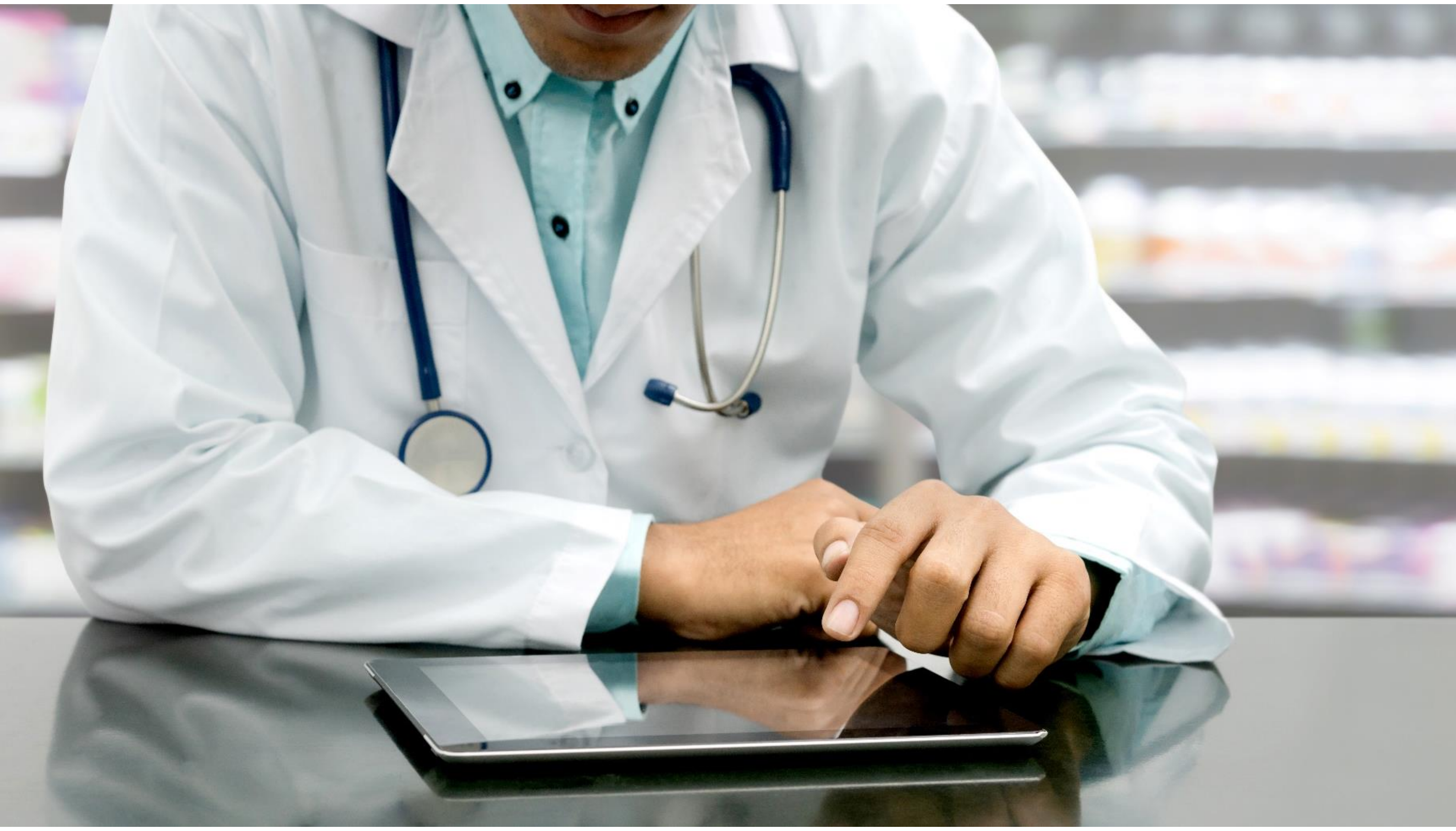
PHARMA SECTOR
AN OVERVIEW

BDO IN INDIA
2023



India’s Pharmaceutical Industry is currently the 3rd largest in terms of volume and 14th largest in terms of value.

India has significantly contributed to shaping the healthcare outcomes of patients around the world. The Covid-19 pandemic brought about a paradigm shift in the sector. Today, the pharma landscape is continuously evolving with changing regulations, geo-political and technological development.

The pharmaceutical industry is a knowledge-driven sector that demands highly skilled professionals. India has an edge due to its ever-increasing pool of talented scientists, engineers, and entrepreneurs along with its demographic advantage. However, it will be critical to invest in building an ecosystem for skilling to stay globally competitive and adapt to changing times.

To scale up to the next level, the industry needs to invest more in R&D. However, given that the risk of failure in case of new product research is around 90%, pharma companies would be required to be incentivised to encourage them to spend more on R&D.

While some of the critical life saving drugs and vaccines are subject to GST @ 5%, most of the other medicines attract GST @ 12%, while food supplements and the like are taxable @ 18%. Given the lower rate of 5%/12% on most of the pharma products and most of the raw materials being subject to 18%, the pharma industry is under inverted duty structure.

INCENTIVES

The Government of India has taken various policy initiatives to strengthen scientific research and development in pharmaceutical sector.

The Income-tax Act, 1961 (‘Act’) offers certain incentives to activities undertaken for Research and Development. Some of the key benefits / incentives offered under the Act are:

- Concessional corporate tax regime provided to companies setting up new manufacturing or production facilities on or before 31 March 2024. Enhanced deduction for hiring new employees, subject to certain conditions.
- The expenditure incurred on scientific research or in-house research & development facility as approved by the Department of Scientific & Industrial Research are allowed as a deduction to Companies. Further, entire capital expenditure incurred (other than land) for research & development is eligible to be claimed as deduction in the year in which expenditure is incurred, instead of claiming deprecation on such expenditure over a period of time.
- Contributions made to scientific research association or to any university, college, or other institution, for the purpose of scientific research approved by the concerned authority shall be allowed as deduction under the Act.

ITC reversal on Expired Stock, Physician Samples, Promo Material etc.

In view of the regulatory obligations and expiry of products, the pharma industry is required to destroy expired pharma products. This in turn necessitates the taxpayer to reverse the corresponding Input tax credit claimed in respect to such "goods destroyed." This increases costs in the hands of the pharma companies, while such inevitable consequences are factored in the costing/pricing of products, on which applicable GST is paid. Similar, ITC reversal concerns exist in cases of free medical samples given to various doctors/hospitals as a part of marketing/promotional initiatives. These free sample distribution costs are also factored in pricing of the products. This being one of the major ways in which pharma companies promote the use of their drugs and considering it is a core business exigency, it is expected that the Government takes necessary steps and permit ITC in such cases as it is integrally connected to the business. The calculations for such reversals are also complex and may lead to difference in views with the tax authorities.

Refund on FOB value instead of the CIF value

The tax authorities have issued certain clarifications wherein it has been clarified that the refund of taxes paid on export of goods shall be granted only on the basis of FOB value and not on the CIF value. This has resulted in higher accumulation of the accrued credit and lower refund.

Lack of benefits / concessions for R&D activities

Leaders of the pharmaceuticals industry have urged the government to prioritise schemes to enhance innovation and research along with tax incentives on drug development expenditure which will help propel the industry to the top globally. Tax incentives on R&D expenditure, allocation of funds for setting up centres of excellence across the country by way of collaboration between industry players and academic institutions will be key steps in the right direction.

CHALLENGES UNDER DIRECT TAX:

Disallowance of deduction of expenses incurred in promotion

In order to promote the brand of a drug, pharmaceutical and allied health sector products/ services industries give gifts, in cash or in kind, travel facility, hospitality, cash or monetary grant to medical practitioners and their professional associations. Section 37 of the Act provides that deduction shall not be allowed in respect of any expenditure incurred for any purpose which is an offence or prohibited by law. Further, the Central Board of Direct taxes ('CBDT') has issued a circular clarifying that expense incurred in providing the above benefits are in violation of the provisions of Indian Medical Council (Professional conduct, Etiquette and Ethics) and same shall be disallowed as it is the expense prohibited by the law. Also, this is a matter that has been subject to litigation in various courts.

Scientific research expenditure

Section 35(2AB) of the Act provides a deduction of a sum equal to 100% of the expenditure incurred by a Company engaged in the business of biotechnology on scientific research on inhouse research and development facility. However, there are certain areas which are prone to litigations such as a) Expenditure incurred outside the R&D facility – whether allowable or not. b) Income from sale of IP developed by R&D Facility – Should it be reduced for computation of expenditure allowable u/s 35(2AB) or not. c) Expenditure incurred prior to the date of approval of the R&D facility – Allowable or not. etc.

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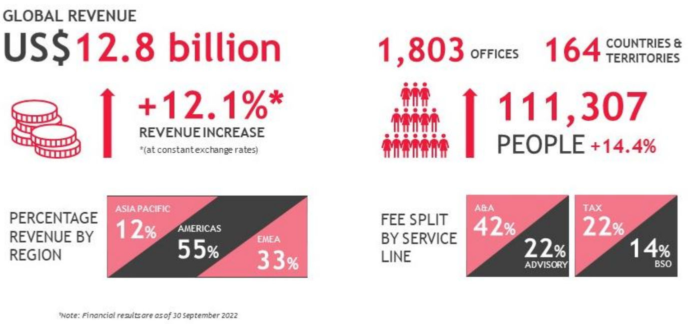

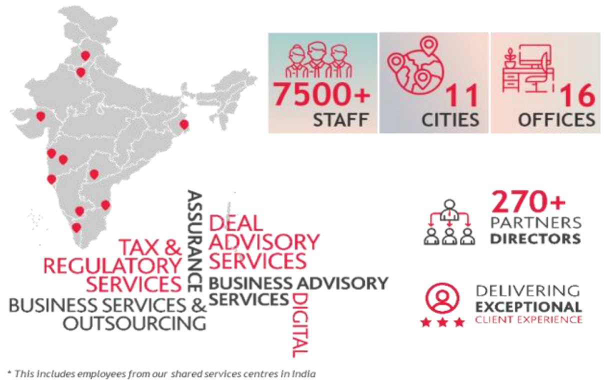

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