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.