KPMG

Life Sciences

Tax Newsletter

About the newsletter

Life Sciences Tax Newsletter is our new initiative to share informative tax insights, important developments and interesting interviews with business leaders focusing on the ever evolving field of life sciences.

Foreword by Vijay Chawla

The Life sciences sector has been undergoing a massive makeover with health and wellness taking centre stage post-pandemic. As per industry estimates, India's pharmaceutical industry is expected to increase at a CAGR of 12-15 per cent and reach USD120-130 Billion by 2030.

With an aim to reduce dependence on imports, we witnessed the launch of several PLI schemes last year with a focus on Active Pharmaceutical Ingredients (APIs) and formulations. This can aid in building scale and provide impetus to local manufacturing, which in a big way can lead to generating significant job opportunities. Further, developing medical device parks could prove to be a cost-effective ecosystem for the country. The journey for self-sufficiency has begun as India Inc. integrates with global supply chains on the back of its infrastructure, cost competitiveness and favourable government policies.

Going forward, as we witness a drastic growth from alternate channels like e-commerce/organised retail, we could also expect the industry to augment efforts around predictive analytics models along with 'Big Data' (essential and timely data generated by medical devices) to improve the quality of care and patient outcomes. A well-balanced ecosystem and increased impetus to R&D could potentially uplift the overall economy of India.

Foreword by Santosh Dalvi

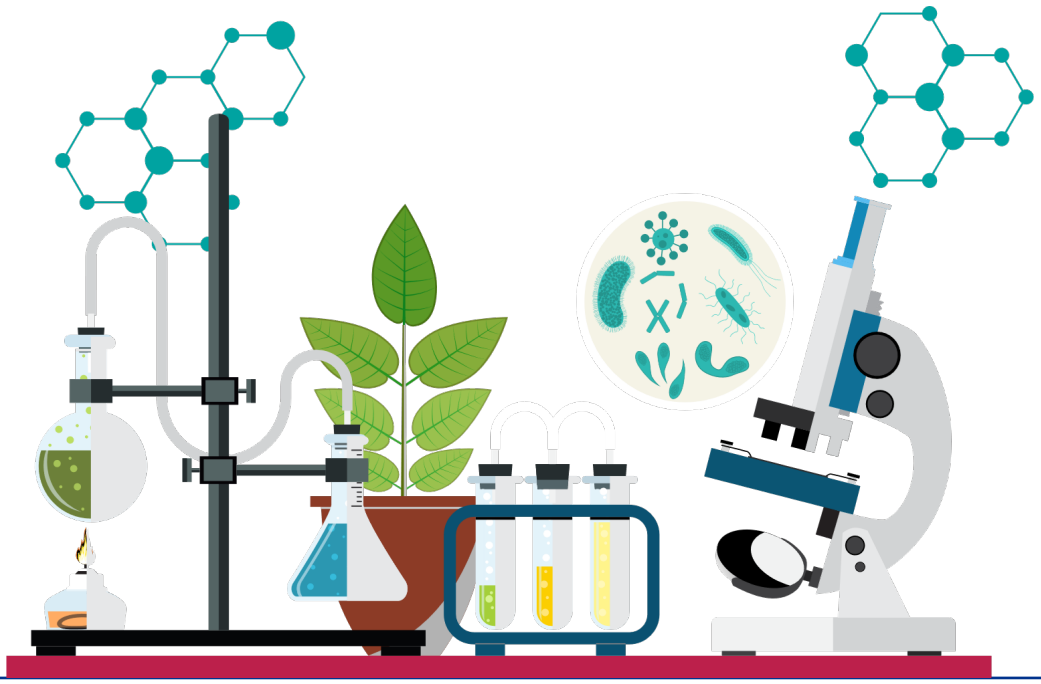
While the world is looking at India as 'Pharmacy of the world' owing to exponential growth potential and well-developed infrastructure, the life-sciences sector needs substantial capital and continuous stimulus to cater to the demand. Recognizing this, the Indian Government has provided impetus to support the sector in the form of Production Linked Incentive Schemes (PLIS), Medical Device Parks, Bulk Drug Parks etc. Separately, on tax front, the sector has seen a lot of buzz around Base Erosion and Profit Shifting (BEPS), Medical Freebies, Faceless Regime, GST reconciliations, etc. including Fiscal Budget 2022 amendments and a Supreme Court judgement in relation disallowance of medical freebies. We have woven the theme of the present edition of newsletter around these developments and trust that it will be an interesting read for our esteemed readers. We would like to acknowledge the life science core tax team members instrumental in bringing this newsletter together. We look forward for your feedback and suggestions on the newsletters. Your comments will certainly be of great value.

Tax officers to monitor the policies of the healthcare sector

Rapid enhancements in technology and research have yielded in improved medicine and medicinal tools available for better patient care. These developments need to be educated to the mercenaries of patient care, i.e., the medical practitioners, which warrants need for conducting seminars, distribution of samples other informative materials by the pharmaceutical companies. Thus, the relationship between pharmaceutical companies and medical practitioners is an important thread in ensuring optimum healthcare support.

In India, the ethical aspect of the relationship is, inter alia, governed by certain guidelines, some mandatory such as IMCR[1] and others voluntary such as UCPMP[2]. These guidelines are not unique to India. Certain overseas jurisdictions also regulate the healthcare industry with varied levels of strictness. However, since 2012, India has stepped up its efforts to bring its tax net around expenses incurred by this industry in violation of such guidelines. The CBDT in its 2012 circular[3] issued a clarification that expenses in violation of IMCR shall be considered as incurred for "any offence or prohibited by law" under section 37 of the Income-tax Act, 1961 and would be in-admissible for computing taxable profits.

The said Circular has been subject of intense litigation between the pharmaceutical companies and regulators, primarily because IMCR are not applicable to pharmaceutical companies but to medical practitioners. Some courts have taken a favourable view on this matter, whereas others a contrary view, leading the litigation right to the Supreme Court of India. The Supreme Court of India, vide its order dated 22 February 2022, has brought an end to the controversy. It held that when acceptance of freebies is punishable by the MCI (the range of penalties and sanction extending to ban imposed on the medical practitioner), pharmaceutical companies cannot be granted the tax benefit for providing such freebies, and thereby (actively and with full knowledge) enabling the commission of the act which attracts such opprobrium.



1. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (updated in 2003, 2004, 2009 and 2016)
2. Uniform Code of Pharmaceutical Marketing Practices, 2014.
3. Circular No 5/2012, dated 1 August 2012

Incidentally, few weeks before the Supreme Court rendered its verdict, the Government, *vide* Finance Act 2022, made a far-reaching amendment to Section 37 of the Income-tax Act, 1961. The amendment, *inter alia*, clarifies that providing any benefit or perquisite to a person and acceptance of such benefit or perquisite by such person is in violation of any law or rule or regulation or guideline shall be deemed as expenditure incurred for an offence or which is prohibited by law.

Although the aforesaid amendment is with effect from financial year 2021-22, it may become practically superfluous in light of the Supreme Court's verdict, that was in the context of the pre-amended law and laid down the law of the land as it was always meant to be.

Some of the key impact areas arising out of the above are as under:

1. Companies may need to closely relook at their doctor spends and evaluate if expenditure meets with IMCR or falls outside the purview of IMCR.
2. Wherever required, for the past years, tax provisioning (including applicable interest) may have to be recalculated.
3. Companies may have interest liability if careful examination of spends is not undertaken in calculating advance-tax estimates.
4. The income-tax return for financial year 2020-21 will have to be filed or revised - basis the Supreme Court's decision.
5. Suitable disclosures for non-deductible expenditure will have to be made in the Tax Audit Reports.
6. During assessments or reassessments, the Revenue can seek information regarding doctor spends and ask pharma companies to demonstrate whether the expenditure is in accordance with MCI guidelines.
7. Another googly in Finance Act, 2022 is the introduction of TDS under section 194R. As per section 194R, a person is required to withhold TDS at the rate of 10% before providing any benefit or perquisite to a resident arising from business or exercise of a profession, subject to a threshold limit of INR 20,000 per financial year. The 'tax cost' of doctor spends may further increase once the TDS provisions in section 194R comes into force.

To sum up, there are benefits of joint seminars, samples distribution, etc. and thus, there is a need to carefully craft the thin divide between permissible and impermissible. The Government has clarified the tax position on the above matter. It is time for the Medical Council to introduce clarifications, FAQs, examples to the IMCR. Suitable representation may have to be made to the regulatory authorities to clarify the contentious issues which can reduce the scope for future tax litigation. As for an immediate action, pharmaceutical companies will have to revisit their policy/Standard Operating Procedures for doctor spends. This will have to be done keeping in mind the implications, *inter alia,* under section 37 and 194R of the Income-tax Act. Robust technology tools and tracking mechanisms will have to be deployed to identify red flags/TDS triggers. Data warehousing may become more important than ever to be able to navigate through the tax assessments.

Production Linked Incentive Schemes - The Way Forward

Government of India launched Production Linked Incentive Schemes (PLIS) for the pharmaceutical sector with an aim to enhance manufacturing capabilities in the sector and create global champions from India having potential to grow in size and scale using cutting edge technologies. PLIS had been launched in multiple phases including:

1. PLIS for domestic manufacture of select Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs): This scheme[4], notified in July 2020 with financial outlay of INR 6,940 crore, approved 50 applications over two rounds. On account of un-allotted slots, Government had invited fresh applications with deadline of 12 March 2022 where allotment is pending.

2. PLIS for domestic manufacture of Medical Devices: This scheme[5], notified on 21st July 2020 with financial outlay of INR 3,420 crore, 21 applicants over two rounds with committed investment of INR 1,059.33 crore and employment generation of about 6,411.

3. PLIS for domestic manufacture of Pharmaceuticals: This scheme[6], notified on 3rd March 2021 with financial outlay of INR 15,000 crore, approved 55 applicants over one round.

The above PLIS would help Government to achieve its vision of making India self-reliant and make Indian manufacturers penetrate the global value chain. While the PLIS provides a much-needed impetus to the sector's growth plans, the sector looks forward to the following from the Government:

Fair and quick assessment of disbursement applications

Ease of quarterly and annual compliances

Timely disbursement of incentives

Effective monitoring of the scheme to ensure objective is achieved

Also, the above PLIS focused mainly on manufacture of goods only. One of the important lessons learnt from Covid pandemic is that India needs to recuperate on its research & development efforts in the field of life-sciences. This leads to the need of a scheme for setting-up Research & Development center in India to make India a R&D hub. Government should consider releasing a scheme to encourage research and development centers in India focusing on pharmaceutical products.

Further, the PLIS notified in March 2021 approved applicants basis criteria such as ANDA, past revenues etc. On account of these criteria, a lot of companies could not be selected despite considerable investment plans, growth potential, employment creation and foreign exchange earnings. In view of this, Government should consider working on a new additional scheme to bridge this gap and cover the additional ground. The incentives may be based on the amount invested by company with commensurate increase in percentage production capacity. Also, the scheme may aim at multinationals setting up new facilities in India / shifting manufacturing facilities to India.

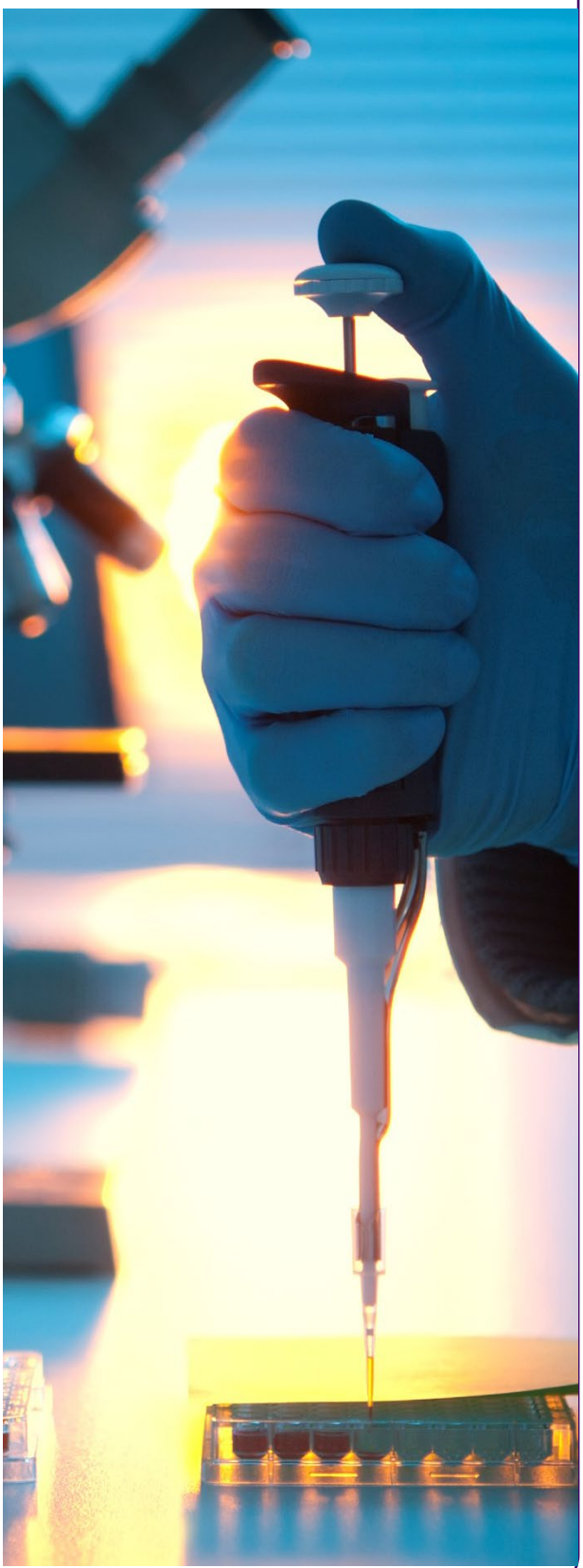
4. Notification No. 31026/16/2020 - Policy dated 21st July 2020 of Department of Pharmaceuticals

5. Notification No. 31026/08/2020 - MD dated 21st July 2020 of Department of Pharmaceuticals

6. Notification No. 31026/60/2020 - Policy-DoP dated 3rd March 2021 of Department of Pharmaceuticals

On the part of approved applicants of earlier PLIS, these applicants should start planning their investment and application process to optimize their incentives. Basis the PLIS guidelines, approved applicants may consider the following:

- The initial application process did not cover detailed information / data and there were quite a few grey areas in the PLIS. Selected applicants may make sure to disclose and clear out on such issues so as to avoid any disputes once the investment process has started.
- The selected applicant shall have the option to change the product mix approved to them during the tenure of the scheme, maximum 5 times, with the prior approval of the DoP. It is time for the selected applicants to work out the details of product mix forecast for the entire period of scheme and put together an optimal product mix plan by balancing their market demands, product development cycle, incentive quantum and maximum number of changes to product mix.
- Approved applicants are required to furnish self-certified Quarterly Review Report (QRR) within 30 days from the end of the quarter to Project management authority (PMA) in the prescribed format. This also includes Revenue from Operations and Imports details and entails that the impact of Ind-AS should be given on quarterly basis so that the correct revenue is disclosed in the appendix.
- Quarterly compliances for the PLIS should be taken as an opportunity to work in tandem with the Government and achieve the goal of growth of pharmaceutical industry leading towards the goal of 'Atmanirbhar Bharat'.
- In case your organisation has also open-ended questions which requires clarifications, please feel free to reach out to us, we shall be happy to discuss further and may approach DoP for issuing necessary clarifications on the subject.



Tech bytes: Embedding technology to automate TDS & TCS processes

Timely and accurate compliances of transactional taxes like tax deducted at source (TDS) and taxes collected at source (TCS) is a key area of concern for many organisations including those in life sciences sector which have voluminous transactions.

Moreover, with Government's focus on such transactional taxes, multiple levels of data collection and extensive use of data analytics to identify anomalies, organisations often find it challenging to provide explanations to such anomalies due to lack of adequate governance & well-defined processes.

On the other hand, reconciliation of TDS & TCS credits as per Form 26AS and books of accounts is another challenge for organisations, leading to huge leakage of tax credits and possible impact on cashflow for the cash-sensitive businesses.

Though numerous processes are set by organisations internally, they still face many challenges due to:

Though numerous processes are set by organisations internally, they still face many challenges due to:

- Lack of centralised data
- Manual handling of voluminous transactional data, lower tax deduction certificates, compliances, etc.
- Tracking transactions with unorganised set of business partners e.g. doctors, small hospitals, medical representatives
- Tax positions on complex transactions such as R&D expenses, doctor spends, etc.
- Unreconciled 'tax data' with data submitted to other tax authorities
- Potential interest & penalty exposure for delays and defaults

To overcome these challenges, an effective end to end TDS/TCS compliance process requires a combination of:

- Process improvement – Fixing data at ERP level
- Leveraging tax knowledge/experience catering to changing landscape of TDS/TCS laws
- Deployment of tax technology to automate routine processes
- Strong governance through data analytics.

This will help ensure time and process efficiency and accuracy in outcomes and proactive multiple level reconciliations.

So, how can organisations take advantage of technology to improve control on the process

- Start by improving process for data capturing at source e.g. nature of transactions, vendor details, HSN/SAC classification etc., which can be a significant enabler in automating tax rate determination.
- Deployment of Robotic Process Automation, a software robot (Bot) which can undertake pre-defined repetitive tasks on large volumes of data with minimal human intervention. This can be effectively used for bulk PAN verification
- Automated workflows and data blending tools for preparation of returns and reconciliations and bulk e-mailer utilities for providing TDS certificates
- Multi-dimensional analytical dashboards
- ERP sensitization for tax (e.g. incorporating new tax rates, section thresholds, etc.) is another measure for streamlining internal tax processes and reduce manual adjustments

Similarly for TDS and TCS reconciliations on income, one can leverage automated reconciliation workflows between books and Form 26AS with in-built logics and get enhanced visibility on tax credit leakages through dynamic analytical dashboards.

While the above approach includes utilization of technology, the important of knowledge and experience in the field of tax remains prime due to the changing nature of regulations. Hence, to sum up, having a technology focused approach while leveraging tax technical knowledge for automating TDS & TCS processes will surely benefit organisations in terms of better risk management associated with TDS & TCS.

What's the deal!

During last few months, Lifesciences sector has seen moderately strong deal activity with significant M&A deals of large ticket sizes and significant fund raising from private equities. A few of them are as under:

Particulars of the deal	Buyer	Target	Deal Size
Panacea Biotec has entered into an agreement to sell its formulation business in India and Nepal to Mankind Pharma for Rs 1908 crore[7].	Mankind Pharma	Panacea Biotec	INR. 1,908 crore
Therapeutics company Bugworks Research said it has scooped up Series B1 funding of USD18 million (around Rs 135 crore) led by Lightrock India[8].	Lightrock India	Bugworks Research	INR. 135 crores (USD18 million)
GOQii Inc, a tech-enabled healthcare platform, said it has raised USD50 million (around Rs 375 crore) in a Series C funding round led by Sumeru Ventures[9].	Sumeru Ventures	GOQii Inc	INR. 375 crores (USD50 million) (USD5.50 million)
Bengaluru based healthcare startup MediBuddy has announced raising USD125 million in series Cround of funding from Quadara Capital, Lightrock India[10].	Quadara Capital and Lightrock India	MediBuddy	INR. 940 crores USD125 million

7. Mankind Pharma signs agreement to buy Panacea Biotec Pharma's domestic biz, Business Standard, Sohini Das, 1st February 2022
8. Therapeutics platform Bugworks Research snags $18 mn as Series B1 led by Lightrock India, VCCircle, Anuj Suvarna, 9th February 2022
9. Healthcare platform GOQii raises $50 mn led by Sumeru Ventures, VCCircle, Anuj Suvarna, 16th February 2022
10. MediBuddy Bags $125 Mn In Series C Funding From Quadria Capital & Lightrock India, Inc42, Debarghya Sil, 22nd February 2022

Did you know?

Did you know who referred to as the father of Indian Pharmaceutical Education?

Mahadev Lal Schroff is the father of Indian Pharmaceutical Education. He was born in Bihar in 1902 and completed his higher studies in the US. He was instrumental in setting up first Department of Pharmaceutical Education and went on to be recognized as 'Father of Indian Pharmaceutical Education'[11].

Happy Reading!

11. Mahadev Lal Schroff: Father of Indian Pharmaceutical Education, The Pharmstudent, Vol. XXIV, 2003-04

KPMG in India contacts:

Santosh Dalvi
Partner & Deputy Head,
Indirect Tax
KPMG in India
T: +91 22 3090 2685
E: sdalvi@kpmg.com

home.kpmg/in

home.kpmg/in/socialmedia

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