KPMG

Life Sciences

Union Budget 2017-18

Post-Budget sectoral point of view

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Setting the context

Where are we

- A sustainable healthcare system is imperative for a country's evolution from a developing to a developed economy; the life sciences sector is a predominant contributor to the healthcare ecosystem, in turn boosting economic development
- Today, the Indian life sciences sector not only exports affordable and high quality generics, but also intermediates and Active Pharmaceutical Ingredients (APIs), to both regulated and semi-regulated markets world-wide
- Globally, it is ranked third by volume and fourteenth by value[1] and is likely to enter the top-10 ranking by value[1] by 2020
- In 2015-16, the country's pharmaceutical market including exports was estimated at INR2400 billion[2] which is expected to grow at approximately 12 per cent compound annual growth rate (CAGR) over the next three years
- The rising burden of lifestyle diseases, growing population and increasing healthcare awareness are positively contributing to growth and domestic consumption in the sector
- Players in the sector are strengthening existing portfolios through mergers, acquisitions and marketing agreements. Various domestic players have already started leveraging their acquisitions in the U.S. and Europe to strengthen their presence across the more regulated and developed markets
- The sector has been able to create an ecosystem that fosters innovation while focussing on process development skills, building quality infrastructure and nurturing its talent pool to create a firm academic base.

Key issues/challenges

- There are multiple regulatory bodies which directly or indirectly frame rules and guidelines for the life sciences sector. This multiplicity is responsible for creating inefficiencies in the drug approval process, stretching it to a period longer than the sector may desire
- Complex approval processes and tough guidelines to conduct clinical trials are impacting the growth of the sector
- An unpredictable price control regime has created uncertainty and a trust deficit in the system
- High dependency on China for sourcing many critical APIs has created some vulnerabilities in the health security of the nation
- During FY16, many Indian life sciences companies received several warning letters from the U.S. Food and Drug Association (FDA), which also impacted the inflow of Foreign Direct Investment (FDI) into the sector (USD0.75 billion in FY16 compared with USD1.49 billion in FY15)[3]
- Inadequate support for pre-proof of concept pharmaceutical/biotechnology research and late-development stages research mars the Research & Development (R&D) and innovation efforts in the sector. Further, the sector–academia collaboration in India continues to be low owing to the lack of a common platform, different foci and a closed innovation culture
- There is slow infrastructure development in the form of clusters and mega API/pharma parks. Further, the sector lacks R&D infrastructure, such as incubation centres, technology development centres and data centres.

[1] "India-U.S. trade – a formidable economic force", KPMG in India, June 2016
[2] "Indian pharmaceuticals industry worth $39.5 billion", CRISIL industry research, accessed on January 2017
[3] "Pharma industry's outlook looks healthy on increasing export, government initiatives", Livemint, 03 November 2016

Government's stance

- The government has rolled out the new Intellectual Property Right (IPR) policy in May 2016 to foster innovation, increase predictability, clarity and transparency in India's IP regime.[4] The new IPR policy is expected to help in effective protection of patents that can encourage Multinational Corporations (MNCs) launch their products in India
- The government is planning an overhaul of the drug policy. Under the new rules, the government is planning to scrap the need to renew various licences and ease regulations to allow medical and drug research, among others
- In 2016, the Central Drugs Standard Control Organisation (CDSCO) has further relaxed clinical trials guidelines, for example, the previous cap of three clinical trials per clinical researcher has been removed, now a clinical researcher is allowed as many trials as approved by the ethics committee[5]
- The government is planning to implement a mandatory code that is expected to replace the current voluntary Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for increased adherence and governance
- The government is planning to create a new ministry for pharmaceuticals and medical devices. A unified ministry is required to establish efficiency, streamline regulatory approval processes, and improve transparency and predictability
- Niti Aayog is planning to streamline the drug price control regime in order to encourage investments in the sector[6]
- CDSCO has recently released new biosimilar guidance and narrowed the scope to issue waivers required to run Phase III trials.[7] This policy is expected to help the growth of the biosimilar sector in India
- In order to streamline the medical device sector, the government is seeking public and industry comments on the second draft regulations.

Expectations

Policy

- Public expenditure should increase to 2.5 – 3 per cent of Gross Domestic Product (GDP) from the current 1.3 per cent. This can help increase accessibility of life sciences products[8]
- There is a need to re-enact the Drug & Cosmetic Act to match the current regulatory requirements related to quality, efficacy and safety of drugs
- Patent box regime covers royalty income and is not applicable to players using patents for in-house manufacturing. However, this benefit needs to be extended to taxpayers who sell products developed in-house as well
- The government needs to share a road map to implement the setting up of pharma parks announced earlier
- The sector needs incentives for R&D in the form of tax rebate and fund allocation given the capital intensive nature of the sector and long gestation periods
- As innovation is high on the government's agenda, more clarity is required on incentives under the new National Intellectual Property Policy
- The government could relax licencing conditions for pharmaceutical/API/biotechnology manufacturing units to encourage investments
- A simplified regulatory regime without any multiplicity can aid faster policy-making and drug approval

[4] "Cabinet approves National Intellectual Property Rights Policy", Press Information Bureau Government of India Cabinet, 13 May 2016
[5] "Centre relaxes clinical trial norms to woo global researchers", Indiatoday, 6 Aug 2016
[6] "Modi government planning a major overhaul of country's drug policy", Economic Times, 4 October 2016
[7] "India tweaks biosimilar guidelines to narrow waivers in clinical trials", FiercePharma, 5 July 2016
[8] "Public health expenditure data, 2013", The World Bank Data, accessed on 11 January 2017

- The government needs to create a robust framework — a cluster-based approach to diminish the dependency on China for the import of crucial APIs
- Simplified and streamlined clinical trial regulations can help strengthen clinical research and boost innovation in the sector
- Several Small and Medium Enterprises (SMEs) in the life sciences sector could benefit from the soft loan facility, which can then be utilised to upgrade existing manufacturing facilities to comply with Current Good Manufacturing Practice (CGMP)
- The sector is eagerly awaiting important initiatives related to medical device regulation (Medical Devices Act, 2016) and regulatory clarity on Fixed Dose Combinations (FDCs)[9]
- FDI limit in brownfield projects could be increased to 100 per cent under the automatic route to increase the inflow of funds
- E-commerce players are looking for a policy push to streamline the regulatory environment for e-pharmacies

Direct tax

- Central Board of Direct Taxation (CBDT) has a proposed reduction of weighted deduction of expenditure incurred on scientific R&D from 200 per cent to 100 per cent, which could hamper the innovation edge of the sector. The government needs to continue these weighted deductions along with deductions for expenditure incurred on overseas clinical trials, product approval expenses, and patenting under Section 35 (2AB) of the Income Tax Act
- The government needs to provide clarity on allowability of expenses on account of promotional medical give-aways
- The maximum rate of depreciation available from FY 2017-18 is 40 per cent which is in line with the government's roadmap for phasing out deductions and incentives along with the corporate tax rate. The higher rate of depreciation is available on certain medical equipment which is on account of the obsolescence of the equipment and not an incentive; the depreciation rate should be increased to 60 per cent for all medical / surgical / pathological equipment including life - saving medical equipment
- In order to promote R&D in India, the amount of weighted deduction should be deducted while computing book profits for the purpose of MAT
- Weighted deduction should be allowed in respect of certain expenditure incurred outside the R&D facility for a period of 10 years
- The DSIR should not decide the quantum of R&D expenditure entitled to weighted deduction
- Considering the longer time taken in R&D and its benefit available, the Government should clarify that the unutilised R&D weighted deduction should be available for carry forward for at least 8 to 12 years
- The government's move to announce the sunset clause for SEZs needs to be extended for few more years; SEZs should also be relieved from paying MAT
- The preferential patent tax regime should be extended to outsourced R&D and to existing IP which are further developed in India.

Indirect tax

- Clarification to allow credit on R&D operations carried outside the factory, as, ultimately these are linked to manufacturing activities; merely because they done outside the factory, credit should not be denied
- Services in the nature of R&D activities/clinical trial provided to foreign customers should be treated as export and should not be liable to service tax

[9] "Delhi HC scraps government ban on 344 fixed dose combination drugs", Hindustan Times, 01 December 2016

- The central excise duty structure on inputs and outputs (inverted duty structure) on pharmaceutical 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) which is expected to positively impact various aspects of business
- Service tax exemption on clinical trials on newly developed drugs could be continued

Transfer Pricing (TP)

- For the contract research and development of generic drugs in the pharmaceutical sector, a rationalisation of the prescribed operating margin under the Safe Harbour Rule (SHR) is needed as it is currently very high
- Central Board of Direct Taxation (CBDT) has notified safe harbour rules for IT/ITES, KPO etc. prescribing margins to avoid litigation under transfer pricing regulation. Similar guidelines need to be provided for pharmaceutical companies that are exporting products as contract manufacturers.

Key policy proposals

Key announcements[10]

- The government has proposed to amend the Drugs and Cosmetics Rules to enhance the availability of drugs at reasonable prices and promote the use of generic medicines
- It has proposed to draft new regulations for medical devices in line with international standards
- The government has prepared an action plan to eliminate Kala-Azar and Filariasis by 2017, leprosy by 2018, measles by 2020 and tuberculosis by 2025
  - Similary, an action plan has been prepared to reduce Infant Mortality Rate (IMR) from 39 in 2014 to 28 by 2019; and Maternal Mortality Rate (MMR) from 167 in 2011–13 to 100 by 2018–20
- For the MSME sector, the Budget proposed to reduce the income tax for companies with an annual turnover of up to INR50 crore to 25 per cent
- The government is committed to implement the GST; extensive reach-out efforts to trade and industry for the implementation is expected to begin from 1 April 2017
- It has proposed to extend the Pradhan Mantri Kaushal Kendras to more than 600 districts across the country
- The allocation to the Ministry of Health and Family Welfare has increased from INR38,206 crore in 2016–17 to INR48,853 crore in 2017–18
- The government is planning to phase out the Foreign Investment Promotion Board (FIPB) and further liberalise the FDI policy.

Direct tax – no major tax reforms were announced for the life sciences sector

[10] "Union Budget 2017-18", Ministry of Finance, accessed February 2017

Indirect tax

- Though the Budget reiterated the commitment of introducing the GST, no clear roadmap was provided; however, it is expected that the GST is likely to address the inverted duty structure in the scetor
- The service tax rate has been kept unchanged as against the expectation of an increase in the rate.

Impact

- The amendments in the Drugs & Cosmetic Rules, with a focus on price and usage of generics, may increase price control and impact life sciences companies
  - The new rule may encourage prescription of medicines by generic names which would lead to stiff competition and change in brand promotional strategies by life sciences companies
  - With the pressure to ensure drugs at reasonable prices and use of generic medicines, pharmaceutical companies could look at compliance around uniform code, MCI guidelines and fair market value as the new avenue for cost reduction and improvement of profits
- The promulgation of medical device regulations in harmony with international standards can bring much-needed clarity on the regulatory regime for this growing sector. It could also help promote domestic manufacturing of medical devices
  - New rules are also likely to bring in more frequent intervention from the Indian regulator; medical device manufacturers will thus need to be prepared for a higher level of compliance and investigations as commonly seen in regulated markets
- Life sciences companies could play a significant role to help the government achieve the goal of eradicating certain communicable diseases
- Vaccines manufacturers can benefit from the government's plan to reduce IMR and MMR
- The increasing number and geographic spread of Pradhan Mantri Kaushal Kendras could enhance the availability of skilled manpower in the long run
- The budget allocation to the Ministry of Health and Family Welfare is 23 per cent higher than the last year; it could give a much needed impetus to the National Health Mission and increase access to medicines
- Abolishment of FIPB could increase FDI and M&A activities in the sector

Did it meet expectations/did not meet expectations

- The life sciences sector had great expectations from the Budget not only from a fiscal incentives perspective, but also from a regulatory angle; more so, given the government's vision of making India one of the top-three pharmaceutical markets by 2020
- However, this year, too, no specific impetus was given to the sector. While the Budget offered some positive steps — moves to eradicate certain diseases; the proposal to set up two new AIIMS; additional post-graduate medical seats; proposed amendments in the Drugs and Cosmetics Rules; and new rules for medical devices, it did not specifically address the imminent challenges directly affecting the sector
- In order to stay competitive in the overseas markets and given the uncertain global climate, it was expected that specific impetus or incentives would be given to innovation in the form of weighted deduction on R&D, incentives for patents, exemptions of certain duties and taxes, etc. However, these demands have remained largely unaddressed, giving no specific reason for cheer for the sector as a whole in 2017–18.

Unfinished agenda

What remains

- The revitalisation of the API segment to reduce import dependency on China has been left unanswered in the Budget
- A road map to develop clusters and bridge the infrastructure gap was missing from this Budget as well
- Exports is a major contributor in the Indian life sciences sector; however, policy and fiscal incentives were not announced to support exports from this sector
- The sector is capital-intensive and requires fiscal support to remain competitive; however, no fiscal incentives were announced in the Budget
- R&D and innovation are integral to the sector's growth trajectory; these were not addressed in the Budget
- Inverted excise duty structure, 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
- The long over-due demand of increasing the national spend on life sciences, providing tax holidays and research-based deductions as incentives have been left unanswered in this Budget.

What is expected going forward

- To streamline regulatory processes, the government needs to create an independent pharmaceutical ministry which would help simplify regulatory approval processes and improve transparency and predictability
- Steps are required to simplify regulations for clinical trials as they can help boost drug discovery efforts in the country
- There is a need to review the drug price control policy to attract investments in the life sciences sector
- Since the government has decided against a bulk drug policy, the import dependency on China needs to be reduced by developing bulk drug parks
- Due to growing regulatory challenges, the MSME segment requires fiscal support for technology upgrades
- A single-window clearance system is required to streamline licencing requirements for pharmaceutical/API/biotechnology manufacturing units to encourage investments.

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