CHAPTER II
FINDINGS ON RULES, REGULATIONS, SYSTEMS AND INTERNAL CONTROLS

We have arranged the audit findings in this chapter under three sections. Section A contains findings related to weaknesses, omissions or distortions in the Acts, rules, instructions and notifications on central excise that adversely affect the collection of central excise duty. Section B covers an issue relating to pricing of medicines and Section C has findings on the internal controls. Certain illustrative cases have been used to highlight the issues.

SECTION A: RULES, REGULATIONS AND SYSTEMS

2.1 Assessment of physician samples

The Board has clarified in April 2005 that the assessable value of free samples of medicines given to physicians should be determined under Rule 4 of Central Excise Valuation (Determination of Price of Excisable Goods) Rules, 2000. Rule 4 states that the excisable value of goods shall be based on the value of such goods sold by the assessee for delivery at any other time nearest to the time of removal of such goods.

Upto 7 January 2005, duty on pharmaceutical products was levied on the transaction value (production cost) under section 4 of Central Excise Act, 1944. From 8 January 2005, duty was levied for allopathic medicines on Maximum Retail Price (MRP) less abatement allowed, if any.

In our opinion, these provisions show that the excisable value of allopathic physician samples was to be based on transaction value under Section 4 upto 7 January 2005 and thereafter on MRP based value under Section 4A.

We found that in 38 cases, the duty on physician's samples was paid on transaction values which were 15 per cent to 62 per cent less than the corresponding MRP based values. The resultant short payment of duty was Rs. 5.67 crore. In 15 cases with a revenue impact of Rs. 85.34 lakh, the department accepted the audit observations. Of these, in 10 cases the department further recovered a sum of Rs. 32.71 lakh. In 10 other cases, the department issued 'Show Cause Notices (SCNs)' for Rs. 3.79 crore without specifically accepting the audit observations.

Two such cases are illustrated below: -

(i) M/s A to Z Life Sciences, Thavalakuppam, in Puducherry commissionerate, cleared physician samples of 'Patent or Proprietary (P or P)' medicines during the period from January 2005 to September 2008. Duty was paid on transaction value which was Rs. 5.32 crore less than the MRP based value and there was short payment of duty amounting to Rs. 80.42 lakh.

(ii) M/s Themis Laboratories (P) Ltd., in Thane I commissionerate, cleared (during the period from March 2008 to September 2008) physician samples of several medicines by paying duty at transaction values. One such medicine 'Cytogard OD' had MRP of Rs. 51.34 (four tablets) whereas four tablets pack of physician samples was cleared at excisable value of Rs. 43.54. The short payment of duty in all the cases was of Rs. 27.49 lakh.

Recommendation No. 1

- *The Government may consider amending the Act and the Rules to have a uniform system for assessment of medicines irrespective of their being cleared as physician samples or for trade.*

During the exit conference the Ministry agreed on a uniform system for assessment of medicines and stated (January 2010) that the larger bench of the CESTAT, Mumbai has given a similar ruling in the case of M/s. Cadila Pharmaceuticals Limited. It was decided that a circular would be issued by the Board to field formations for implementing the decision of the larger bench.

2.2 Ayurvedic and homeopathic products

As mentioned in the last paragraph, from 8 January 2005, allopathic medicines were shifted to MRP based levy under section 4A. The ayurvedic and homeopathic medicines continue to be assessed to under Section 4.

The assessments under different sections have given rise to some issues which are discussed in succeeding paragraphs: -

2.2.1 Excisable value

We found that, as in the case of allopathic medicines, the MRP is also printed mandatorily on homeopathic and ayurvedic products under the provisions of Drugs and Cosmetics Act/Standards of Weights and Measures Act, 1976. Therefore, they are also sold at MRP and, in our opinion, they qualify for getting notified under section 4A for MRP based assessment.

We observed that the excisable value of homeopathic and ayurvedic products are being based on the agreed prices and transaction values under Section 4. In 26 cases the excise duty would have increased by Rs. 37.79 crore, if MRP based assessment had been applied. A few such cases are illustrated below: -

(i) M/s. Maksons Industries Pvt. Ltd., in Hyderabad I commissionerate, entered into a contract with M/s GlaxoSmithKline Pvt. Ltd., for manufacture of an ayurvedic product 'Iodex Rub' on job work[2] basis. The terms of agreement provided that the job worker would procure the raw material, affix the principal's logo, the trade mark and MRP on the manufactured products and send the goods to the principal's depots after clearance by payment of duty on mutually agreed prices. We found that the agreed prices for packages of different weights on which duty was paid by the job worker ranged between

[2] 'Job work' means processing or working upon of raw material or semi-finished goods supplied to the job worker, so as to complete a part or whole of the process resulting in the manufacture or finishing of an article or any operation which is essential for aforesaid process and the expression 'job worker' shall be construed accordingly.

Rs. 3.12 and Rs. 12.30. The MRPs of these products were much higher and ranged between Rs. 16.50 and Rs. 55.00. The excise duty would have increased by Rs. 17 crore (during the period from April 2005 to September 2008) if MRP based assessment had been done.

(ii) M/s Aswini Homeo Pharmacy, in Hyderabad IV commissionerate, during the period April 2005 to September 2008 cleared 4,70,98,348 bottles of 'Aswini Homeo Hair Oil' by paying duty on transaction value of Rs. 49.07 crore. The corresponding MRP based value under section 4A worked out to Rs. 81.92 crore. The duty difference was Rs. 4.94 crore.

(iii) M/s Charak Pharma Ltd., in Vapi commissionerate, had cleared the ayurvedic medicines, 'Vigomax capsules - 10 nos.' and 'M2 tone syrup 200 ML', at the transaction values of Rs. 30.40 and Rs. 26.49 respectively whereas the MRP based values under section 4A worked out to Rs. 66.00 and Rs. 55.00 respectively. The assessee cleared 32 consignments of these medicines during the period April 2006 to September 2008 on which the excise duty would have increased by Rs. 2.47 crore if assessment had been done under Section 4A.

(iv) M/s. Gelnova Laboratories Ltd., in Belapur commissionrate, had paid duty on several ayurvedic products under section 4 on a value of Rs. 2.03 crore whereas the corresponding value under Section 4A worked out to Rs. 5.50 crore. The duty difference was Rs. 56 lakh.

(v) M/s VIVIMED Labs, in Hyderabad IV commissionerate, engaged in manufacture of 'Sapat Plus Malam' (an ayurvedic product) on job work basis on behalf of M/s. Sapat and Co (Bombay) Ltd., purchased raw materials and cleared the material as job worker on the agreed price. The principal in turn sold the goods at MRP which was much higher than the agreed price. This led to short realisation of duty of Rs. 11.77 lakh on 15,11,146 units of these goods cleared during the period from February 2005 to April 2007.

2.2.2 Categorisation of ingredients

M/s. Atra Pharmaceuticals (P) Ltd., in Aurangabad commissionerate, had manufactured 'Calcium Sandoz tablets' for M/s. Novartis India Ltd., using calcium carbonate and citric acid which were inorganic chemicals and the tablets were cleared as proprietary ayurvedic medicine. However, these two ingredients were described as ayurvedic ingredients namely, *khatika churna* and *nimbu ka malam*. Since inorganic chemicals were used, the tablets should have been cleared under Section 4A, based on MRP. Clearance under Section 4 resulted in short realisation of duty of Rs. 4.39 crore during 2005-06 to 2007-08.

On this being pointed out (August 2008), the department stated that since calcium carbonate and citric acid are the constituents of the ayurvedic ingredients such as *khatika churna* and *nimbu ka malam* respectively, calcium sandoz tablets should be treated as an ayurvedic product.

The department's reply is not tenable because the active ayurvedic ingredients approved by 'Food and Drug Administration (FDA)' were *khatika churna* and *nimbu ka malam*, whereas the purchase orders for the raw materials showed that the assessee had used inorganic chemicals such as calcium carbonate powder and anhydrous citric acid.

Therefore, the duty of Rs. 4.39 crore was recoverable in this case. However, the bigger issue is that this matter would not have arisen at all, if ayurvedic medicines had also been brought under Section 4A.

Recommendation No. 2

- *To check against undervaluation of ayurvedic and homeopathic medicines and consequent revenue loss, the Government needs to bring these commodities under MRP based assessment (section 4A).*

The Ministry stated in the exit conference (January 2010) that the suggestion had been noted for examination.

2.3 Cenvat to PLA ratio

Assessees pay excise duty either in cash by debiting their 'Personal Ledger Account (PLA)' or by reducing the accumulated cenvat credit in their cenvat credit account. There is a potential risk of duty evasion by accumulating cenvat credit in an irregular manner. Therefore, instances of excessive payment through cenvat credit account compared with PLA account should be examined.

The details of central excise duty collected from pharmaceutical products (chapter 30) under 82 commissionerates is summarised in the following table: -

Table no. 1

Central Excise revenue data relating to Pharmaceutical products

(Amount in crore of rupees)

Commodity and chapter	Year	No. of units	Duty paid through PLA	Duty paid through cenvat	Total duty paid	Percentage of cenvat to PLA	Percentage of cenvat to PLA for all commodities
Pharmaceutical products (chapter 30)	2005-06	1379	2074.72	1538.89	3613.61	74.17	86.36
	2006-07	1428	1995.89	2261.41	4257.30	113.30	109.42
	2007-08	1426	1647.43	1775.37	3422.80	107.77	123.14

Figures furnished by commissionerates.

- The table shows an increasing trend in the use of cenvat credit for all commodities. Pharmaceutical products showed a slight decrease in 2007-08 but had a net increase during the three years.
- The percentage of cenvat credit to cash was 74.17 during the year 2005-06 and jumped to 113.30 during the year 2006-07. The sudden rise by 52.75 per cent in one year is a risk indicator and needs to be examined by the department.
- We also found that in Vadodara I and Rohtak commissionerates, percentages of cenvat to duty paid in cash in respect of pharmaceutical products during the year 2006-07 were as high as 1,718.02 per cent and 739.53 per cent, respectively. Similarly, in Siliguri and Indore commissionerates, the same percentages, during 2007-08, were as high as

626.66 per cent and 498.03 per cent respectively. These high percentages need to be investigated.

- These risks have to be considered in the background that misuse of cenvat credit is quite rampant and we have also found (details in Chapter 3 of this report) in the course of this audit, misuse of Rs. 91.79 crore of cenvat credit.

Recommendation No. 3

- *The Government may ascertain the reasons for increasing incidence of duty payment by cenvat credit, take necessary corrective action and use cenvat to PLA ratio as a risk factor based on which internal audit/ investigation may be undertaken.*

The Ministry stated (January 2010) that factual reports had been called from the Commissionerates to investigate the excessive use of cenvat, as pointed out by audit.

2.4 Abatement on Maximum Retail Price

In MRP based assessment under Section 4A, an abatement based on rates of central excise duty, sales tax, service tax and any other taxes, payable on such manufactured goods, is allowed on the MRP to eliminate double taxation. Therefore, any reduction in applicable taxes should translate to reduced abatement rates and vice versa.

When MRP based assessment was introduced for allopathic products, on 8 January 2005, the abatement from MRP to arrive at the assessable value of pharmaceutical products, was fixed at 40 per cent taking into consideration the rates of sales tax which varied between 8 and 10 percent in various states. With effect from 1 April 2005, VAT was introduced with fixed rate of four percent on pharmaceutical products all over India, but the percentage of abatement on MRP was not reduced. In fact, the rate of abatement on pharmaceutical products was increased from 40 per cent to 42.5 per cent with effect from 1 February 2007 although there was no increase in the rates of excise duty and other taxes. It was, thereafter, reduced to 35.5 per cent with effect from 1 March 2008 due to reduction in rate of excise duty from 16 to 8 per cent.

In our opinion, the increase in abatement rates on pharmaceutical products in February 2007 was not appropriate and on introduction of uniform rate of VAT of 4 per cent, the rate of abatement on pharmaceutical products should have been reduced substantially. By not resorting to such reduction, the Government lost an opportunity to recover additional revenue. We did a reverse calculation, starting from the total revenue collected on pharmaceutical products and estimated that the loss of revenue could be in the range of Rs. 684.38 crore (Rs. 226.52 crore, Rs. 200.72 crore and Rs. 257.14 crore during the year 2005-06, 2006-07 and 2007-08 respectively).

Recommendation No. 4

- *The Government may rationalise the present rates of abatement based on the various changes that have taken place in the rates of taxes.*

The Ministry agreed with the recommendation during the exit conference and stated (January 2010) that these issues would be placed with the abatement committee which has been set up to prescribe the rates of abatement.

2.5 Quantity discounts, bonus quantities, etc. cleared without payment of duty

The larger bench of CESTAT, Ahmedabad, had held that the quantity discount applicable for valuation under Section 4, is not applicable under section 4A. As allopathic products are covered under section 4A, quantity discounts (free or at reduced prices) are not to be allowed.

2.5.1 We found that M/s Macleods Pharma Ltd. (Unit II and III), in Daman commissionerate, was packing medicines (Aluminium strips) in printed boxes on which MRP was printed (primary packing). The boxes were then put into cartons (secondary packing) for the purpose of transportation. We found that some additional boxes with primary packing were being added to each carton. These were treated as quantity discounts and duty was not paid on these additional boxes. Since there was no provision for such discount for allopathic medicines, excise duty of Rs. 3 crore (including cess), interest of Rs. 94 lakh and penalty of Rs. 3 crore was payable on goods valued at Rs. 18.51 crore which were removed by the assessee in this irregular manner.

On this being pointed out (November 2008 and March 2009), the department accepted (January 2009 and April 2009) the audit observation for levy of excise duty of Rs. 3.94 crore including interest in case of both the units II and III.

2.5.2 Similarly, M/s. Jagadale Industries, in Bangalore III commissionerate, had cleared medicines (Tichialan – 20 Tablets) worth Rs. 2.05 crore under 'bonus scheme[3]' during the period from January 2007 to September 2007, without paying duty. For every 110 units cleared, duty was paid only on 100 units. The duty short paid in these cases, Rs. 37.12 lakh, penalty of Rs. 37.12 lakh and interest were recoverable.

On this being pointed out (April 2008), the department quoted (April 2008) the Supreme court judgements in respect of M/s Vinayaka Mosquito Coils and M/s Surya Food and Agro Ltd. and opined that the value of free items need not be included in the assessable value under section 4A.

The reply is not tenable. The Supreme Court judgments related to cases where MRP was not printed on the free items. In the cases pointed out by audit, the 'free goods' had MRPs printed on them and there was no evidence to show that they were not sold at MRP.

[3] A scheme under which some articles are given free akin to discount in kind.

Recommendation No. 5

- *The Government may amend the enabling Rules, to levy duty on products cleared free of duty under the guise of quantity discount, bonus scheme, etc. but which have MRPs printed and are sold in the market at MRP and are otherwise assessed under MRP based (section 4A) assessments.*

The Ministry agreed with the recommendation during the exit conference and stated (January 2010) that the CESTAT, Ahmedabad had given a decision which was similar to our recommendation. While, the decision had been challenged in courts, it was decided in the exit conference that the Board will issue a circular to its field formations for adoption of the decision of the CESTAT, provided no stay had been granted yet by any court.

SECTION B : PRICING OF MEDICINES

2.6 Non-scheduled formulation[4] packs of medicines

As mentioned in the chapter 1, the rate of abatement on formulation packs of medicines was reduced from 42.5 per cent to 35.5 per cent with effect from 1 March 2008 due to reduction in excise duty from 16 to eight per cent.

The NPPA advised (10 March 2008) all manufacturers and marketing companies of non-scheduled formulation packs of medicines to pass on the benefit of this excise duty reduction to the consumers by reduction of MRP by 4.58 per cent.

We found that in 17 cases, detected in nine commissionerates, the manufacturers saved estimated excise duty of Rs. 11.39 crore during the period March 2008 to September 2008 but the admissible benefit of Rs. 9.82 crore was not passed on to the consumers by reducing the MRP. The volume of trade of these formulations is significant (Rs. 311 crore of duty collected in the 82 commissionerates selected for audit) and hence the benefits that were not passed on to the customers would also be quite high. This indicates that the NPPA was unable to ensure compliance with its advice and the manufacturers were able to retain the benefits of the excise duty reduction at the cost of the consumers.

Recommendation No. 6

- *Penal provisions should be included in the Drugs (Prices Control) Order, 1995 to ensure that the manufacturers of pharmaceutical products pass on the benefits of duty reduction to the consumers.*

The NPPA stated (February 2010) that instructions were issued to companies to pass on the benefit of reduction in excise duty to the customers.

We feel that unless the NPPA gets the powers to take penal action to ensure compliance with its instructions, the probability of recurrence of such

[4] A non-scheduled formulation does not contain any bulk drug that features in the schedule of the Drugs (Prices Control) Order, 1995.

instances cannot be ruled out. Further, the action is required to be taken early in such cases because even if the recovery is done later, the consumers cannot be compensated directly for the higher price paid by them.

SECTION C : INTERNAL CONTROLS

Internal controls are activities and safeguards that are put in place by the management of an organisation to provide reasonable assurance that its activities are being carried out efficiently and cost effectively and in terms of its stated policies. The major inadequacies in the internal controls which were observed during our audit, are described in this section.

2.7 Cases pending adjudication

Short payment/non-payment of duty on any excisable goods is to be recovered by issuing a Show Cause Notice (SCN) under section 11A of Central Excise Act, 1944, to be followed up with adjudication and recovery proceedings. The period of limitation for issue of SCN is one year in normal cases and five years in cases of non/short levy due to fraud, collusion, etc. The SCN has to be adjudicated within six months in the former case and within one year in the latter case.

We found that 211 cases of adjudication of SCNs issued to manufacturers of pharmaceutical products by 82 commissionerates, involving revenue of Rs. 26.92 crore, were pending for adjudication for more than one year. Thirty per cent of the cases, constituting 42 per cent of the total revenue involved, were more than five years old. Furthermore, 16 per cent of the cases, constituting eight per cent of the total revenue involved, were more than three years but less than five years old.

A case is illustrated below:

We found that the joint commissioner, Surat II commissionerate, had served three SCNs during 1996 and 1997 to M/s RPG Lifescience Ltd., demanding duty and penalty of Rs. 19.79 lakh. The notices were required to be adjudicated within six months but remained unattended till 25 September 2008.

Recommendation No. 7

- *The Government may monitor the pendency of adjudication cases, specially cases pending for more than five years and issue instructions to commissionerates to investigate the reasons for such long pendency.*

The Ministry agreed with the recommendation during the exit conference and stated (January 2010) that a special cell had been created in the Directorate General of Inspection (DGI) to monitor such cases and a drive had been started to reduce the pendency.

2.8 Scrutiny of assessments

The Central Excise Rules, 2002 provide that the assessee has to do a self assessment and submit a return. The CBEC's Excise Manual of Supplementary Instructions, 2005, read with the Board's circular dated 15 July 2005, provides that the departmental officials have to scrutinise the returns within three months of the date of receipt of return. An initial scrutiny is carried out for all returns and thereafter, up to five per cent of the total returns received are selected on prescribed criteria and a detailed scrutiny is carried out.

We found from the scrutiny of the returns relating to pharmaceutical products in Bhopal, Indore commissionerates and Ranges V&VI, Bhiwari, of Jaipur I commissionerate that scrutiny of the returns was not done as per provisions. The returns were also not selected for scrutiny of assessments for the period April 2005 to September 2008 although they fulfilled the conditions of selection. The process of selection and mandatory scrutiny of all returns is required to be streamlined to ensure that the prescribed control is applied.