Chapter I: Introduction

1.1 Introduction

Indian Pharmaceuticals Industry has witnessed a robust growth⁴ over the past few years. The industry ranks 3rd in terms of volume and is 14th in terms of value globally thereby accounting for around 10 *per cent* of world's production by volume and 1.5 *per cent* by value. It has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of products. It has established its presence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies. Globally, it ranks 4th in terms of generics production and 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, West Europe, Japan and Australia.

The annual turnover of the Indian Pharmaceutical Industry vis-a-vis share of export of Drugs, Pharmaceuticals and Fine Chemicals for the last four years ending 31 March 2013 is given below.

Table 1.1: Annual Turnover vis-a-vis Export

(₹ in crore)

Year	Total Turnover	Export	Percentage of Export over Turnover
2009-10	1,04,209	42,154	40.45
2010-11	1,04,944	47,551	45.31
2011-12	1,19,076	47,363	39.78
2012-13	1,21,016	55,693	46.02

Source: Annual Reports for the years 2010-11 to 2013-14, Government of India, Ministry of Chemical and Fertilizers and Department of Pharmaceuticals.

The industry has developed excellent Good Manufacturing Practices (GMP) compliant facilities for the production of different dosage forms. The strength of the industry is in developing cost effective technologies in the shortest possible time for drug intermediates and bulk activities without compromising on quality. This is realized through the country's strengths in organic chemicals' synthesis and process engineering. Due to this, there is demand from both domestic as well as international markets. This has resulted in a robust growth since the beginning of the 11th Plan in 2007 from about ₹ 71,000 crore to over

4 Increase of turnover of approx. US \$ 1 billion in 1990 to US \$ 20 billion in 2010 of which the export turnover is approximately US \$ 8 billion (as per reports of Department of Pharmaceuticals)

₹ 1,21,015 crore in 2012-13 comprising some ₹ 65,323 crore of domestic market and exports of over ₹ 55,692 crore⁵, thereby making it a vital economic sector with corresponding potential for Government revenue.

1.2 Why we chose the topic

Considering the robust growth in pharmaceutical industry in the last four years and the Government support in the form of fiscal incentives i.e. deduction against business profits in the Income Tax Act and concessional rate of excise duties and State VAT, we felt it appropriate to select Pharmaceutical sector for performance evaluation to seek assurance that exemptions and deductions allowable to Pharmaceuticals Sector under Income Tax Act, 1961 (Act) have been allowed as per entitlement and there exists a proper machinery to exercise necessary checks/controls in the area of probable misuse of the provisions relating to tax concessions.

Previously, we have conducted a performance evaluation on the working of companies in Pharmaceutical Sector in the year 2001⁶ in which we had raised issues pertaining to compliance issues of the Act. However, Public Accounts Committee did not select this report for discussion. The present review was selected to seek assurance on compliance aspect of the Act as well as systemic issues relating to assessment of assessee of Pharmaceuticals Sector.

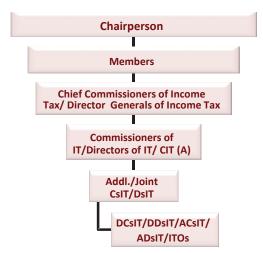
1.3 Organizational set up

Central Board of Direct Taxes (CBDT), as a part of Department of Revenue, Ministry of Finance, is the apex body charged with administration of Direct Taxes. CBDT is headed by the Chairperson and comprises of six Members. In addition to functions and responsibilities, the Chairperson and Members are responsible for exercising supervisory control over field offices of the CBDT, known as Zones. In scheme of reorganization Principal Chief Commissioner of Income Tax (PCCIT) is the Cadre Controlling Authority of each zone whose jurisdiction is generally coterminus with state. Organogram of CBDT showing the hierarchy of various formations is shown in Graph 1.1

⁵ Planning Commission Working group on Drugs and Pharmaceuticals

⁶ Report of the Comptroller and Auditor General of India for the year 2001-02 (Report No.13 of 2003-Direct Taxes)

Graph 1.1 Organogram of CBDT



1.4 Legal Provisions

Pharmaceutical industry is mainly R&D oriented industry and many of its units are located in certain special category States. Also, there has been significant increase in the exports by the industry over the years. The assessees engaged in the Pharmaceuticals Sector are governed by all the provisions of the Act which are applicable to the assessees. However, these assessees are mainly availing deductions under Section 35(1)(iia), 35(2AB), 10B and 80IC which are briefly discussed in the table below:

Section 35(1)(iia)

A deduction of 125 *per cent* of any sum paid to a company to be used by it for scientific research subject to fulfilment of prescribed condition.

Section 35(2AB) A deduction of 200 *per cent* of the expenditure incurred by the company engaged in the business of bio-technology or in any business of manufacture or production of any article or thing, not being an article or thing specified in the list of the Eleventh Schedule on scientific research (not being expenditure in the nature of cost of any land or building) on inhouse research and development facility as approved by the Secretary, Department of Scientific & Industrial Research (DSIR), Government of India.

Section 10B Deduction of profit and gain derived by a 100 *per cent* export oriented undertaking from the export of article or things or computer software subject to the fulfilment of prescribed condition.

Section 80IC In computing the total income of the assessee, a deduction of profits and gains as specified in sub-Section (3) shall be allowed, where the gross total income of an assessee includes any profits and gains derived by an undertaking or an enterprise from any business referred to in sub-Section (2) in accordance with and subject to the provisions of this Section.

Assessees of Pharmaceuticals Sector apart being governed by the Act for tax purposes, are also regulated by bodies like Medical Council of India and National Pharmaceuticals Pricing Authority and Department of Scientific and Industrial Research. We have also correlated the guidelines/instructions issued by the above bodies/Department with instructions issued by CBDT in conducting the present Performance Audit.

1.5 Audit Objectives

The review is intended to focus on

- **a.** Whether the exemptions and deductions allowable to Pharmaceuticals Sector have been allowed as per entitlement.
- **b.** Whether the administrative and procedural adequacy for taxation of Pharmaceuticals Sector exists.
- **c.** Whether the deduction of Research and Development (R&D) expenditure to the assessees in Pharmaceuticals Sector has contributed to the growth in industry as well as in tax revenues.

1.6 Audit Scope

The Performance Audit covered assessments completed during the period from 2010-11 to 2013-14 and up to the date of audit of (September 2014) assessees dealing in Pharmaceuticals sector. In case of major audit observations assessment records of previous assessment years were also checked/linked wherever found necessary.

1.7 Sample Size

We filtered and segregated data provided by Director General of Income Tax-(System) in respect of Pharmaceutical assessees and Demand & Collection Register (D&CR) of the selected assessing charge. Within the selected units, we selected all cases of scrutiny assessments pertaining to assessees in Pharmaceuticals sector for this Performance Audit. We requisitioned 3,432 assessment records from the assessment units of the Income Tax Department (ITD) located all over India. However, the ITD produced and we audited 2,868 (83.57 per cent) assessment records.

1.8 Audit Constraints

The ITD was not having separate database for identification of sector wise assessees. This hampered the selection of the assessment records of assessee engaged in the Pharmaceuticals Sector. As a result of this sample size was restricted to the extent of data available with the ITD and assessee identified by

the audit from Demand and Collection Register maintained by the respective Assessing Officer (AO) and data received from the DGIT (Systems) which was also not complete. Therefore, some of the significant cases related to the Pharmaceuticals Sector may remain out of coverage from the scope of audit in the absence of details.

1.9 Acknowledgement

We acknowledge the cooperation of ITD in facilitating the audit by providing necessary records and information in connection with the conduct of this Performance Audit. An entry conference with CBDT was held on 11 July 2014 wherein audit objectives, scope of audit and the main focus areas of audit examination were explained.

We issued draft report to the Ministry in December 2014 for their comments. After receipt of the Ministry's reply in January 2015, we held exit conference on 15 January 2015 to discuss our findings and recommendations vis-a-vis the Ministry's comments. We again issued draft report in January 2015 containing Ministry's views and audit stand thereon for their further comments. We received further comments from the Ministry on 29 January 2015 which has also been appropriately incorporated in the report together with audit comments thereon.