price of the units is recommended as the price for the industry. (iii) If there are more than one manufacturer producing the same bulk drug and inter se variation in estimated fair selling price of their product is more than 10%, then an appropriate proposal to be made before the Authority after taking into consideration import parity price, export parity price, prevailing market price, demands/supply status, quantity of imports/exports etc.

29/10/12

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