KPMG

Pharmaceuticals

Union Budget 2016

Post-Budget sectoral point of view

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Context

Where we are

The pharmaceutical sector is one of the key 25 sector identified by the Government of India under the ambitious 'Make in India' initiative, which is likely to provide the necessary impetus to the sector in order to achieve its true potential. At present, the Indian pharmaceuticals industry is third largest in volume and the tenth largest in value, globally.[1] The country's domestic pharmaceutical market is estimated at INR2,400 billion[2] and is expected to grow at approximately 12 per cent Compound Annual Growth Rate (CAGR) over the next three years. A significant increase in domestic consumption due to the higher incidence of lifestyle diseases, increasing health awareness, growing population, greater penetration in rural markets, and a nascent, yet fast growing health insurance industry, are some factors impacting the growth of the pharmaceutical market.[3] Moreover, the country's low-cost production base and the patent cliff in the global arena significantly affect the export market, play an important role in the growth of the industry.

However, despite an attractive value proposition, the Indian pharmaceuticals industry is facing multiple challenges in terms of growing concerns over the quality of drugs, price control measures, over dependence on China for bulk drugs and lack of clarity and predictability in regulations and the Intellectual Property Rights (IPR) regime. Complex approval procedures and stringent regulations too have led to a considerable slowdown in the clinical trials industry, impacting the innovation and drug discovery environment in the country.

Key issues/challenges

- A unified ministry with policymaking and implementation powers that can reduce multiplicity in drafting regulations in the sector has long been overdue
- Lack of transparency in the regulatory system has hampered the drug approval process, and the lack of a single-window clearance system for setting up manufacturing units has made the process tedious and time-consuming
- An unpredictable price control mechanism has brought in uncertainty and a trust deficit into the system
- In recent times, certain data integrity issues reported in the country by the United States Food and Drug Association (USFDA) has led to an import ban on products made by Indian companies and have marred the image of the Indian pharmaceutical industry
- Heavy dependency on China for sourcing many critical intermediaries and Active Pharmaceutical Ingredients (APIs) could potentially create vulnerabilities for the health security of the population
- Complex procedures to conduct clinical trials, low investment in Research and Development (R&D), a lack of focus on cluster development, and ambiguity around the enforcement of IPR laws need to be tackled as well.

Government's stance

- A task force was constituted by the government to address issues relating to the promotion of domestic pharmaceutical manufacturing. It is, at present, working on various proposals and recommendations suggested by the same[4]
- The government had declared '2015 as the Year of Active Pharmaceutical Ingredients' and is now planning to announce the new bulk drug policy soon, which aims to bring down imports of bulk drugs and increase the domestic output. It also aims to make India self-reliant on bulk drugs[5] by 2020
- A high-level committee would be set up to enable a single-window clearance system for the industry.[6]
- The government is also working on a proposal for setting up of a venture capital fund with corpus of about INR500 crore[7]
- A move to establish a separate pharma ministry in the next one year[8] is expected to bring the Central Drugs Standard Control Organisation (CDSCO), Drug Controller General of India (DGCI) and National Pharma Pricing Authority (NPPA) under one ministry to streamline rules and regulations
- The government is expected to release a new IPR policy that is likely to increase predictability, clarity and transparency in the IP regime

1. Study on Indian Pharmaceutical Industry, Export-import Bank of India, via ISI emerging market databases, accessed February 2016;
2. Indian pharmaceutical industry valued at USD 36.8 billion:, CRISIL database accessed February 2016;
3. KPMG in India analysis 2016;
4. Union Minister of Chemicals & Fertilizers released a Task Force report on enabling the Private Sector to lead the growth of pharmaceutical sector, Press Information Bureau, Ministry of Chemicals and Fertilizers, 22 June 2015;
5. Govt may come out with new bulk drug policy in a month: Minister Hansraj Ahir, Economic Times, 16 February 2016;
6. Single-window clearance for pharma sector on anvil: Union Minister Ananth Kumar, DNA India, 23 June 2015;
7. Government plans Rs 500 crore pharma technology upgradation fund, 5 January 2016;
8. Govt to create separate ministry for pharma in one year: Ananth Kumar, Business Standard, 10 December 2015;

- In the last 20 months, another 450 drugs have been added under the pricing control to the earlier list of 400 drugs, making a total of 850 drugs[9] under price control, in an effort to improve accessibility to affordable medicines
- The government intends to expand 'Jan Aushadhi' scheme to offer more medicines and medical devices at affordable prices, by opening 3,000 'Jan Aushadhi' stores by 2017, from the current number10 of 121
- It also plans to strengthen the drug regulatory system in the country with an investment of INR1,750 crore[11] during 2015-16 to 2017-18
- In its election manifesto for 2014, the government had planned to initiate a new healthcare policy to provide universal healthcare and reduce out-of-pocket spending.[12] However, due to the high cost of this project (INR1.16 trillion for four years)9, the government has shelved this project.[13]

Expectations (policy/fiscal/tax)

Policy

- The government needs to increase expenditure on public health from the current 1 per cent to 2.5 per cent of GDP in the next two years. This is expected to increase access for healthcare and pharmaceutical drugs
- Introduction of a revival plan for API industry is expected to diminish India's over dependence on China for imports of critical APIs. The government needs to adopt a cluster-based approach under which infrastructure with common facilities and other financial incentives could enhance local manufacturing of APIs
- A unified ministry could end the policy fragmentation as there are various departments under different ministries that are currently dealing with pharmaceutical regulations and approvals
- Simplified clinical trial regulations are likely to boost clinical research and innovations in the pharmaceutical sector
- Government is expected to strengthen its regulatory capacity to streamline the drug review process and bring down approval time
- Small and Medium Enterprises (SMEs) in the pharmaceutical sector are looking for a soft loan facility from the government for upgrading existing manufacturing facilities in order to meet international standards of quality
- Improvement in healthcare infrastructure and capacity development could be key to achieving universal healthcare access and increasing access to medicines.

Direct tax

- The pharmaceutical and biotech Special Economic Zones (SEZs) needs to be exempted from Minimum Alternate Tax (MAT) for additional three to five years due to longer regulatory gestation
- The government's move to announce the sunset clause for SEZs from March 2017 needs to be extended for a few more years, as in the pharmaceutical industry, the validation of facilities takes about two to three years time.
- The Central Board of Direct Tax (CBDT) has proposed reduction of weighted deduction for expenditure incurred on scientific R&D from 200 per cent to 100 per cent, which could hamper the innovation edge of the pharmaceutical industry. The government needs to continue these tax exemptions along with provisions for weighted deductions for expenditure incurred on overseas clinical trials, product approval expenses, and patenting under Section 35 (2AB) of the Income Tax Act.

Indirect tax

- Services in the nature of R&D activities/clinical trial provided to foreign customers should be treated as export and should not liable to service tax
- The central excise duty structure on inputs and outputs (inverted duty structure) on pharma goods should come to an end
- Swachh Bharat cess should be brought into the CENVAT credit chain
- A clear road map needs to be provided for implementation of Goods and Service Tax (GST). This is expected to positively impact every aspect of business
- Contract Research Organisations (CROs) involved in preclinical research need to be exempted from tax in order to enable more companies to do R&D
- Service tax exemption on clinical trials on newly developed drugs could be continued like earlier.

9. NDA more eager to cap drug prices than UPA, Business Standard, 14 January 2016;
10.Govt to sell 439 key drugs at low prices, Times of India, 27 January 2016;
11.Government approves scheme to strengthen drug regulatory system, 26 February 2016;
12.Election Manefesto 2014, Bhartiya Janta Party, 2014;
13.India's universal healthcare rollout to cost $26 billion, Reuters, 30 October 2014

M&A tax

- Definition of 'industrial undertaking' under section 72A(7)(aa) of the Income Tax Act, 1956 ('Act') needs to be amended to include R&D activities to enable the carry forward of accumulated business losses on merger of companies housing R&D units
- For companies engaged in scientific research claiming a weighted deduction under section 35 of the Act, computation of minimum alternate tax on book profits under 115JB needs to also provide for a weighted deduction. This could ensure that the actual benefit of weighted deductions for tax computation is made available to such companies, thereby providing a level playing field for such companies engaged in scientific research. Further, on account of long gestation periods for break-even for such companies, the accumulated MAT credit created on account of weighted deduction also remain unutilised
- Section 72 of the Act is expected to provide for carry forward of losses for an indefinite period by companies engaged in scientific research and claiming a weighted deduction under section 35 of the Act.

Transfer Pricing (TP)

- In case of Contract R&D, rationalisation of the prescribed safe harbour operating margin is expected. The current operating margin as per the safe harbour rules is very high and, thereby, the programme is not opted by taxpayers. Also, there is an expectation that the time frame for applicability of safe harbour could increase from one year to five years, which could reduce compliance burden to taxpayers
- Detailed guidance on vexed issues like marketing intangibles, location savings, application of profit split approach to R&D centres, economic ownership, intra-group service charges, etc. is expected
- Increasing the threshold on TP documentation from INR1 crore to INR20 crore is expected to keep it in line with the specified domestic transactions threshold. This could benefit small taxpayers from an onerous compliance burden
- Director remuneration and tax neutral transactions are expected to be excluded from purview of specified domestic transaction
- India endorses the Base Erosion and Profit Shifting (BEPS) project of Organisation for Economic Co-operation and Development (OECD). As an outcome of the BEPS project there is an expectation that the three-tier TP documentation regime could be introduced in India with effect from the financial year (FY) beginning 1 April 2016. The three-tier documentation structure consists of master file, local file and a country-by-country (CbyC) reporting requirement.

Key policies/fiscal and tax proposals

Key announcements[1]

- The government announced to reinvigorate the supply of generic drugs and announced its plan to open 3,000 stores under the Prime Minister's Jan Aushadhi Yojana, during 2016-17
- A new health protection scheme was introduced to cover poor and economically weaker sections of the society, under which a health coverage of INR1 lakh for a family is expected to be provided. Further, to safeguard senior citizens of age group 60 years and above, within the same section of the population, an additional benefit of INR30,000 has been announced
- A National Dialysis Services Programme has been launched under the National Health Mission (NHM). The programme aims to provide dialysis services in district hospitals via a PPP model. Additionally, to reduce the cost of dialysis, certain parts of the dialysis equipment have been exempted from custom duty, excise, Countervailing Duty (CVD) and special additional duty (SAD)
- A special patent regime has been proposed with 10 per cent rate of tax on income from worldwide exploitation of patents developed and registered in India by a resident
- About 1,500 multi-skill training institutes are expected to be set up in the country with an allocation of INR1,700 crore
- For start-ups set up between April 2016 and March 2019, a 100 per cent deduction of profits for three out of five years has been introduced.

Tax reforms and its implications[1]

Direct tax

- The government has proposed a special patent regime with 10 per cent rate of tax on income from worldwide exploitation of patents developed and registered in India by a resident
- It has proposed to amend Section 35 of the Income-tax Act so as to reduce the weighted deduction under Section 35(1)(ii), 35 (2AA) and 35 (2AB) to 150 per cent from FY2017-18 to FY2019-20, and from FY2020-21 onwards the deduction shall be restricted to 100 per cent. It also proposed that the deduction under Section 35(1) (iia) and (iii) of the Income-tax Act shall be reduced from 125 per cent to 100 per cent with effect from 1 April 2017.
- It proposed to amend Section 10AA of the Income-tax Act to provide for a sunset date of 31 March 2020 for commencement of activity of manufacture or production of any article or thing, or providing services by a unit located in an SEZ for availing the deduction under the said section.

The provision for a 10 per cent tax on income from patents is likely to benefit pharmaceutical companies with a global footprint and encourage the industry to invest in innovations and further leverage on them. However, the reduction of weighted deduction to 150 per cent could be detrimental to boosting innovation culture.

- For an existing domestic company, the proposed corporate tax rate of 29 per cent (of total income is applicable if the total turnover or gross receipts of the company in the previous year 2014-15 does not exceed INR5 crore whereas for new domestic company, the proposed corporate tax rate of 25 per cent is applicable if the company has been setup and registered on or after 1 March 2016, provided it does not claim profit-linked or investment-linked deductions, and do not avail of investment allowance and accelerated depreciation.

Lower tax outflow as well as the reduced administrative burden and lesser tax disputes are expected going forward with this proposed change, since no claim to tax exemptions and incentives is expected.

- The determination of residency of a foreign company on the basis of Place of Effective Management (POEM) has been proposed to be deferred by one year, and is expected to be effective from FY2016-17
- The General Anti Avoidance Rules (GAAR) is likely to be implemented from 1 April 2017
- Some of the measures related to speedy dispute resolution, heavy penalty for underreporting/misreporting of income were also proposed in the Budget.

Deferral of POEM and GAAR are in line with the expectations as this could give companies time to restructure their existing agreements.

1. Union Budget 2016-17, http://indiabudget.nic.in/glance.asp, 29 February 2016

Indirect tax

- One of the major expectations from the Budget was to provide a clear road map on implementation of GST. However, the Budget has disappointed on this front, though the Finance Minister has reinforced the commitment of passing the bill
- Another area which has been part of various pre-budget expectations is transferring of CENVAT credit by brand owners to contract manufacturers. The government has proposed an amendment in the CENVAT credit provisions, thereby allowing the brand owner to transfer the credit as an input service distributer to an outsourced manufacturing unit (contract manufacturer/job worker). This is seen as a major relief which can enable companies to transfer credit to eligible units rather than accumulate the same
- There has been not much change in customs and excise duty rates on pharma products, except on disposable sterilised dialyser and micro barrier of artificial kidney, wherein exemption has been provided from both the duties, thereby providing relief to patients
- As expected, the service tax rate has increased by owing to the introduction of the Krishi Kalyan cess at the rate of 0.5 per cent, thereby increasing the effective tax rate from 14.5 per cent to 15 per cent. The same shall be applicable on all taxable services with effect from 1 June 2016.

Transfer Pricing (TP)

- The OECD report on Action 13 of the BEPS Action plan provides for revised standards for TP documentation and a template for CbyC reporting of income, earnings, taxes paid and certain measure of economic activity. India has been one of the active members of the BEPS initiative and a part of the international consensus
- This Budget has proposed to provide a specific reporting regime with respect to the three-tiered documentation structure, i.e. (i) a master file (ii) a local file; and (iii) a country-by-country report. It is proposed to include the essential elements in the Act while the remaining aspects will be detailed in rules
- Non-furnishing of the above reports have stringent penalty implications proposed
- There are few more procedural changes in the transfer pricing such as the introduction of stringent penalty provisions for misreporting in case of transfer pricing adjustments, Dispute Resolution Panel (DRP) directions cannot be appealed by the revenue authorities, reduction of the time limit for scrutiny by three months.

The pharmaceutical companies, which are Indian resident parent companies could be affected by this newly introduced regulation. Their compliance burden is likely to increase to maintain the three tier documentation requirements. In fact, the CbyC reporting template will have to be filed along with the return of income, due by 30 November 2017.

In addition, subsidiaries of multinational pharmaceutical companies, may also have to file the master file and local file with the tax authorities in India. The master file can provide an overview of the entire group TP policies.

Impact

As was the case with some of the preceding Budgets, the Union Budget 2016 has not announced any specific measures for the pharmaceuticals sector. While the government has taken some positive steps to improve innovation, affordability of medicines, skill development, etc., it has not addressed challenges directly related to the sector, such as export incentives, cluster development, incentives for API industry and streamlining regulations.

Did it meet expectations/did not meet expectations

- The establishment of 'Jan Aushadhi' stores are likely to increase the accessibility to affordable generic medicines for the masses
- The proposed patent regime with 10 per cent rate of tax on income, from worldwide exploitation of patents developed and registered in India, is expected to propel innovations and local manufacturing
- The proposed health protection scheme is expected to increase the accessibility of healthcare services and consumption of pharmaceutical products. This is also likely to have a direct impact on reducing the burden of healthcare expenditure and increase the penetration of insurance
- The proposed National Dialysis Services Programme is expected to upsurge the consumption of renal care drugs
- The establishment of multi skill training institutes is expected to play an important role in enhancing the availability of skilled manpower in the long run
- The flat corporate tax structure of 25 per cent for companies commencing manufacturing operations after 1 March 2016 is expected to boost drug manufacturing in the country
- The reduction in weighted tax deduction on the R&D to 150 per cent after 2017-18 from the current 200 per cent is a matter of concern for the pharmaceutical sector.

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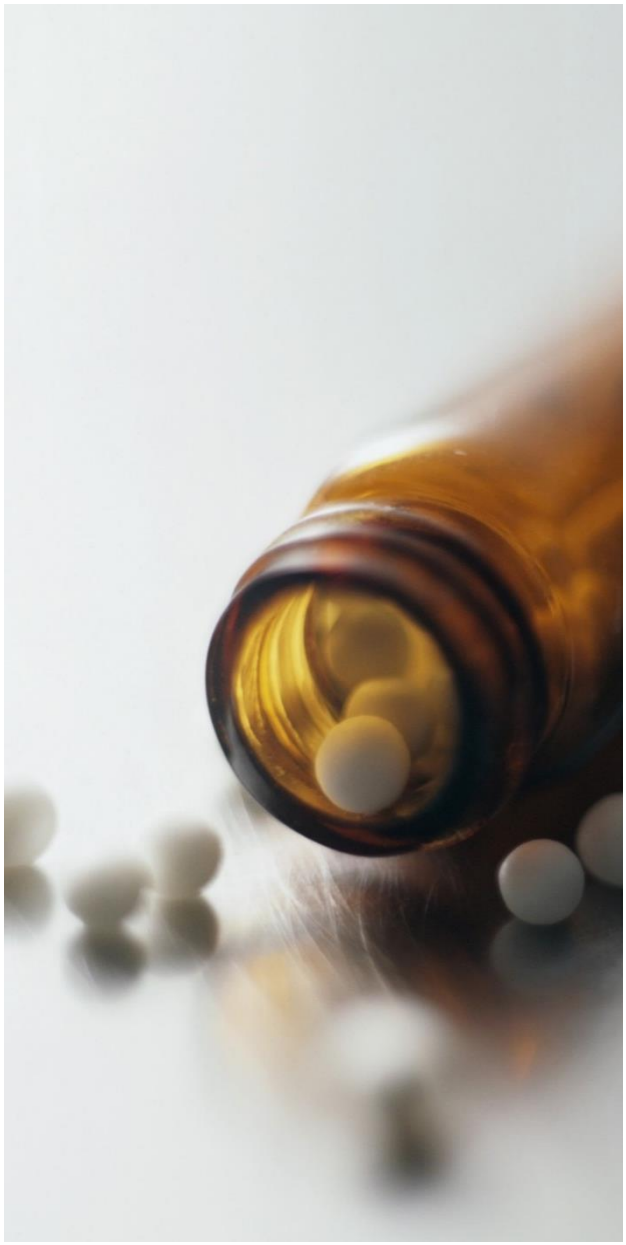
Our point of view

In a nutshell, the pharmaceutical sector, yet again, did not receive due attention in this year's Budget. The Budget is, however, being seen as a positive one, on its overall intent toward benefiting the weaker section of the society.



Unfinished agenda

What remains

- Government support to bridge the infrastructure gap and develop clusters for the pharmaceutical sector was missing from this Budget
- Steps to improve the regulatory regime and removing multiplicity in making a policy have not been touched upon in the Budget
- A revival plan for the Indian API industry to become self-reliant for many crucial drugs, and to maintain health security of the country, has not been talked about
- The tax incentives to boost investments in the pharmaceutical sector have not been announced
- R&D drives innovation, and innovation drives growth. However, very few incentives were announced to support research in the Budget
- Many pharma SMEs were expecting some soft loan facility from the government. However, no such scheme has been announced for small companies
- Inverted duty structure in excise taxes, i.e., higher rate of taxes (12.5 per cent) on inputs vis-à-vis lower rate of 6 per cent on formulations has negatively impacted this sector.

What is expected going forward

- Overall, the Union Budget 2016 did not have anything promising for the pharmaceutical sector. However, it can be viewed at best as having a neutral impact on the industry
- Concerted efforts could be taken under the 'Make in India; initiative to enable the sector's progress
- Despite an attractive value proposition, the Indian API industry is struggling with increased import dependency on China. The proposed new bulk drug policy is expected to provide specific measures in terms of cluster development, funding assistance to SMEs to upgrade facilities to meet global standards and incentives
- The recent regulatory amendments in clinical trials regulations have provided some clarity to put India on the global clinical research map. However, further steps are desired to simplify regulations in order to boost drug discovery efforts in the country
- Since export is a major revenue earner for the pharmaceutical sector, fiscal incentives and policy formulation in this direction could help India to retain its position as the pharmacy of the world
- The Indian pharmaceutical sector needs a robust framework to grow so that it can contribute toward the country's growing healthcare challenges. A unified ministry of pharmaceuticals is required to streamline regulatory approval processes, to bring in efficiency, transparency and predictability
- A clear roadmap along with the government procurement policies, fund allocation and guidelines, can help the pharmaceuticals industry work with the government to achieve 3,000 'Jan Aushadhi' stores by 2017.

KPMG

KPMG in India contacts:

Nitin Atroley
Partner and Head
Sales and Markets
T: +91 124 307 4887
E: nitinatroley@kpmg.com

Utkarsh Palnitkar
Partner and Head
Advisory and Life Sciences
T: +91 22 3090 2320
E: utkarshp@kpmg.com

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