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Sector overview



Sector overview

India has achieved an eminent global position in the pharma sector. The Indian pharmaceutical industry is estimated to grow at 20% compound annual growth rate (CAGR) over the next five years, as per India Ratings, a Fitch Group company.

As per IBEF report, the market is dominated majorly by branded generics, which constitute nearly 70-80% of the market.

Growing at an average rate of about 20%, India's biotechnology industry comprising biopharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics may reach the US\$ 7 billion mark by the end of FY15, according to an industry body. BioPharma is the largest sector contributing about 62% of the total revenue, with revenue generation to the tune of over Rs 12,600 crore (US\$ 2.03 billion). The bio-pharma sector comprises vaccines, therapeutics and diagnostics.



The growing Indian population with increase in urbanisation has resulted in lifestyle related ailments such as heart attack, diabetes, cancer, hypertension, obesity etc. The number of people suffering from chronic diseases is set to double in India by 2020.

The government has allowed FDI up to 100% under the automatic route for manufacturing medical devices subject to specified conditions.

The government has unveiled 'Pharma Vision 2020' that is aimed at making India a global leader in end-to-end drug manufacturing. It has reduced approval time for new facilities to boost investments.

Telangana has proposed to set up India's largest integrated pharmaceutical city spread over 11,000 acres near Hyderabad, complete with effluent treatment plants and a township for employees, in a bid to attract investment of Rs 30,000 crore (US\$ 4.85 billion) in phases. Hyderabad, which is known as the bulk drug capital of India, accounts for nearly a fifth of India's exports of drugs, which stood at Rs 90,000 crore (US\$ 14.56 billion) in 2013-14. Indian and global companies have expressed 175 investment intentions worth Rs 1,000 crore (US\$ 161.78 million) in the pharmaceutical sector of Gujarat.



Sector overview



Challenges

The most important challenge for the Industry comes from regulators in developed markets, which have passed strictures against several leading Indian pharma exporters for failing to comply with good manufacturing practices. There is an urgent need for improvement in pharmaceutical manufacturing practices across the country.

As per pharmnewswire website, the country is increasingly facing constraints in providing healthcare benefits to a vast majority of its population. This is mainly because of the following key reasons:

- Low public spending on healthcare
- Fragile healthcare infrastructure
- Very low penetration of health insurance system for all strata of society
- Poor healthcare delivery system
- Absence of 'Universal Health Coverage'

Pharmaceuticals, being covered under the 'Essential Commodities Act', empower the government to announce the 'administered price' for essential medicines.



As India does not have a detailed health care system, it is imperative that the health insurance facility should be stronger. This can be done by increasing the deduction for the health insurance premium for self, for family members, senior citizens, persons with disability etc.

In case of pharma, India is globally recognised as an attractive hub for contract R&D work. However, there are no specific tax benefits available to units engaged in the business of R&D or contract manufacturing. Currently, the weighted deduction of expenditure is provided only in respect of "in-house research and development facility". On the fiscal side, as per survey carried out by Grant Thornton, an emphatic majority considered it necessary to allow weighted deduction in respect of expenses incurred outside the R & D facility which are sometimes necessitated by the industry's business needs.



Key expectations

Industry expectations

- India's healthcare infrastructure is lagging when compared with other developing countries. There exists a huge gap between demand and supply of healthcare infrastructure facilities available in the country. Hence, it is necessary that a greater impetus is given to the healthcare sector and the Budget allocation to the sector is increased
- In order to make healthcare services more affordable, the industry has been expecting the government to address its concern regarding CENVAT credit accumulation. The output services being exempt, the procurement of goods and services required for provision of healthcare services results in cash outflow
- Income Tax/ MAT exemption for at least 15 years for domestically manufactured medical technology products to promote "Make in India"
- To promote in-house R&D in India, the amount of weighted deduction under Section 35(2AB) of the Act should be deducted while computing book profit for the purpose of MAT
- Un-utilised R&D deduction should be available for carry forward and set off indefinitely

- All expenditure related to research i.e. clinical trials, bioequivalence studies, regulatory and patent approvals should be eligible for weighted deduction as per
- incurred in rural/ semi urban areas should be provided under Section 35AD
- The quantum of deduction under Section 80D to be increased
- All medical devices used in critical care, consumables used with devices in the from customs duty
- Custom duty on oats to be eliminated, excise on breakfast cereals to be brought down to 2%
- Clinical trials conducted for foreign service recipients should qualify as export of service thereby not attracting service tax in India for the clinical research by the CROs



Section 35(2AB), even if these activities are carried outside the approved R&D facility

A weighted deduction for healthcare infrastructure expenditure (other than hospitals)

specific critical care treatment procedure and their spare parts should be exempted

organisations (CROs) and also enable refund of service tax on input services availed

Budget impact – our view

"Hardly any tangible incentives for the healthcare sector other than the proposal for overall corporate tax reductions which may reap some savings in the medium term. Increase in the rates of service tax will result in additional accumulation of credits for the healthcare delivery which is usually exempt from service tax. Pharma as a sector didn't receive any mention which has disappointed an industry which has been following the Make in India campaign for several years already"





Budget announcements - Key policy initiatives



Some key announcements

- Allocation of Rs 33,150 crore for the healthcare sector
- New scheme for providing physical aids and assisted living devices for senior citizens living below the poverty line
- Preventive health care under Swach Bharat Abhiyan for building awareness
- Rationalisation of conditions for FDI in the medical devices sector



- a premium Rs 12 per year
- ٠ risk of Rs 2 lakh for a premium of Rs 330 per year for the age group 18-50
- Atal Pension Yojana to provide a defined pension, wherein the Government will years, in the new accounts opened before 31 December 2015



Pradhan Mantri Suraksha Bima Yojna to cover accidental death risk of Rs 2 lakh for

Pradhan Mantri Jeevan Jyoti Bima Yojana to cover both natural and accidental death

contribute 50% of the beneficiaries' premium limited to Rs 1,000 each year, for five

Budget announcements - Key policy initiatives



Senior citizen welfare fund

Unclaimed deposits of about Rs 3,000 crore in the PPF and approximately Rs 6,000 crore in the EPF corpus to be used for creation of a Senior Citizen Welfare Fund



- J&K, Punjab, Tamil Nadu, Himachal Pradesh and Assam
- AIIMS like institute to be set up in Bihar
- National Institute of Pharmaceutical Education and Research to be set up in Maharashtra, Rajasthan and Chhattisgarh
- An Institute of Science and Education Research to be set up in Nagaland and Odisha



All India Institutes of Medical Sciences (AIIMS) to be opened in five states namely

Budget announcements - Direct tax proposals

Key amendments

Medical insurance premium

- Existing limit of Rs 15,000 and Rs 20,000 for senior citizens has been increased to Rs 25,000 and Rs 30,000 respectively
- Deduction of Rs 30,000 has been introduced in respect of medical expenses incurred on very senior citizens (individuals who are of 80 years and above)

Deductions for investments

 Deduction for medical and insurance expenditure incurred on persons with disabilities increased from Rs 50,000 to Rs 75,000 and for persons with severe disabilities from Rs 1,00,000 to Rs 1,25,000

Deductions for medical treatment of chronic and protracted diseases

 The benefit of deduction for treatment of certain chronic/protracted diseases has been raised from Rs 60,000 to Rs 80,000 for very senior citizens (individuals who are of age of 80 years and above)



- For claiming weighted deduction under Section 35(2AB) of the Income-tax Act, audit of accounts along with furnishing of prescribed reports
- Donations made to National Fund for Control of Drug Abuse (NFCDA) shall be eligible for 100% deduction
- 10(23)(iiiac)
- Order passed by prescribed authority for hospital or other institutions for ITAT, if aggrieved
- Act
- crore
- 100% deduction for contributions, other than by way of CSR contribution, to Swachh Bharat Kosh and Clean Ganga Fund



the company to enter into agreement with the prescribed authority for cooperation in research. Also to fulfill the prescribed condition with regard to maintenance and

Mandatory return filing by hospitals and medical institutions referred to in Section

treatments under sub-clause (via) of Section 10(23C) can be appealed further to

To include yoga within the ambit of charitable purpose under Section 2(15) of the

The specified domestic transaction threshold increased from Rs 5 crore to Rs 20

Budget announcements - Direct tax proposals



Income tax rates - Individuals:

Income tax rates - Companies:

- Basic rate of tax, slabs and education cess remain unchanged for all individuals
- Surcharge increased from 10% to 12% for individuals having taxable income exceeding Rs 1 crore

Basic rate of tax and education cess remain unchanged

Surcharge for domestic companies increased by 2% as under:

- Surcharge @ 12% (if the taxable income > Rs 10 crore)

Surcharge for foreign companies remain unchanged

- Surcharge @ 7% (if the taxable income > Rs 1 crore but < Rs 10 crore)

The Finance Minister proposes to phase out exemptions and bring corresponding

reduction in Corporate Tax Rate from 30% to 25% over next four years



- Basic rate of tax and education cess remain unchanged
- Surcharge increased from 10% to 12% where the taxable income exceeds Rs 1 crore



Wealth tax to be abolished

The proposal to reduce corporate tax along with phasing out of exemptions is a welcome step towards ease of doing business. However, no roadmap in this regard has been laid out.



Budget announcements - Indirect tax proposals

Key amendments

Service tax - (Effective from date of enactment of Finance Bill, 2015; unless otherwise specified)

- Service tax rate has been increased from 12% to 14%
- Additional 2% proposed to be charged on taxable service value in the form of Swachh Bharat cess (SBC)
- Service tax exempted on ambulance services ٠
- Government clarifies the intention to include all reimbursable expenditure in the value of taxable services
- A uniform abatement @ 70% has been prescribed for transport by rail, road and vessel. Service tax shall be payable on 30% of the value of such services subject to a uniform condition of non-availment of Cenvat Credit on inputs, capital goods and input services
- Manpower supply and security services when provided by an individual, HUF, or partnership firm to a body corporate has been shifted from partial reverse charge to full reverse charge

Customs - (Effective from date of enactment of Finance Bill, 2015; unless otherwise specified)

- BCD and CVD has been exempted on artificial heart
- year

CENVAT Credit - (Effective from 1 March 2015; unless otherwise specified)

- (effective from 1 April 2015)
- under Central Excise Act and Rules



Procedural requirements eased out for patients, particularly with respect to validity of certificate required by individuals for importation of life saving drugs made valid for 1

The period of availing CENVAT credit on inputs and input services extended from six months to one year from date of invoice/ challan or other specified documents

CENVAT credit of service tax paid under domestic reverse charge now allowed to claimant, without linking it to the payment of services to the input service provider

'Exempted goods or final products' for CENVAT credit reversal now includes nonexcisable goods; value for CENVAT reversal to be invoice value or value determined

Budget announcements - Indirect tax proposals

Key amendments

CENVAT Credit - (Effective from 1 March 2015; unless otherwise specified)

- The period of availing CENVAT credit on inputs and input services extended from six months to one year from date of invoice / challan or other specified documents
- CENVAT credit of service tax paid under domestic reverse charge now allowed to claimant, without linking it to the payment of services to the input service provider (effective from 1 April 2015)
- 'Exempted goods or final products' for CENVAT credit reversal now includes nonexcisable goods; value for CENVAT reversal to be invoice value or value determined under Central Excise Act and Rules
- Effective from 1 April 2015, CENVAT credit wrongly taken (i.e. availed) or utilised by manufacturer or output service provider to attract recovery proceedings under Central Excise Act and service tax law respectively with similar penalties; thus reenforcing earlier Supreme Court verdict

- service provider
- manufacturer/ output service provider increased from six months to two years
- tax



CENVAT credit on inputs and capital goods allowed to manufacturer or output service provider, as the case may be, even in case of direct receipt of such goods in the premises of the job worker on the direction of principal manufacturer / output

The time limit for return of capital goods from premises of a job worker to principal

Penalty provisions rationalised in favor of taxpayer in Customs, Excise and Service



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