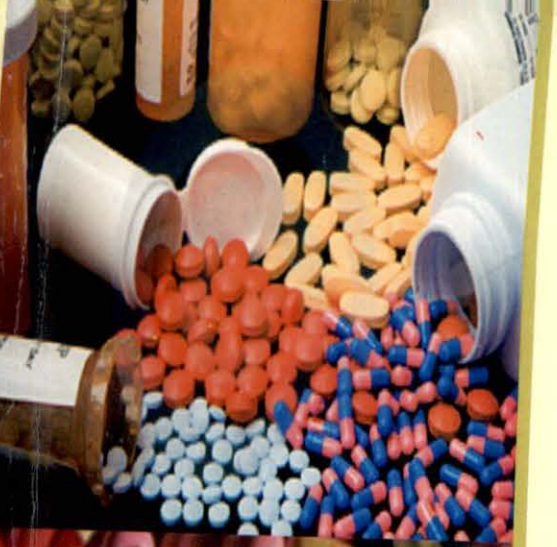

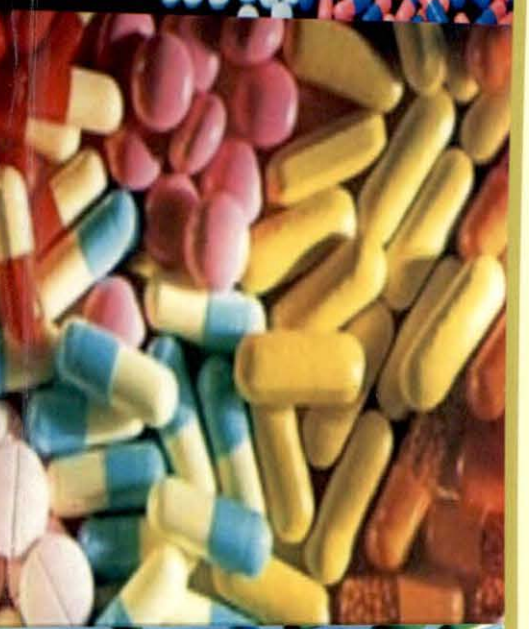

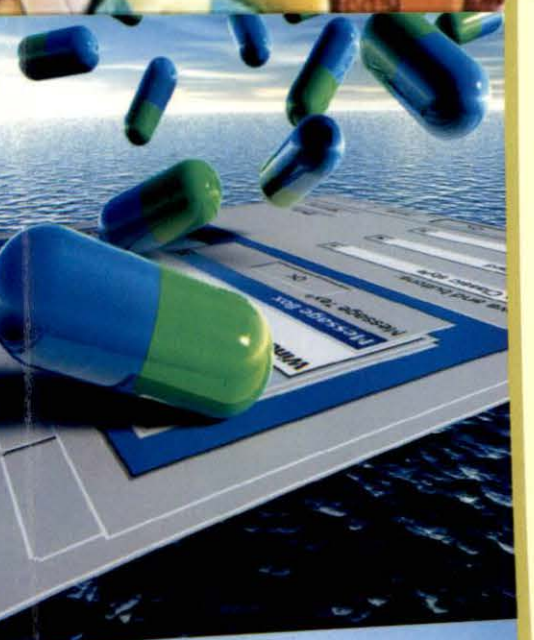

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Report of the Comptroller and Auditor General of India

PERFORMANCE AUDIT ON EXCISE DUTY ON PHARMACEUTICAL PRODUCTS

Union Government
(Indirect Taxes - Central Excise)
(Performance Audit)
No. 11 of 2010-11

PERFORMANCE AUDIT ON EXCISE DUTY ON PHARMACEUTICAL PRODUCTS

Report of the
Comptroller and Auditor General of India
for the year ended March 2009

Union Government
(Indirect Taxes - Central Excise)
(Performance Audit)
No. 11 of 2010-11

Laid on the table of Lok Sabha and Rajya Sabha on ..... 16 अगस्त AUG 2010

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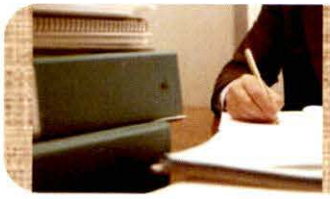
PREFACE

This report for the year ended March 2009 has been prepared for submission to the President of India under Article 151(1) of the Constitution of India.

Audit of Revenue Receipts – Indirect Taxes of the Union Government is conducted under the Section 16 of the Comptroller and Auditor General of India (Duties, Powers and Conditions of Service) Act, 1971.

The observations included in this report have been selected from the findings of a performance audit carried out during the year 2008-09 and covered the collection of revenue during the period 2005-06 to 2007-08.

The results of our audit alongwith recommendations are contained in this report.



EXECUTIVE SUMMARY

We conducted a performance audit on levy of excise duty on pharmaceutical products (Chapter 30 of Central Excise Tariff Heading) to evaluate the adequacy of provisions of the Act, Rules and instructions in ensuring proper assessment, collection and allocation of revenues.

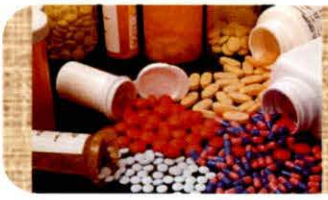
We found a few system and compliance weaknesses relating to the assessment and collection of duty. The key findings and related recommendations are: -

- Assessment of allopathic physician samples was based on transaction value under section 4 instead of on MRP based value under Section 4A. To ensure uniformity, the Government may consider amending the Act and the Rules to provide for a uniform system of assessment of medicines cleared as physician sample or for trade. In 38 such cases, we found Rs. 5.67 crore of revenue has been foregone.
- Ayurvedic and Homeopathic products are not covered by MRP based assessment under section 4A although they were sold at MRP. To check against the undervaluation of Ayurvedic and Homeopathic products, the Government needs to bring these commodities under MRP based assessment (section 4A). In 26 such cases, we found that Rs. 37.79 crore of revenue has been foregone.
- The percentage of cenvat to PLA (duty paid in cash) in respect of pharmaceutical products increased by 52.75 per cent from 74.17 in 2005-06 to 113.30 in 2006-07. In four commissionerates, duty payment by cenvat during 2006-07 and 2007-08 was significantly higher than that paid by PLA (498 to 1,718 per cent). The excessive use of cenvat credit compared to cash duty payment indicates a risk of misuse of cenvat by these manufacturers. Since we have also identified incorrect use of Rs. 91.79 crore of cenvat credit, the issue requires examination. We recommend that the Government may ascertain the reasons for the 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.
- Rates of abatement were not reduced despite reduction in applicable state taxes (post removal expenses). The Government should rationalise the rate of abatement allowed on products under section 4A assessment consequent to the various changes that have taken place in the rates of taxes. The estimated revenue loss on this account was Rs. 684.38 crore.
- Boxes of medicines with printed MRP were treated as quantity discounts and bonus quantities and were cleared without payment of duty. These were packaged along with duty paid medicines. The Government may amend the enabling Rules, to levy duty on such products which are 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. In two cases observed in audit, the revenue loss was estimated to be Rs. 8.62 crore.

- The benefit of reduction in excise duty rates was not passed on to consumers, despite instructions of the Government of India. The NPPA should review its price monitoring mechanism to make it effective in timely detecting such cases. The Government should include penal provisions in the Drugs (Prices Control) Order, 1995 (DPCO) for the manufacturers of pharmaceutical products who do not pass on the benefit of duty reduction to the consumers. We found that the consumers were overcharged Rs. 9.82 crore in 17 cases by way of non reduction of medicine prices.
- The Department officers have to do an initial scrutiny of all the returns and thereafter a detailed scrutiny upto five per cent of total returns received is to be done by the departmental officers within three months of the date of receipt. We found that the scrutiny was not done. The process of selection and mandatory scrutiny of all returns is required to be streamlined.
- Several cases were noticed where the manufacturers of pharmaceutical products did not pay the applicable service tax of Rs. 182.81 crore. We recommend that the excise and service tax returns be integrated to mitigate the risk of evasion of duties/tax and the Government has agreed to address the issue while introducing the GST. In the light of our findings, we suggest that in the interim the Government can make it mandatory that manufacturers should declare on their excise returns, whether they have provided any output services or received any service from foreign service providers.
- We noticed instances where prices of scheduled drugs were not arrived at by manufacturers as per the formula prescribed by the Government of India. The NPPA should review all cases of prices of pharmaceutical products where 'Maximum Allowable Post-manufacturing Expenses (MAPE)' was required to be restricted to the prescribed cap. The excess amount charged by the manufacturers of such pharmaceutical products should be recovered. We found that in five cases, the consumers were overcharged Rs. 32.07 crore by way of non reduction of medicine prices.

INTRODUCTION



CHAPTER I
INTRODUCTION

1.1 Pharmaceutical products – a brief description

Voltaire, the great philosopher and writer, had said in the eighteenth century, 'the art of medicine consists in amusing the patient while nature cures the disease'. Had he followed the human civilisation upto the twenty first century, he may have changed his mind as mankind discovered new diseases and perhaps created new ones. Today good health is equated as much to healthy living as to treatment and medication.

The pharmaceutical industry develops, produces and markets generic and branded drugs licensed for use as medications. Medicines are categorized into bulk drugs and formulations. A bulk drug means any pharmaceutical, chemical, biological or plant product which conforms to pharmacopoeia standards and is used as such or as an ingredient in any formulation. A formulation is a medicine prepared from one or more bulk drugs with or without the use of any pharmaceutical aids. This formulation does not include ayurvedic, siddha, unani and homeopathic system of medicines.

The first known drugstore was opened by Arabian pharmacists in Baghdad in 754 and thereafter spread throughout the middle east and eventually medieval Europe. Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Legislation was enacted thereafter to test and approve drugs and to affix appropriate labelling. The first Indian pharmaceutical company appeared in Calcutta in 1930. Since 1947 when the production value was only Rs. 10 crore, the Indian pharmaceutical industry has taken great strides, has a current production of around Rs. 75000 crore and provides employment to around three million people.

India holds a modest 1-2 per cent share in the global market, but the industry has been growing at approximately 11 per cent per annum for the domestic market with the growth in exports being higher at roughly 20 per cent per annum. The Indian pharmaceutical industry is today the 4th largest in terms of production volume after USA, Japan and China and 14th in terms of value. It has also become a major player in outsourced clinical research as well as contract manufacturing. There are 74 US FDA (Food and Drug Administration) approved manufacturing facilities in India, more than any other country outside the USA.

The Drugs (Prices Control) Order was first passed in 1970 and then revised in 1979, 1987 and 1995. The Drugs (Prices Control) Order, 1995 (DPCO) was notified by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petro Chemicals on 6 January 1995. Its first schedule lists 74 bulk drugs, the prices of which including their formulations are regulated and controlled. These drugs that are under price control constitute only 20 per cent of the pharmaceutical market and there is no control at entry level prices in

respect of the balance 80 per cent of the market comprising non-scheduled drugs and their formulations.

From the Budget 1999-2000, duty at the rate of 16 per cent was levied on pharmaceutical products. There was no change in the rate of duty upto 29 February 2008. It was reduced to eight per cent from 1 March 2008. From 9 July 2004, education cess at the rate of two per cent of the duty and from 1 March 2007 secondary and higher education cess at the rate of one per cent of the duty is also leviable. With effect from 8 January 2005, pharmaceutical products were brought under section 4A of Central Excise Act, 1944 and were to be assessed, accordingly, on the basis of MRP less abatement[1] allowed from time to time. In this review, the terms 'pharmaceutical products' and 'medicines' have been used interchangeably.

1.2 The key players

Most of the players in the market are small-to-medium enterprises; 250 large companies control 70 per cent of the Indian market. Some of the largest companies are M/s. Ranbaxy Laboratories, Dr. Reddy's Laboratories, M/s. Nicholas Piramal, M/s. Cipla, M/s. Biocon, etc.

The National Pharmaceutical Pricing Authority (NPPA) is an independent body of experts constituted by the Government of India in August 1997, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines in the country, as provided under the DPCO. It is also entrusted with the task of recovering amounts overcharged from the consumers by manufacturers of controlled drugs.

The Central Board of Excise and Customs (CBEC) is a part of the Department of Revenue under the Ministry of Finance, Government of India. It deals with the tasks of formulation of policy concerning levy and collection of central excise duty and service tax in all sectors of the economy, including the pharmaceutical industry.

1.3 Why we chose the topic

Pharmaceutical products was 14th on the list of commodities and yielded excise duty of Rs. 2265.17 crore, Rs. 2007.23 crore and Rs. 1739.45 crore during the years 2005-06, 2006-07 and 2007-08 respectively. They are classified under chapter 30 of Central Excise Tariff Act (CETA), 1985. The percentage share in the total collection of central excise receipts under the chapter was 1.41 per cent during 2007-08. We selected this topic because of the substantial revenue generation and due to the importance and sensitivity of the sector as it relates to health and well-being.

[1] Abatement is provided by the Central Government to the manufacturers of goods assessable under MRP in order to avoid taxation on the amount of duty of excise, sales tax, service tax and any other taxes, payable on such manufactured goods.

1.4 Audit objectives

The objectives of our audit were to ascertain whether: -

- the relevant Acts, Rules and instructions issued by the Ministry of Finance/Central Board of Excise and Customs ensured proper assessment, collection and allocation of revenues,
- credit of duty paid on inputs/capital goods was taken correctly under cenvat,
- conditions for grant of exemptions of duty were being fulfilled,
- service tax on services provided/received by manufacturers were paid correctly, and
- prices of medicines were being regulated and reviewed to protect the interest of consumers.

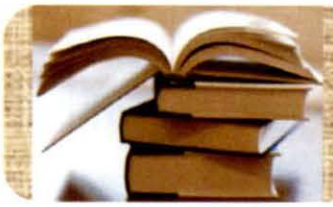
1.5 Scope of audit

For selecting the sample for our performance audit, we collected the details of state wise revenue yield from pharmaceutical products during the year 2006-07 and short listed the top fourteen contributing states for coverage in the review. These states are Andhra Pradesh, Assam, Gujarat, Goa, Haryana, Jammu & Kashmir, Karnataka, Kolkata, Punjab, Madhya Pradesh, Mumbai, Rajasthan, Tamil Nadu and Uttar Pradesh. For selection of units for audit, the units were divided into two categories, (i) units paying duty of Rs. 1 crore and above through PLA and Cenvat, and (ii) units paying duty less than Rs. 1 crore. We selected 50 per cent of the units from category (i) and added high revenue earning units from category (ii) in such a way that at least 20 per cent units manufacturing pharmaceutical products in each state were covered. By applying this criteria we selected 324 out of 1426 units all over India. These units fall under 82 out of total 94 commissionerates of central excise in the selected 14 states. The audit sample size was 22.72 per cent of the population in terms of numbers of units, which contributed Rs. 1,041.73 crore i.e. 60 per cent of the total revenue of Rs. 1,739.45 crore during the year 2007-08.

1.6 Acknowledgement

The Indian Audit and Accounts Department acknowledges the cooperation extended by the Ministry of Finance and its field formations in providing the necessary information and records during the conduct of this audit. The objectives, scope and audit methodology for the performance audit were discussed in an entry conference held on 28 November 2008. The draft report containing the audit findings and recommendations was issued to the Ministry of Finance and Ministry of Chemicals and Fertilizers in November 2009. The audit findings and recommendations were discussed in an exit conference held on 12 January 2010 with the officers of both the Ministries. The written responses of the Ministries to the recommendations, received in January/February 2010 and responses of the department, wherever received, have been incorporated appropriately by us in this report.

SYSTEM ISSUES



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 pe need to be investigated.

- These risks have to be considered in the background that misuse credit is quite rampant and we have also found (details in Chapter 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.*

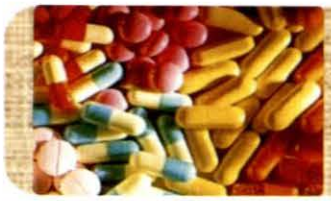
The Ministry agreed with the recommendation during the exit conference and stated (January 2010) that a special cell had been created in the Directorate General of Inspection (DGI) to monitor such cases and a drive had been started to reduce the pendency.

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.

COMPLIANCE ISSUES



CHAPTER III
CENVAT CREDIT

A manufacturer/service provider uses capital goods such as plants and machinery, inputs such as raw material and input services such as security services, management, maintenance or repair services, etc. to make a final product. The excise duty/service tax paid on any of these three items is credited and accumulated under a cenvat credit account. Whenever the manufacturer has to pay duty on finished goods and service tax on output services, it can utilise the accumulated cenvat credit for the payment subject to fulfillment of certain conditions. This ensures that the inputs are taxed only once.

During the course of this audit, we found 227 cases of incorrect availing of cenvat credit with duty impact of Rs. 91.79 crore. The department agreed with our observations in 140 of these cases, involving duty of Rs. 6.34 crore and recovered Rs. 3.00 crore in 130 cases. In another 23 cases the department has issued SCNs for Rs. 11.02 crore without specifically accepting the audit observations and has not furnished any reply in the remaining 64 cases. A few of these cases are elucidated in the following paragraphs.

3.1 Inputs for both dutiable and exempted final products

Rule 6(1) of the Cenvat Credit Rules, 2004, (CCR) stipulates that cenvat credit cannot be taken on inputs which are used in the manufacture of final products which are exempt or have 'nil' rate of duty.

Rule 6(3) (1) of the CCR provides that if cenvat credit is taken on inputs which are used in the manufacture of both exempted as well as dutiable goods, separate accounts of their use must be maintained failing which the manufacturer shall pay an amount equal to eight per cent (ten per cent from 10 September 2004) of the total price of the exempted goods excluding taxes.

We found many instances where the assessees did not keep such separate accounts and the penal amount of 10 per cent was not imposed. A few of these cases are narrated hereafter.

3.1.1 We found that M/s Albert David (P) Ltd., in Ghaziabad commissionerate, did not maintain the stipulated separate accounts during the period April 2005 to September 2008. The assessee had cleared exempted medicines valued at Rs. 141.46 crore. Therefore, 10 per cent of the value of the exempted goods i.e. Rs. 14.15 crore and interest of Rs. 1.63 crore were recoverable.

3.1.2 In another similar case, M/s Piramal Health care Ltd., in Raigad commissionerate, had not maintained separate accounts of exempted and dutiable final products. An amount of Rs. 6.78 crore, which was 10 per cent of the value of the exempted medicines cleared during the period April 2005 to March 2008, was recoverable with interest.

3.1.3 M/s Wockhardt Ltd., in Aurangabad commissionerate, availed of cenvat credit on the services utilised for the manufacture of exempted as well as dutiable medicines at its corporate office which was the 'Input Service Distributor (ISD)[5]'. The credit was distributed to various manufacturing units. The corporate office did not keep separate accounts of the input services for the exempted products manufactured at its 'Chikalthana' plant located in Aurangabad. It had distributed the entire cenvat credit, including the portion pertaining to Chikalthana plant, to other manufacturing locations. The assessee had cleared Rs. 50.29 crore of the exempted medicine 'Wosulin' from the plant at Aurangabad during the period April 2005 to June 2008. Therefore, it had to pay ten per cent of the value of medicines cleared i.e. Rs. 5.03 crore alongwith interest of Rs. 1.32 crore (till March 2009).

3.1.4 M/s Ahlcon Parenterals (India) Ltd. Bhiwadi, in Jaipur I commissionerate is manufacturing patent or proprietary medicines. We found that for the period from April 2005 to September 2008, the assessee maintained pro rata accounts (as certified by chartered engineer) for inputs (furnace oil) used for dutiable and exempted final products. This was irregular as the rules did not provide for pro rata accounting. Moreover, the assessee had not maintained separate accounts for the input services used for manufacture. The total value of exempted goods cleared between April 2006 and September 2008 was Rs. 17 crore. Therefore, ten per cent of this amount i.e. Rs. 1.70 crore was recoverable alongwith interest of Rs. 27 lakh (till March 2009).

3.1.5 M/s. Concept Pharmaceuticals Ltd., in Aurangabad commissionerate, engaged in the manufacture of pharmaceutical products, had availed of cenvat credit of service tax paid on input services that were used in the manufacture of both exempted and dutiable goods but no separate accounts were maintained. The assessee was, therefore, liable to pay Rs. 1.24 crore, equal to ten per cent of the value of exempted goods cleared during the period from April 2005 to March 2008 alongwith interest of Rs. 31.55 lakh (till March 2009).

On this being pointed out (August 2008), the department stated (January 2009) that proportionate service tax credit of Rs. 1.64 lakh was reversed alongwith interest of Rs. 0.13 lakh in August 2008. The reply is not tenable. As separate accounts had not been maintained, there was no reliable basis for ascertaining the amount of input services on exempted goods and the penal rate of ten per cent was payable as per provisions.

3.1.6 M/s Emcure Pharmaceuticals Ltd. (unit II), in Pune I commissionerate, had not kept separate accounts and had availed of service tax credit on the services utilised for the manufacture of exempted goods as well as dutiable goods. The assessee reversed the service tax credit availed to the extent of Rs. 18.80 lakh whereas he was required to pay 10 per cent of the total value of the exempted goods. While an SCN for Rs. 6.27 crore was issued, there was a delay of 18 months from the date of reversal of credit. The demand case has not been adjudicated.

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[5] The input service distributor is a unit which receives and takes cenvat credit on all the inputs, input services and capital goods. It distributes the total credit to other units of the same company which utilise the inputs, input services and capital goods for manufacture or for providing output service.

3.1.7 M/s Cure Medicines (India) Pvt. Ltd., in Pune I commissionerate, had availed of service tax credit on the services utilised for the manufacture of exempted goods as well as dutiable goods. The irregular service tax credit availed on exempted goods during the period from August 2006 to October 2007 amounting to Rs. 11.97 lakh was reversed by the assessee in February 2008 which was in contravention of rule 6(3) (i) of CCR. The assessee was required to pay 10 per cent of total value of the exempted goods. However, the department failed to issue SCN in time which has resulted in loss of revenue of Rs. 69.73 lakh (10 per cent of value of exempted goods) and interest of Rs. 12.84 lakh (till March 2009). No action has been initiated by the department.

3.1.8 M/s Maan Pharmaceutical Ltd., in Ahmedabad III commissionerate, engaged in manufacture of pharmaceutical products, cleared both dutiable and exempted goods but did not maintain separate accounts. The assessee was liable to pay Rs. 92.70 lakh on clearance of Rs. 9.27 crore worth of exempted goods from April 2006 to March 2008. On this being pointed out (March 2008), the department issued SCN (April 2008) for recovery of duty of Rs. 48.52 lakh for the period April 2006 to March 2007 and intimated (June 2008) the recovery of Rs. 3.53 lakh. Report on recovery of the remaining amount has not been received (March 2010).

3.1.9 M/s Gland Pharma Ltd., in Hyderabad IV commissionerate, was availing of cenvat credit on certain common inputs without maintaining separate accounts for inputs used in dutiable and exempted products. It manufactured and cleared the exempted patent or proprietary medicine 'low molecular weight Heparin' by paying duty and passed on the incidence of the wrongly paid duty to customers. It did not pay 10 per cent on the value of the 'Heparin' cleared on the pretext that it had paid duty on this exempted product. This argument is not tenable because in terms of section 5A of the Central Excise Act, 1944, the assessee has no option to pay duty on exempted items. By paying duty in an irregular manner, he actually overcharged the consumers and simultaneously inflated his cenvat credit with the inputs used for manufacturing Heparin. Therefore, he was liable to pay the penal rate of ten per cent for not keeping separate accounts. During the period from January 2004 to March 2006, the assessee cleared the exempted medicine 'heparin' valuing Rs. 27.93 crore. Therefore, Rs. 2.79 crore was recoverable with interest. On this being pointed out (July 2006/May 2007), the department reported (February 2009) that the assessee has paid Rs. 5.89 lakh including interest in March 2009 and the department has issued (March/October 2007) SCN for Rs. 1.44 crore. Report on recovery of the balance amount has not been received (March 2010).

3.2 Excess availing of service tax credit by 'Input Service Distributor (ISD)'

Under rule 7(b) of the CCR, if any unit of an assessee is engaged in manufacturing exempted goods or providing output services which are exempted from payment of service tax, the share of that unit in cenvat credit cannot be distributed by the input service distributor to other units of that assessee. Such credits are to be deducted from the distributable credit and surplus credit reflected in ST-3 returns and reversed from cenvat credit account.

We found that some assesses distributed the share of cenvat credit attributable to manufacture of exempted goods and the excess credits were recoverable. The cases are narrated below.

3.2.1 M/s Johnson & Johnson Ltd., in Mumbai ST commissionerate, availed of full service tax credit in their corporate office as input service distributor (ISD). The pro-rata credit pertaining to units at duty free zones (Baddi units) was not reduced from the closing balance of input tax credit as per ST-3 returns[6] of the corporate office. The excess credit involved was Rs. 1.40 crore.

On this being pointed out in audit (January 2009), the department stated (October 2009) that SCN for Rs. 1.40 crore had been issued in August 2009.

3.2.2 In another similar case, M/s. Wockhardt Ltd., in Mumbai (Service Tax) commissionerate Mumbai, availed of full service tax credit in their corporate office as input service distributor (ISD). The pro-rata credit of Rs. 1.09 crore pertaining to units at duty free zones (Baddi units under area based exemption) was not reversed from the cenvat credit account and incorrectly distributed to the manufacturing units at other locations.

On this being pointed out (January 2009), the department issued SCN for Rs. 1.09 crore in August 2009 and reported (October 2009) that the assessee had admitted the observation, reversed credit of Rs. 65.67 lakh and deposited interest of Rs. 3.37 lakh. Details of the recovery of the balance amount are awaited (March 2010).

3.3 Cenvat credit of service tax on inadmissible input services

The CCRs stipulate that cenvat credit can be taken for 'input service' which means any service used by the manufacturer whether directly or indirectly in or in relation to the manufacture of final products and storage of final products upto the place of removal and includes various specified services.

We found instances of assessees taking inadmissible cenvat credit for services that were not falling within the definition of 'input service' in the CCRs as they were not directly related to manufacturing activities and were also not specified categories of input services. The cases are as follows.

[6] ST-3 return is a form required to be filled by any person liable to pay the service tax. The return is required to be filled on a half yearly basis.

3.3.1 M/s IPCA Laboratories Ltd., Ratlam, in Indore commissionerate, engaged in manufacture of pharmaceutical products, availed of inadmissible cenvat credit of service tax paid on services like rent-a-cab scheme operator, clearing and forwarding agent, courier, personal insurance, outdoor caterer services, outward freight charges, car maintenance charges, canteen service charges, telephone and cell phones charges etc. Thus, the cenvat credit of service tax of Rs. 63.63 lakh taken during the period 2006-07 to 2007-08, was recoverable.

On the matter being pointed out (March 2008), the department stated (January 2009) that SCN for Rs. 63.63 lakh for the period 2006-07 to 2007-08 had been issued (November 2008).

3.3.2 Similarly, in seven other cases in Indore, Bhopal and Mumbai (LTU) commissionerates, the assessees had availed of cenvat credit of service tax paid on inadmissible input services. The cenvat credit of Rs. 1.17 crore taken during the period April 2005 to September 2008, was recoverable.

3.4 Default in payment of duty

Rule 8 (1) of the CCR provides that duty is to be paid by the stipulated dates. As per proviso to rule 3(4) of the CCR, cenvat credit shall be utilised only to the extent it is available on the last day of the month, for payment of duty relating to that month. In the event of any failure, it shall be deemed that goods have been cleared without payment of duty.

M/s Mega International Pvt. Ltd., Gurgaon, in Delhi III commissionerate, engaged in manufacture of pharmaceutical products paid duty amounting to Rs. 1.82 crore during the period from October 2007 and September 2008 through cenvat credit account.

We found that the records of the assessee showed negative balances in its cenvat credit account throughout this period. Therefore, the entire payment through cenvat account is to be treated as default in payment of duty. The entire amount of Rs. 1.82 crore is recoverable alongwith interest of Rs. 11.83 lakh (till March 2009). Additionally, a penalty of Rs. 1.82 crore is also leviable.

3.5 Simultaneous availing of cenvat credit on capital goods and depreciation under Income Tax Act

According to Rule 4(4) of the CCR, if cenvat credit is taken for duty paid on acquiring capital goods, the amount of credit taken shall be deducted from the value of capital goods while calculating depreciation under section 32 of Income Tax Act, 1961.

Three assessees, M/s Cassel Research Laboratories Pvt. Ltd., M/s. A to Z Life Sciences and M/s Fourtts (India) Laboratories Pvt. Ltd., in Chennai IV, Puducherry and Chennai III commissionerates respectively, took cenvat credit on capital goods but did not deduct them while claiming depreciation. Credit of Rs. 46.21 lakh was taken incorrectly in this manner during the period from April 2005 to March 2008.

On this being pointed out (February 2009), the department accepted (March 2009) the audit contention in the cases of M/s A to Z Life Sciences, Puducherry and M/s Fourtts (India) Laboratories Pvt. Ltd. It intimated the recovery of Rs. 16.12 lakh with interest of Rs. 1.88 lakh in February - March 2009. Reply in respect of the third assessee was awaited (March 2010).

CHAPTER IV
EXEMPTIONS

Under section 5A(1) of the Central Excise Act, 1944, the Government is empowered to exempt goods, fully or partially, from the levy of excise duty subject to the conditions specified in the notification granting the exemption.

During the course of our audit we have observed instances of violation of notifications relating to SSI exemption and availing of credit facility while paying duty under area based exemptions.

4.1 Exemption to Small Scale Industries

Notification No. 8/2003 CE dated 1 March 2003, as amended, stipulates that manufacturers whose aggregate value of clearances for domestic consumption in the preceding financial year did not exceed Rs. four crore were eligible for exemption from duty upto an aggregate value not exceeding Rs. one crore (Rs. 1.5 crore with effect from 1 April 2007). To determine the aggregate value of clearances for applying the maximum limit of Rs. four crore, the clearances at 'Nil' rate of duty are also to be included as per notification No. 6/2003 of March 2003, as amended in March 2006. One of the conditions for availing the above exemption was that the manufacturer was not to take cenvat credit of duty paid on inputs.

4.1.1 M/s B.M. Pharma Ltd., in Chandigarh commissionerate, engaged in manufacturing of pharmaceutical products availed the SSI exemption during 2007-08. Test check of records, revealed that assessee had made clearances of Rs. 6.86 crore during the year 2006-07. It had excluded clearances of Rs. 2.98 crore made at nil rate of duty to arrive at a net turnover below Rs. four crore. This was not permitted as per notification No. 6/2003. Therefore, the assessee was not entitled for SSI exemption in the next year i.e. 2007-08 and central excise duty of Rs. 23.98 lakh was leviable on the clearances of Rs. 1.49 crore made during 2007-08.

On this being pointed out (November 2008), the department stated (August 2009) that two SCNs for Rs. 23.98 lakh (Rs. 3.16 lakh and Rs. 20.82 lakh) had been issued in April and August 2009.

4.1.2 Two assessees, M/s Burgeon Pharmaceuticals, Singaperumalkoil, in Chennai III commissionerate and M/s Pharmafabrikon, in Madurai commissionerate, were manufacturing their own products as well as products for other customers. They availed the benefit of the above notification, for clearances of their own products upto the limit prescribed. For the manufacture and clearance of products of other customers, no exemption was availed and duty was paid for clearances from 1 April 2005 onwards. However, the assessees availed cenvat credit of duty paid on inputs used in the

manufacture of products of other customers. The condition prescribed in the notification, bars the availing of cenvat credit on inputs and does not distinguish between inputs used for own products and products of other customers. Accordingly, the assessees were not eligible to avail the benefit of the notification cited above and were liable to pay duty for clearances of its own products also from 1 April 2005 onwards. The non-payment of duty by the assessees during the period from April 2005 to September 2008 worked out to Rs. 34.37 lakh.

4.2 Irregularities relating to area based exemption in Kashmir

4.2.1 Incorrect credit on account of education cess and secondary and higher education cess

Notification No. 56/2002, dated 14 November 2002 stipulates that refund of central excise duty and additional duty of excise will be given under area based exemption. Thus education cess and secondary and higher education cess are not refundable.

M/s Lupin Ltd., EPIP, Bari Brahmana, in J & K commissionerate, was registered (14 July 2007) with the central excise department for formulation of allopathic pharmaceuticals came under the LTU[7] regime with effect from 12 May 2008. The assessee claimed (August 2007) refund of basic excise duty, cess and Secondary and Higher Education Cess from the assistant commissioner, central excise department, Jammu. It allowed the refund of basic excise duty and rejected the other refunds as they were not covered by the area based exemption notifications.

The assessee continued to claim refunds totalling Rs. 18.88 lakh and Rs. 9.46 lakh on account of education cess and secondary and higher education cess respectively upto July 2008 with the assistant commissioner, central excise department, Jammu. Although no refund orders were issued, the assessee credited these claims totalling Rs. 28.34 lakh in its PLA under notification no.65/2003, dated 6 August 2003, in August 2008, by which time it had shifted to the jurisdiction of LTU, Mumbai. It paid duty using these credits made in the PLA. This action was irregular as the assessing officer had refused the claims and the assessee disregarded these orders and credited its claims to PLA. The PLA credit of Rs. 28.34 lakh and interest of Rs. 3.68 lakh (till March 2009) is recoverable.

On this being pointed out (March, 2009), the central excise department, J&K, forwarded the copy of the observation to the assistant commissioner central excise, office of commissioner LTU Mumbai, in whose jurisdiction assessee falls now. Response from LTU, Mumbai has not been received (March 2010).

[7] Large tax payer unit

4.2.2 Eligibility conditions

The CCRs provide that a manufacturer can take 50 per cent of cenvat credit immediately in respect of capital goods received in the factory premises and the balance only in subsequent financial years. The manufacturer can also take credit for additional duty of customs on imported inputs/capital goods. For availing of area based exemption in J & K under notification No. 56/2002 CE dated 14 November, 2002 it is mandatory to take and utilise cenvat credit for payment of duty. After exhausting the accumulated cenvat credit, the balance of excise duty is paid in cash by the manufacturer and thereafter it is refunded to him by the department.

(i) M/s Medley Pharmaceuticals Pvt. Ltd. Jammu, in J & K commissionerate, engaged in the manufacture of allopathic medicines, acquired capital goods from Mumbai during April/May 2006. The assessee should have taken cenvat credit of Rs. 26.28 lakh and used it to pay duty. However, he did not take any credit and paid the entire central excise duty from PLA account which was subsequently refunded to him. Since the assessee had not complied with the provision, the area based exemption was not available to him in this case and exempted duty of Rs. 26.28 lakh was recoverable with interest of Rs. 8.26 lakh (till March 2009).

On this being pointed out (February 2008), the department intimated (April 2008) that a SCN had been issued to the assessee.

(ii) Similarly, M/s. Cadila Pharmaceuticals Ltd., M/s. Ind-Swift Ltd., M/s. Medley Pharmaceuticals and M/s. Parenteral Pharma, in J & K commissionerate, did not take credit for additional excise duty of Rs. 6.57 lakh on imported inputs/capital goods. Consequently, the ineligible exemption of Rs. 6.57 lakh was recoverable with interest of Rs. 1.34 lakh (till March 2009).

On the observations being pointed out (March 2009), the department admitted (April 2009) these and intimated recovery of Rs. 1.66 lakh in the case of M/s. Ind-Swift Ltd.

4.2.3 Clearance of goods at incorrect assessable value

Section 4A of Central Excise Act, 1944 provides that where goods are cleared with a printed MRP, excise duty will be charged on the MRP less abatement, if any, allowed by the Central Government.

M/s Cadila Pharmaceuticals Pvt. Ltd., Samba, in J & K commissionerate, engaged in the manufacture of tablets, capsules and syrups, was availing of exemption of duty under area based exemption. They had cleared some finished products under section 4A of Central Excise Act, 1944 at lesser assessable value, resulting in short payment of central excise duty of Rs. 13.21 lakh (including education cess of Rs. 0.26 lakh). The assessee is also liable to pay interest of Rs. 2.58 lakh (till March 2009) under section 11AB of Central Excise Act, 1944. The department intimated (April 2009) that necessary action had been initiated and the party had been asked to deposit the pending dues alongwith interest immediately.

CHAPTER V
SERVICE TAX

Service tax was introduced from 1 July 1994 through the Finance Act, 1994. The administration of service tax has been vested with the central excise department under the Ministry of Finance. The Central Board of Excise and Customs has set up a separate apex authority headed by the Director General Service Tax (DGST) at Mumbai for the administration of service tax. Commissioners of central excise/service tax have been authorised to collect service tax within their jurisdiction. Failure to deposit service tax attracts penalty equal to service tax not paid, under section 78 of the above Act.

During the course of our audit we have observed that manufacturers of pharmaceutical products have received services from foreign service providers and provided output services as well. However, some of them have not paid or short paid service tax on various categories of services. Those cases are illustrated below: -

5.1 Services received from foreign service providers

5.1.1 Banking and other financial services

The Service Tax Rules provide that a person receiving taxable services in India has to pay service tax on services received from a person/ company who is a non-resident or is from outside India and does not have any office in India.

M/s Panacea Biotech Ltd., in Division II of Delhi commissionerate, issued foreign currency convertible bonds for US $ one billion (equivalent to Rs. 446.20 crore) in February 2006 for which they paid commission of US $ 30.85 lakh (equivalent to Rs. 13.77 crore) to Merril Lynch International London, their foreign merchant banker.

We found that M/s Panacea Biotech Ltd. neither deducted nor paid the applicable service tax of Rs. 1.41 crore on such commission. Penalty of Rs. 1.41 crore and interest of Rs. 38.03 lakh from March 2006 to March 2008 was leviable.

On this being pointed out (March 2008), the department intimated (February 2009) that SCN for Rs. 1.41 crore was issued to the assessee.

5.1.2 Intellectual property rights and management consultancy services

M/s Ranbaxy Laboratories Ltd., Dewas, in Indore commissionerate, availed of taxable services namely intellectual property rights and management consultancy services from foreign service providers during the years 2005, 2006 and 2007.

We found that royalty and service charges of Rs. 412.61 crore in foreign currency were paid during that period but the applicable service tax of

Rs. 47.91 crore, including cess of Rs. 1.10 crore, was not paid by the assessee and was liable to be recovered together with interest of Rs. 12.65 crore (upto March 2009) and penalty of Rs. 47.91 crore. The total amount recoverable was Rs. 108.47 crore.

5.1.3 Business auxiliary services

5.1.3.1 M/s. Lupin Ltd. (Plant I), Mandideep, Raisen, in Mumbai (LTU) commissionerate, paid Rs. 203.57 crore to foreign service providers in foreign currency during April 2005 to March 2008 for business promotion and analytical charges. The assessee did not pay the service tax of Rs. 23.69 crore (including cess) under BAS which was recoverable with interest of Rs. 5.73 crore (upto March 2009) and penalty of Rs. 23.69 crore. The total amount recoverable worked out to Rs. 53.11 crore.

5.1.3.2 Similarly, M/s Modi Mundi Pharma (P) Ltd., in Meerut I commissionerate, paid commission and technical know-how fees to foreign service providers in foreign currency amounting to Rs. 12.35 crore during the period April 2005 to March 2008 but did not pay service tax of Rs. 1.44 crore. This was recoverable alongwith interest of Rs. 30.71 lakh (upto March 2009) and penalty of Rs. 1.44 crore. The total recoverable amount was thus Rs. 3.19 crore.

5.1.3.3 M/s Albert David Ltd., in Kolkata I commissionerate, sold medicines to different countries through foreign agents and paid them commissions/fees in foreign currency. The assessee also paid bank charges in foreign currency to foreign banks for banking services. These services fell under BAS and banking and other financial services. The assessee did not pay service tax and education cess of Rs. 36.52 lakh for these services during the period April 2004 to March 2007 which was recoverable with interest of Rs. 9.50 lakh (upto March 2009) and penalty of Rs. 36.52 lakh.

On this being pointed out (March 2008), the department admitted the observation and stated (February 2009) that SCN is being issued.

5.2 Technical testing and analysis services provided by assessee

The service of technical testing and analysis was covered under service tax with effect from 1 July 2003. In the context of pharmaceutical products, an insertion in Finance Act, 2006 clarified that technical testing and analysis includes testing and analysis undertaken for the purpose of clinical testing of drugs and formulations and does not include testing or analysis for determining the nature of diseased condition, identification of a disease and prevention of any disease or disorder in human being or animals.

5.2.1 M/s. Johnson & Johnson Ltd. India, in Mumbai (ST) commissionerate, conducted clinical trials of new drugs and formulations for its parent/associated company i.e., Johnson & Johnson PRD in USA. It received payments of Rs. 4.19 crore from May 2006 to February 2007 from the parent company but did not pay service tax of Rs. 51.26 lakh including cess.

On being pointed out, the company accepted the observation and paid (January 2009) the service tax and interest amounting to Rs. 62.98 lakh.

5.2.2 M/s Lupin Ltd. (Plant I) Mandideep, Raisen, in Mumbai (LTU) commissionerate, did technical testing and analysis of quality control samples on behalf of a sister concern and received Rs. 6.11 crore as service charges during the years 2005-06 to 2007-08. The applicable service tax of Rs. 74.09 lakh (including cess) was not paid and was recoverable alongwith interest of Rs. 14.98 lakh (upto March 2009) and penalty of Rs. 74.09 lakh.

5.3 Business auxiliary services provided within the country

Business auxiliary service has been brought under service tax net with effect from 1 July 2003. It is defined as any service in relation to production or marketing or sale of goods or promotion or marketing of services or any customer care services in any manner to a client.

5.3.1 Receipts on account of market authorisation fee

M/s. Ranbaxy Laboratories Ltd., Dewas, in Indore commissionerate had disclosed receipts of Rs. 18.16 crore for services rendered and on account of market authorization fee for the years ended 2005, 2006 and 2007. These receipts were covered under BAS. The assessee did not pay service tax of Rs. 2.20 crore (including cess) which was recoverable with interest of Rs. 49.59 lakh (upto March 2009) and penalty of Rs. 2.20 crore.

5.3.2 Services provided by job worker on conversion charges

Service tax is exempted when a service provider acts as a job worker i.e. it processes raw material or semi finished goods supplied by a client and returns the processed items to the client for manufacture of a final product on which excise duty is leviable. The exemption is not available for final products liable to 'nil' rates of duty or otherwise exempted.

M/s Rugby Pharma Pvt. Ltd., in Kolkata V commissionerate, was processing, as a job worker, raw material or semi finished goods supplied by a client M/s Organon (India) Ltd. We found that the assessee did the processing for some pharmaceutical products viz., Novelon, Femilon, Cerazzat, Elogen, Zerocen, Pavulon which were either exempt or had 'nil' rate of excise duty. The assessee collected Rs. 8.10 crore as conversion charges from the client for processing related to these exempted medicines during April 2005 to June 2008. Since no duty was finally paid on these medicines, the assessee was liable to pay service tax under BAS on the conversion charges which was not done. The service tax of Rs. 95.21 lakh including education cess of Rs. 2.59 lakh and penalty of Rs. 95.21 lakh were recoverable with interest of Rs. 18.02 (till March 2009).

5.4 Incorrect grant of exemption from 75 per cent of value of services

Notification No. 32/2004 ST dated 3 December 2004 stipulates that 75 per cent value of taxable service provided by 'Goods Transport Agency (GTA)' to its customer is exempt from the levy of service tax subject to the condition that cenvat credit is not taken by the GTA on inputs or capital goods used for providing such services. The Board clarified on 27 July 2005 that the person availing of exemption under this notification will have to obtain a declaration from its GTA on the consignment notes to the effect that conditions of aforesaid notification have been satisfied.

M/s Albert David (P) Ltd., in Ghaziabad commissionerate, engaged in the manufacture of patent or proprietary medicaments, availed of the services of GTA and paid freight charges of Rs. 14.11 crore during the period January 2005 to March 2008. It paid service tax of Rs. 41.04 lakh, after availing of exemption of 75 per cent on the gross freight charges paid to GTA. The declaration on not availing of cenvat credit was not available on any of the consignment notes issued by the GTA. Exemption of service tax of Rs. 63.65 lakh was, therefore, recoverable alongwith interest of Rs. 8.24 lakh (upto March 2009) and penalty of Rs. 63.65 lakh totalling to Rs. 1.36 crore.

5.5 Other cases

In 57 other cases, the assessees either did not pay or short paid service tax of Rs. 3.51 crore including education cess. In 29 of these cases, the assessees were also liable to pay interest of Rs. 35.68 lakh on short payment of service tax and in 20 of these cases, penalty of Rs. 1.16 crore was chargeable. In 19 out of 57 cases, the department accepted the related audit observations involving service tax of Rs. 1.53 crore and recovered Rs. 1.43 crore in 16 cases (February 2010).

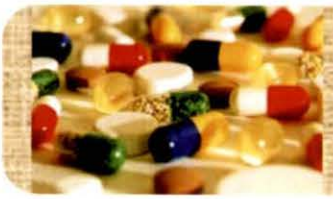
In our opinion, the root cause of cases of non payment of service tax pointed out in this chapter was the absence of any mechanism to ascertain whether manufacturers were providing any output services. This facilitated 67 manufacturers of pharmaceutical products to avoid payment of total service tax of Rs. 182.81 crore under various services.

Recommendation No. 8

- *The Government may consider integrating the excise and service tax returns to mitigate the risk of evasion of duties/tax more so as the environment of all tax administration is becoming e-enabled, especially post introduction of ACES (Automation of Central Excise and Service Tax).*

The Ministry stated (January 2010) during the exit conference that prescribing a common return would not solve the problem. However, the concern flagged by audit would be taken care of when GST is introduced by Government. In the light of the discussions, it is suggested that till the introduction of GST, it

may be made mandatory that manufacturers should declare on their excise returns whether they have provided any output services or received any service from foreign service providers.



CHAPTER VI
PRICING

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 a 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.

6.1.1 During the scrutiny of records, we found that certain manufacturers under Pune III, 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.

CHAPTER VII
MISCELLANEOUS ISSUES

7.1 Non levy of duty, interest and penalty

Rule 19 of the Central Excise Rules, 2002, stipulates that excisable goods can be exported without payment of duty subject to the conditions and procedures as laid down in the notification dated 26 June 2001, as amended. One of the conditions requires that the goods should be exported within six months from the date on which these were cleared for export or such extended period as may be allowed.
Section 11AB of Central Excise Act, 1944, stipulates that where any duty of excise has been short levied or short paid, the assessee shall pay the differential duty with interest.

7.1.1 M/s Leemark Healthcare Pvt. Ltd., in Ahmedabad II commissionerate, had cleared pharmaceutical products for export without payment of duty during the period April 2006 to March 2007. However, neither was any proof of export submitted upto October 2008 nor was any extension of time sought and granted. The department has to recover the duty involved of Rs. 76.98 lakh.

7.1.2 In 14 other cases, where export lapses were noticed by us, loss/short payment of duty of Rs. 91.11 lakh was observed. Of these, in six cases, the department accepted the audit observation of Rs. 3.20 lakh and reported recovery of Rs. 1.65 lakh in five cases.

7.1.3 We found that M/s Ranbaxy Laboratories Ltd., Dewas and M/s. Nicholas Piramal India Ltd., Pithampur, in Indore commissionerate, were engaged in manufacturing of patent or proprietary medicines and had made short payment of duty on physician samples cleared during the period April 2005 to September 2006. They paid the differential duty of Rs. 70.12 lakh including cess in December 2006 and September 2008 but interest of Rs. 17.07 lakh was not levied or paid.

On this being pointed out (May 2007 and February 2009), the department stated (October 2008) that the interest of Rs. 2.69 lakh was deposited in May 2007 by M/s Nicholas Piramal India Ltd., Pithampur and the recovery of the interest of Rs. 14.38 lakh was being pursued (February 2009) with M/s Ranbaxy Laboratories Ltd., Dewas.

7.1.4 Similarly, during the period April 2005 to December 2008 in 25 other cases, the assessees did not pay the duty of Rs. 18.64 lakh in 12 cases, interest of Rs. 26.10 lakh in 17 cases and penalty of Rs. 8.70 lakh was not levied in three cases. On these cases being pointed out, the department accepted 11 cases involving Rs. 17.07 lakh and recovered Rs. 11.16 lakh in 10 cases and issued SCN for Rs. 5.29 lakh in one case.

7.2 E-payment procedure

CBEC vide notification No. 8/2007 CE (NT) dated 1 March 2007 had made e-payment of central excise duties mandatory with effect from 1 April 2007 for the assessees who had been paying central excise duty of Rs. 50 lakh or more.

Audit scrutiny revealed that e-payment procedure had not been followed by six assessees, in five commissionerates, though these were paying duty of more than Rs. 50 lakh during the financial year 2006-07. The monitoring of the implemention of e-payment needs to be strengthened.

7.3 Acceptance of proof of export by division

The Board directed (vide circular dated 6 November 1996) that a special drive should be initiated to liquidate the pendency in acceptance of proof of exports as an export facilitation measure. Thereafter, acceptance of proof of exports was to be conveyed within 15 days of receipt.

A scrutiny of the records of Division VI in Delhi commissionerate revealed that M/s Panacea Biotech had submitted the proof of exports involving duty of Rs. 21.12 crore during the period 31 May 2006 to 29 September 2007 for acceptance. The certificates of acceptance were not issued by the division upto May 2009 in 100 such applications. The delays ranged upto three years.

New Delhi
Dated : 2-7-2010

(SUBIR MALLICK)
Principal Director (Indirect Taxes)

Countersigned

New Delhi
Dated : 2-7-2010

(VINOD RAI)
Comptroller and Auditor General of India

Glossary of terms and abbreviations

Abbreviated form	Expanded form
AC	Assistant Commissioner
ACES	Automation of Central Excise and Service Tax
BAS	Business Auxiliary Services
Board or CBEC	Central Board of Excise and Customs
CCE	Commissionerate of Central Excise
CE	Central Excise
CEGAT	Central Excise and Gold Appellate Tribunal
CENVAT/cenvat	Central Excise Value Added Tax
CESTAT	Customs, Excise & Service Tax Appellate Tribunal
CETA	Central Excise Tariff Act, 1985
CETH	Central Excise Tariff Heading
CGHS	Central Government Health Scheme
DC	Deputy Commissioner
DGS & D	Directorate General of Supplies and Disposals
DPCO	Drugs (Prices Control) Order, 1995
ELT	Excise Law Times
EOU	Export Oriented Unit
FDA	Food and Drug Administration
GOI	Government of India
GTA	Goods Transport Agency
ISD	Input Service Distributor
IT	Income Tax/Information Technology
KPIs	Key Performance Indicators
Ltd.	Limited
LTU	Large Taxpayer Unit
MAPE	Maximum Allowable Post Manufacturing Expenses
MRP	Maximum Retail Price
MSD	Medical Store Depot
NPPA	National Pharmaceutical Pricing Authority
NT	Non-Tariff
P or P	Patent or Proprietary
PLA	Personal Ledger Account
Pvt.	Private

Abbreviated form	Expanded form
RAC	Regional Advisory Committee
RSP	Retail Sale Price
SC	Supreme Court
SCN	Show Cause-cum-Demand Notice/Show Cause Notice
SEZ	Special Economic Zone
SSI	Small Scale Industries
ST	Service Tax
UNO	United Nations Organisation
VAT	Value Added Tax

PRICE INLAND: Rs.65.00
Foreign: US$ 5
(including postage/air mail)