

6.1 Pricing of scheduled Formulations

The Drugs (Prices Control) Order, 1995 provides that the Government may fix the MRP for a bulk drug in the first schedule. The MRP is calculated using formula prescribed in the DPCO. The formula contains a variable element 'MAPE' (Maximum Allowable Post-manufacturing Expenses) which is the sum total of all costs incurred by a manufacturer upto retailing and includes trade margin and margin for the manufacturer. DPCO prescribes that MAPE shall not exceed one hundred per cent for indigenous scheduled formulations.

During the scrutiny of records, we found that certain manufacturers under Pune Indore and Mumbai II. commissionerates were producing and clearing bulk drugs specified in the first schedule to the DPCO but the MAPE exceeded the prescribed limit of 100 per cent. Moreover, in these cases, the Government/NPPA had not prescribed the MRP at which the bulk drugs would be sold. Consequently, the MRP got overstated and the consumers ended up paying extra amount of Rs. 23.53 crore. The details are shown in the following table: -

Table no. 2 Excess application of MAPE amount in fixation of MRP

(Amount in lakh of rupees)

Sl. No.	Name of manufacturers	Name of commiss-ionerates	Bulk drug/formulation manufactured	MAPE adopted (as a percentage of cost price)	Excess amount collected from consumers by applying MAPE in excess of the permissible limit of 100%	Period
1.	M/s Aditi Pharmaceuticals (P) Ltd.	Pune III	Prednisolone Eye Drops, 5ml	165 to 234	254.00	April 2006 to September 2008
2.	M/s Nicholas Piramal India Ltd., Pithampur	Indore	Prednisolone Acetate ophthalmic suspension USP (5 ml vial)	446	372.00	April 2007 to March 2008
3.	M/s. Pharma Pack (P) Ltd.	Mumbai II	Multi vitamin drops (15 ml)	502 to 505	1727.38	April 2006 to January 2007
	Total				2353.38	

The overcharged amount of Rs. 23.53 crore was recoverable from these manufacturers.

On this being pointed out (November 2009), the NPPA agreed (February 2010) with the audit observation and stated that a demand notice had been

issued to M/s. Nicholas Piramal India Ltd. The action taken on the other two firms had not been intimated (March 2010).

- **6.1.2** We also found two cases where the NPPA had fixed the ceiling price of certain bulk drugs specified in the first schedule to the DPCO but the manufacturers charged higher prices from the consumers. These cases are discussed in the following paragraphs:
- (i) M/s Tristar Formulations Pvt. Ltd. Puducherry, under Puducherry commissionerate, sold Ecosprin AV75 at Rs. 75 upto February 2008 and Rs. 71.56 upto May 2008 although the NPPA had fixed the price at Rs. 18.63 with effect from 23 March 2007. Similarly Ecosprin AV150 was sold at old price of Rs. 79.46 till April 2008 whereas the revised price of Rs. 18.95 had been prescribed from 24 March 2008.

Though the Government realised central excise duty on the higher MRP adopted for the formulations, the assessee realised an undue benefit of Rs. 7.70 crore by overcharging consumers. The amount was recoverable from the assessee.

On this being pointed out (November 2009), the NPPA agreed with the observation and stated (February 2010) that a demand notice had already been issued and the company had also deposited an amount of Rs. 1.25 crore. Further recovery had been stayed by the High Court at Chennai.

(ii) Similarly, M/s Aditi Pharmaceuticals (P) Ltd., in Pune III commissionerate, was manufacturing 'Prednisolone Eye Drops, 5ml' with the brand name 'Gatiquin-P eye drops' for M/s. Okasa Pharma Ltd. Prednisolone is a bulk drug prescribed in the first schedule to the DPCO. The NPPA fixed a ceiling price of Rs.12.84 inclusive of all taxes for 'Prednisolone Eye Drops, 5 ml plastic bottle with carton' on 1 October 2008. However, the old MRP of Rs. 57.75 was changed during October 2008 and this resulted in undue benefit of Rs. 83.89 lakh to the principal manufacturer which was recoverable.

Recommendation No. 9

> The NPPA should review all cases of prices of pharmaceutical products where MAPE was required to be restricted to the prescribed cap and recover the excess amount charged by the manufacturers of such pharmaceutical products.

The NPPA agreed (February 2010) with the recommendation and stated that the prices of scheduled formulation are fixed by NPPA/Government. The prices of non-scheduled formulation are monitored and excess amount charged is recovered only in the cases where increase in price is more than 10 per cent (the permissible limit) in a year.