Grant Thornton

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Health check

Q3 2019-20

Foreword

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As the Coronavirus (COVID-19) disease pandemic disrupts global value chains, the Indian pharmaceutical industry is staring at multiple challenges.

China, where the disease originated, is the world's leading producer and exporter of Active Pharmaceutical Ingredients (APIs), one of the key raw materials for medicines. With Indian firms procuring over 70% of the APIs from China, vulnerability of the supply chain is inevitable. The situation might appear to be grim, but presents an opportunity for Indian manufacturers to look within.

In terms of performance, the major listed companies* grew their top line at an average of 7% over the third quarter (Q3 FY20). However, revenue remained flat compared to the last quarter.

The second edition of Health Check takes a close look at:

- The challenges and opportunities in healthcare industry and how it will need to relook at its organisational strategies
- Key announcements made by the government in its efforts to make healthcare affordable and accessible in the Union Budget 2020; and
- Key factors to be considered in accounting revenue from contracts.

We hope you find this publication useful and informative.

* Top 10 listed companies by turnover

The big picture

Industry overview

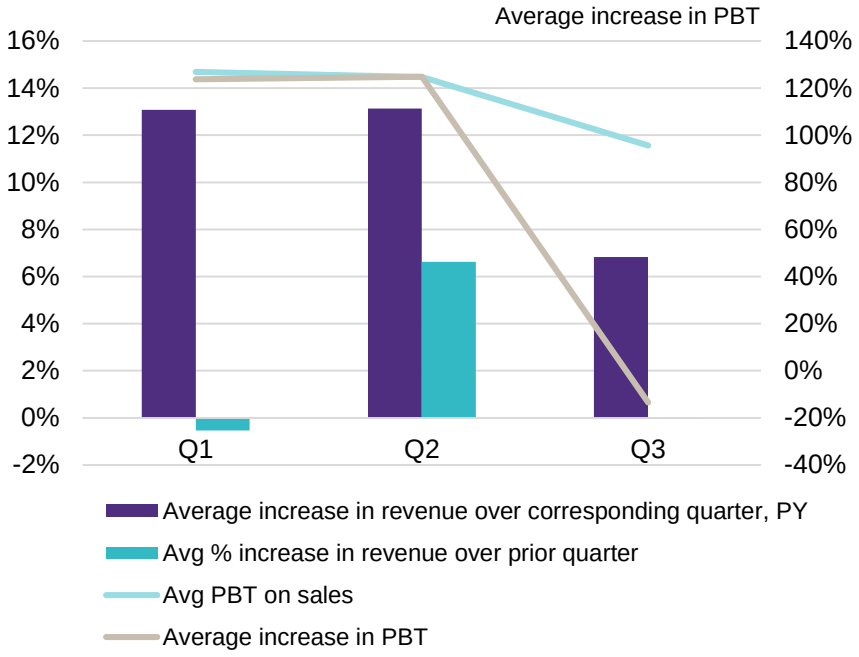
The slowdown in the Indian economy has its impact on the pharmaceutical sector as well. But the sector maintained a reasonable revenue growth of 11%*, primarily driven by exchange rates and domestic growth in sales.

The industry's top-line growth in Q3 was slower at 7%, compared to last year. In Q2, the growth in revenue was 14%. However, the real impact was seen on PBT of the top ten companies. It witnessed an average negative growth of 14% in Q3 over the corresponding quarter last year, owing to impairment losses by Lupin, Dr. Reddy's, etc.

The industry is likely to face pressures on margins, especially due to increasing API prices in the last few weeks.

The revenue of the major listed pharma companies did not rise much in the quarter as compared to Q2. The industry continues to maintain an average PBT of 12% on sales.

Revenue and PBT growth in FY 20



* increase in YTD December 2019 revenue over YTD December 2018 of top 10 listed companies in terms of turnover

Dealing with COVID-19

Impact of Coronavirus on the pharma industry

Coronavirus Disease 2019 (COVID 2019) pandemic, which originated from mainland China, has resulted in over 21,000 deaths globally since its detection in November last year. To contain the spread, China imposed a temporary nationwide shutdown. The factories, however, have now reopened.

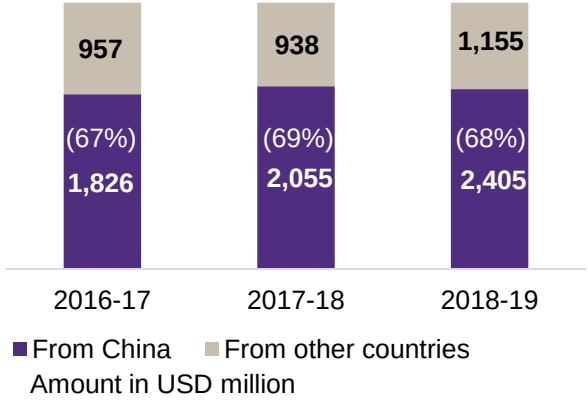
Since China is a major exporter of pharma products, the shutdown has disrupted global supply chains. The pharma industry in India is one of the most affected as it buys around 70%* of its major active pharmaceutical ingredients (APIs) from China.

The rating agency ICRA has recently revised the industry's outlook to "negative" from "stable" in light of the situation. Amid the supply concerns, the industry committed that there will be no shortage in APIs and medicines in the coming days, the Ministry of Chemicals and Fertilizers said in a statement.

Meanwhile, the government has constituted a Task Force on APIs for increasing production of generic drugs in India by evaluating various proposals, including faster environmental clearances. The government has announced a INR 13,000-crore package to boost domestic manufacture of API, drug intermediaries, and medical devices. It has also restricted the export of 26 APIs and started the dialogue with industry to make India self-reliant.

However India may face some drug shortages in the medium term, especially in vaccines and antibiotics segments.

Bulk drug imports – China dependencies



* Source: Directorate General of Commercial Intelligence and Statistics

Taking stock of the domestic pharma industry

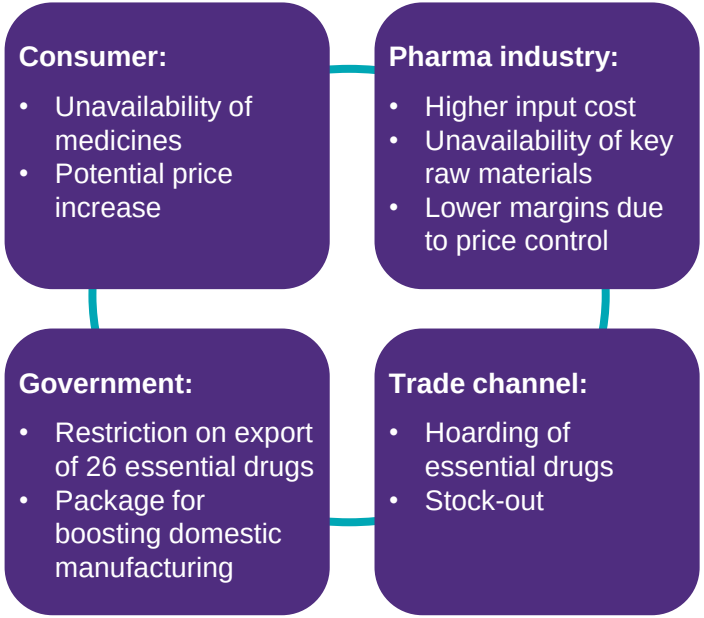
The large pharma companies tend to stock up on inventories for two-three months. This, combined with the inventory maintained in trade channels, means the companies may not see an immediate stock-out situation. However, the **impact may be seen in the market around the April-June quarter.** By that time, it is expected that the Chinese suppliers will be back on their regular supply schedule.

However, small and medium size pharma companies, which do not have large inventories, will have stocks for just 15-20 days. This will create stock out situations for generics, especially anti-infectives, nutritional supplements, and chronic care drugs. Such companies contribute to 30-40% of the total pharma production.

One possible outcome is likely to be a **minor increase in the drug prices.** The prices of key APIs in 2020 are 50-100% higher than a few months ago, according to the data available with Pharmaceutical Export Promotion Council (Pharmexcil).

The National Pharmaceutical Pricing Authority (NPPA) allows a price increase of 10% per year. It is likely that the industry will push for some relief.

Impact and measures by key stakeholders



The price control will result in **margin erosion** for companies and will strain their working capital in an already slow economic environment. The panic will result in drug hoarding. This will push up the sales in the near term. However, the industry is expected to return to normalcy soon.

As on 25 March, more than 616 cases have been reported in India. A number of measures have been taken by the respective state governments such as closures of commercial establishments, schools, and cancellation of mass gatherings. The socio-economic impact of the pandemic will push organisations to develop robust emergency procedures for the future.

Addressing the supply chain issues

Finding a new API supplier is a time-consuming activity. It often takes up to a year. Regulations require pharma companies to perform quality inspections on the API suppliers to ensure the quality of the finished product.

Owing to the cost and time involved in onboarding new suppliers, many pharma companies tend to rely on a single source for APIs. Force majeure events, like an outbreak, can have a disruptive effect on the supply chain and the availability of essential medicines.

Many large pharma companies manufacture APIs internally. However, these APIs are often used for captive consumption for sale in the regulated markets.

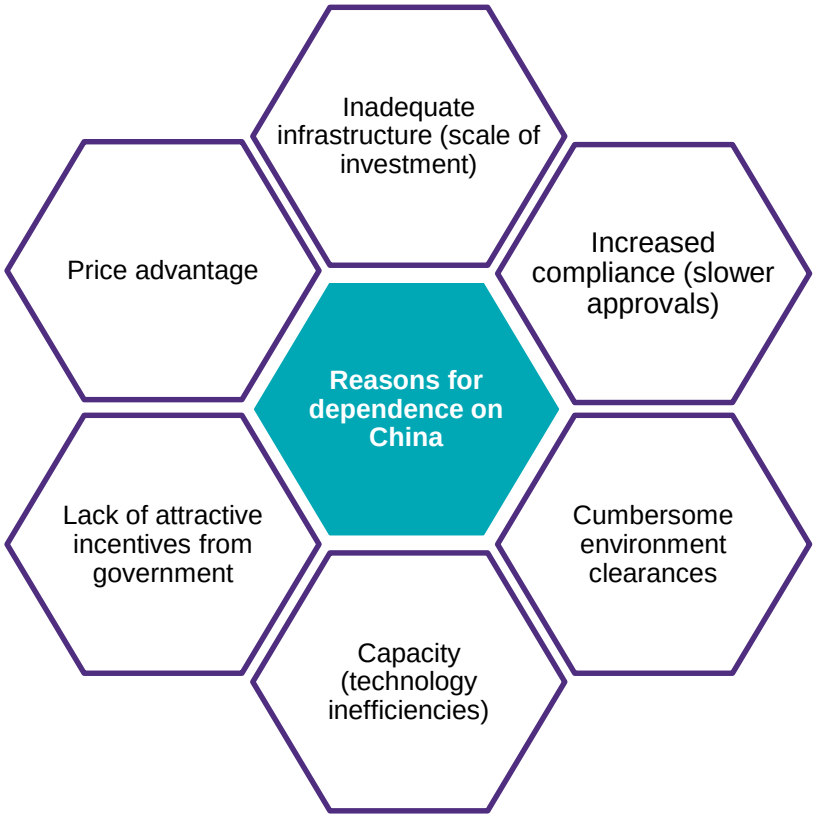
Although most Chinese businesses are operational from February 21, they are dealing with an order backlog. Travel restrictions are still in place, which means that migrant workers from other provinces may not be able to return to work, especially from Hubei and other significantly affected regions.

Hindustan Antibiotics Limited, a sick public sector unit, has submitted a proposal for upgrading their equipment to start manufacturing key fermentation-based APIs. However, it will take around four to six months to upgrade infrastructure. If they succeed, it can be a long-term solution to reduce dependence on China.

Our view

Many Indian companies have failure to supply clauses in their vendor contracts, which can result in significant increase in their costs. However, the companies are, and will be evaluating the pandemic as force majeure event. They will start discussions with customers to avoid additional costs.

Dependence on China



List of major molecules affected:

Molecule	Therapy
Azithromycin	Antibiotic
Ceftriaxone	Antibiotic
Erythromycin	Antibiotic
Meropenem	Antibiotic
Artemisinin	Malaria
Lamivudine	Anti retro viral (HIV)
Gabapentin	Central nervous system
Ibuprofen	Non-steroidal anti-inflammatory
Clindamycin	Antibiotic
Tazobactam	Antibiotic
Paracetamol	Non-steroidal anti-inflammatory

The key drug classes where APIs are imported in large quantities from Chinese suppliers are

1. Antibiotics
2. Nonsteroidal anti-inflammatory drugs (NSAIDs),
3. Antiretroviral (ARVs)
4. Anti-epileptic
5. Basic cancer products

Government action

The government has constituted a Task Force on APIs under the chairmanship of Minister of State for Shipping and Chemicals and Fertilisers Mansukh Mandaviya. The force will make a road map for the enhanced production of generic drugs in India.

The Centre has also approved a INR 13,000-crore package to boost domestic manufacturing of APIs and medical devices. The package is a combination of production-linked incentives (PLI) for domestic manufacturing of 53 identified critical bulk drugs (INR 6,940 crores), and aid to set up three mega bulk drug parks in partnership with states (INR 3,000 crores). The package includes INR 3,820 crores for a similar boost for manufacturing of medical devices.

It has recently placed restrictions on the export of 26 essential drugs and related ingredients, including Paracetamol, Vitamins B1, B6, B12, female hormone drug Progesterone, and Antibiotics – drugs for which raw materials are sourced from China. While this will help in preventing the shortage in India, it could have a cascading effect on the availability of drugs in the regulated markets like the US, where India is a significant supplier.

NITI Aayog, along with health officials, has finalised a list of nearly 60 APIs, including ones for diabetic drugs such as metformin and antibiotics like azithromycin, for which India is highly dependent on China. It has urged the domestic industry to become self-reliant. In order to keep costs competitive, the Centre is also mulling duty cuts on APIs.

Immediate considerations for pharma companies

Risk assessment

- Assessment of company's supply chain dependency on Chinese bulk products
- Determination of critical inventory components and related buffer stock strategy
- Interruption simulations
- Capacity scale-up while balancing challenges in maintaining utilisation
- Production turnaround and infrastructure for scaling up of quality function

Action plan

- Optimisation of production planning, considering risks on account of failure to supply
- Developing alternative sources of supply
- Pre-booking sea and air freight facilities
- Investment in backward integration to establish self-sufficiency in production on some supplies
- Managing working capital requirement to get the supplies first in hand

Other considerations

- Relook at the force majeure clause in supply contracts
- Identify idle capacities to supplement production
- Disaster recovery planning in case of prolonged disruptions
- Identify specific origin of supply from China (Wuhan, Hubei, Guangdong, etc.)
- Determine inventory requirement for next six months

Our view

The Coronavirus pandemic might give the Indian API industry a shot in the arm that it always needed. It is certainly time for the industry to relook at their supply chain strategies. This includes developing alternate supply sources, disaster planning, examining supply contracts, and backward integration by critically examining:

- If the current inventory management strategies can be optimised to handle disruptions
- If this is the time to think beyond China and avoid concentration risk
- If the firms need to relook at force majeure clauses in the supply contracts, including failure to supply clauses and related liquidated damages
- The opportunities presented in the package announced by the government to invest in API, and medical device manufacturing capacities

Disruption in the distribution network

Disruption to traditional pharmacies

Historically, medicines are sold to patients by retail pharmacies based on doctors' prescriptions. The industry has over 80,000 distributors and around one million bricks-and-mortar retail pharmacies.

In the recent years, e-pharmacies have disrupted this space by taking pharma sales online, making the process easier for the digitally-connected customer. The e-pharmacies have also been giving more discounts to the customers. They are advertising their drugs-related activities, which traditional pharmacies are not permitted to do, either by law or general trade understanding.

These discrepancies are due to lack of clear-cut regulations. E-pharmacies were initially governed by the Information Technology Act, 2000, only. But the government has since taken steps to draft a bill to regulate of e-pharmacies. However, the bill is yet to be enacted as law.

Considering the pending regulations, the Delhi High Court (HC) has banned sale of medicines online by unlicensed players. This was followed by a stay on the order by the Madras HC. The Drug Controller General of India (DCGI) has been issuing directives to the state drug controllers to enforce the Delhi High Court ban till regulations are finalised.

Regulatory grey areas:

- Draft bill is yet to be enacted as law
- The Delhi HC order banned online medicine sales
- Stay on the above order by Madras HC
- The DCGI starting to enforce the Delhi HC ban

Indian e-pharmacies: Draft regulations

Most of the regulations envisaged are no different from those applicable to the traditional pharmacies. The draft bill aims to create a level playing field between online and traditional pharmacies, mandating both to sell based on prescriptions, generate valid invoices, etc.

However, the e-pharmacies are likely to face some additional restrictions:

- **Prohibition on selling Schedule X drugs** such as Methamphetamine, Secobarbital, etc. Brick-and-mortar retailers can sell these drugs by retaining the doctor's prescription for two years.
- **Packaging in tamper-proof cover** comes in the light of the logistics journey of drugs sold through the online window, which will result in some additional packaging cost.
- **Proposed India Data Protection Bill 2019** will be imposed on them as they will have significant amount of patient information.

Cracking the whip

- E-pharmacies cannot sell medicines without prescription
- They cannot sell Schedule X drugs
- Valid invoice for every sale is a must
- Facilitate medicine recall upon the government's direction
- Packaging of medicines in a tamper-proof cover under the supervision of a registered pharmacist

E-pharmacies: Funding magnets

The e-pharmacies are also facing a growing opposition from traditional pharmacies and trade bodies.

In August 2019, the All India Organization of Chemists & Druggists (AIOCD), a lobby of over 8 lakh chemist outlets, threatened to boycott Cipla products if it went ahead with it's investment in Medlife, an online pharmacy. Traditional pharmacies have been protesting against e-pharmacies since 2015.

The online pharmacies have continued to operate and grow despite regulatory hurdles and opposition. The industry has attracted significant private equity and other funding recently. The top four online pharmacies -- Pharmeasy, 1mg, Medlife and Netmeds -- have raised around INR 2,000 crores in 2019 alone. The sector is attracting a lot of investments from the global investors like Temasek, Wilson Global Opportunities, Corisol Holdings, Sequoia Capital, etc.

The top 4 online pharmacies -- Pharmeasy, 1mg, Medlife and Netmeds -- have raised USD 300 million in 2019

A Frost & Sullivan report says the market size of the Indian e-pharmacies was estimated to be around USD 512 million (INR 3,500 crore) in 2018. It predicts a compounded annual growth rate (CAGR) of 63% to reach USD 3.6 billion (INR 25,000 crore) by 2022. That will be over 30% of the drugs sold in India a year.

The future of pharmacy

- The e-pharmacies sell drugs at lower prices, enticing customers to buy from online purchases rather than physical pharmacies. The customers can avail discounts up to 40% on some medicines.
- The distribution cost is lower as these pharmacies do not need to provide the requisite margins to stockists and other distributors in the value chain. Inventory holding locations will be fewer which will also reduce the overall cost of the value chain.
- Pharmaceutical companies may welcome online pharmacies as this can only boost their sales and remove the middleman.
- Average price difference between online pharmacies & traditional pharmacies was 15-20%, based on a sample of antibiotics and typical over-the-counter flu medicines.
- Companies like Goaptive and Pharmarack are providing end-to-end supply chain technologies increasing productivity of the distribution network, enabling companies to reach the length and breadth of the country.
- Use of technology in the supply chain will only make it more agile and improve medicine accessibility.

Pros and Cons

- Availability of medicines at lower prices
- Convenient for patients who can't leave their homes.
- Increased choice as a wide variety of medicines available.

- Electronic health records security and privacy concerns.
- Sale of drugs without prescription by some e-pharmacies which lead to harmful consequences.
- Labelling and packaging related issues

Our view

Disruption has been the theme of this century. As internet becomes accessible, e-pharmacies will gain more prominence in future. In a bid to improve accessibility and affordability of drugs, the government will provide the necessary impetus to online pharmacies and at the same time, maintain the interests of traditional pharmacies.

Ind AS 115: Accounting for revenue from licensing contracts

Licensing contracts

The pharma companies are increasingly entering into collaborations with third parties for commercialisation of drugs and medical products in an effort to gain benefits in both the costs and risks associated with research and development (R&D). On the other hand, the companies, which have invested in R&D get the benefit of monetising their non-core assets and utilise their existing production capacities on manufacturing profitable core assets, get the margin protection or royalty benefits out of the manufacturing and supply agreements in collaboration with sale of license agreement.

These arrangements involve activities such as IP transfer, manufacturing, distribution, sales and marketing activities.

Top large revenue deals for this quarter

Revenue deal	Products involved	Deal value (USD mn)
Astrazeneca - Atnahs Pharma	5 ANDA*s	350
Pharmaceutics International - Strides Pharma	18 ANDAs	6.1
Cipla - Sunrise	1 ANDAs	7
Cipla-RV Healthcare	1 ANDAs	5
Cipla-Celltrion	2 ANDAs	2.2

ANDA* Abbreviated New Drug Application or generic drug application with USFDA

Upon entering into such arrangements, the participants frequently exchange up-front licence fee and agree to subsequent payments based on the achievement of sale and distribution targets. Such arrangements are often complex and can vary significantly in scope, terms, and conditions and risk mitigation objectives.

As we approach the financial year-end, it is important to evaluate the accounting treatment for such agreements which can be complex and subjective.

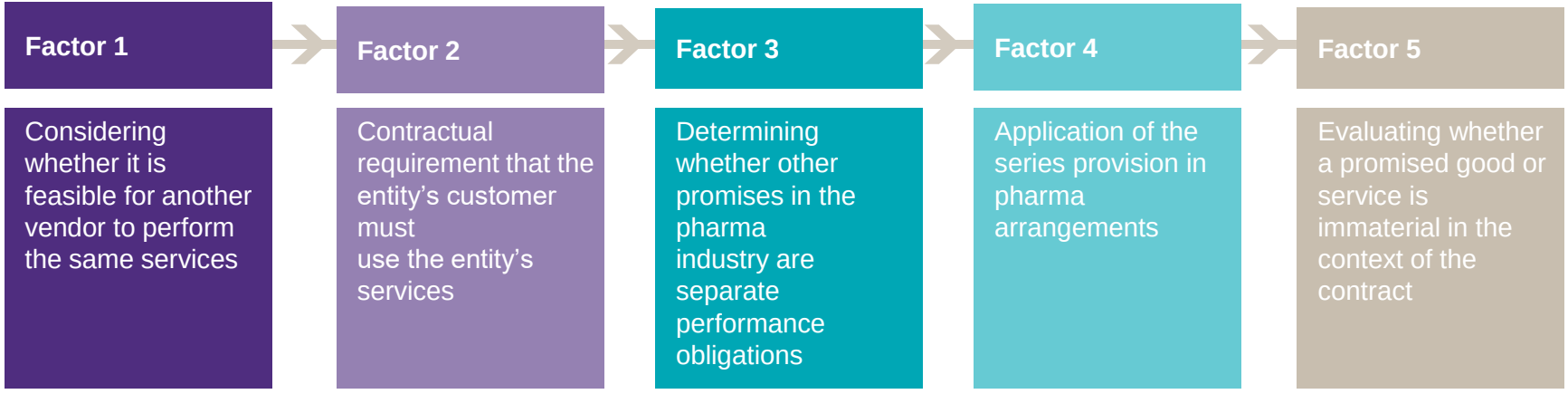
In this section, we take a look at some of the key factors to be considered in accounting revenue from contracts.

Ind AS 115: Revenue from contracts - licence of intellectual property rights and other services

The pharma entities that grant a licence bundled with other services (For example, contract R&D service or contract manufacturing services) may need to use significant judgement while determining whether the goods or services in a contract

1. are capable of being distinct (have stand-alone value) and
2. are not highly interdependent or highly interrelated and do not significantly modify or customise one another (are separately identifiable).

While the analysis of whether the goods or services are capable of being distinct is generally consistent with the analysis of "standalone value" under legacy guidance, the "separately identifiable" concept is new and may require entities to account for a bundle of goods or services, which may represent separate units of accounting under legacy guidance, as a single performance obligation (unit of accounting).



Factor 1 - Considering whether it is feasible for another vendor to perform the same services

Guidance

An entity is required to assess whether promised goods and services have a distinct performance obligation.

Our remarks

Analysis of whether sales of licence is distinct:

a. Licence is distinct if:

- The manufacturing process used to produce the drug is not unique or specialised, and several other entities also can manufacture the drug for the customer
- The customer can benefit from the licence together with readily available resources other than the entity's manufacturing service at the start of contract
- The entity considers that the customer could:
- separately purchase the licence without significantly affecting its ability to benefit from it.
- the licence and the manufacturing service are not highly interdependent or highly interrelated.

b. Licence is not distinct if:

- No other entity can manufacture this drug while the customer learns the manufacturing process and builds its own manufacturing capability because of the highly specialised nature.
- The entity determines that the customer cannot benefit from the licence without the manufacturing service

Factor 2 - Contractual requirement that the entity's customer must use its services

Guidance

A contractual requirement that the entity's customer must use the entity's R&D services or manufacturing services does not change the evaluation of whether the promised goods and services are distinct.

Our remarks

How the customer can benefit from the goods or services should be based on the characteristics of the goods or services themselves instead of the way in which the customer may use them. Consequently, an entity would disregard any contractual limitations that might preclude the customer from obtaining readily available resources from a source other than the entity.

Accordingly, if the licence and the services are otherwise capable of being distinct and separately identifiable, the licence and the services would be accounted for as two performance obligations.

Factor 3 - Determining whether other promises in the pharma industry are separate performance obligations

Guidance

If a good or service is unavailable from alternative providers or available from only a limited number of alternative providers, the entity is not precluded from considering the good or service to be a separate performance obligation.

Our remarks

The unavailability of a good or service from alternative providers is a factor to be considered in evaluating whether the good or service is distinct (and therefore a separate performance obligation), but that factor is not individually determinative.

Entities need to use judgement while evaluating whether a promise to provide a good or service, in addition to other goods or services, is capable of being distinct and is distinct within the context of the contract (i.e., separately identifiable).

Following factors need to be kept in mind while concluding on whether the good or service is separately identifiable:

- Whether there is a significant service of integrating goods or services.
- Whether the good or service significantly modifies or customises another good or service.
- Whether the good or service is highly dependent on or highly interrelated with any other goods or services.

Factor 4 - Application of the series provision in pharma arrangements

Guidance

Contract with a customer may be affected by whether the entity determines that its promises to the customer represent:

- a single combined performance obligation comprising multiple activities that are not distinct or;
- a single performance obligation consisting of a series of distinct increments.

The determination of whether R&D or selling services provided by entities in the pharma industry represent a series may require significant judgement.

Our remarks

Judgement is required for following specific criteria:

a. **The delivery of a specified quantity of goods or services:**
The entity must determine whether each good or service with specified quantity is distinct, and is substantially the same as the other goods or services, and has the same pattern of transfer to the customer as that of the other goods or services.

b. **A stand-ready obligation to provide an indefinite amount of goods or services during a specified period:**
The entity must determine whether, for each increment of time, its promise of standing ready to provide the R&D or selling services is distinct, is substantially the same.

For example, a life sciences entity may commercialise its approved pharmaceutical products by retaining an outsourced sales team to promote its products. The nature of the selling services may differ from R&D services in that each day's service is not modified or customised by another day's service. One day's service is not an input to another day's service that results in a combined output, and each day's service is not highly interdependent or interrelated with another day's service.

Factor 5 - Evaluating whether a promised good or service is immaterial in the context of the contract

Guidance

An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. If the revenue related to a performance obligation that includes goods or services that are immaterial in the context of the contract is recognised before those immaterial goods or services are transferred to the customer, then the related costs to transfer those goods or services shall be accrued.

Our remarks

a. An entity may conclude that a potential good or service is immaterial in the context of the contract if the estimated stand-alone selling price of the potential good or service is immaterial (quantitatively) compared with the total consideration in the contract (i.e., the amount that would be allocated to such good or service is immaterial in the context of the contract).

b. An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer does not consider the potential good or service to be material to the contract.

c. An entity while performing assessment to identify immaterial promised goods or services should also consider evaluating potential material rights.
For example, a medical device company might offer basic training or education services for equipment that it sells to a hospital. The value of this type of service may be immaterial (quantitatively) compared with the total consideration in the contract. Further, the basic training or education may not be a service that the customer considers to be material to the contract.

Union Budget 2020 updates

Key announcements

- The healthcare sector received a budgetary allocation of about INR 69,000 crore, including INR 6,400 crore towards the Prime Minister Jan Arogya Yojana (PMJAY)
- **Eradication of tuberculosis:** 'TB Harega Desh Jeetega' campaign launched to eradicate **tuberculosis by 2025**
- **Availability of affordable generic drugs to be expanded:** Jan Aushadhi Kendra Scheme, a scheme to provide affordable generic drugs through special 'kendras', to be expanded to all districts offering 2,000 medicines and 300 surgical items by 2024
- **Support to domestic manufacturing**
- Handholding support for pharmaceutical industry among others for technology upgradations, R&D, business strategy, etc. The handholding scheme for the pharmaceutical industry proposed to be financed by a scheme of INR 1,000 crore, which will be anchored EXIM Bank and SIDBI. These banks would contribute INR 50 crore each. The amount will be used towards equity and technical assistance
- A health cess, by way of custom duty, is introduced on import of medical equipment, proceeds of which are to be used for viability gap funding of hospitals in aspirational districts
- Proposed a scheme for encouraging manufacture of medical devices

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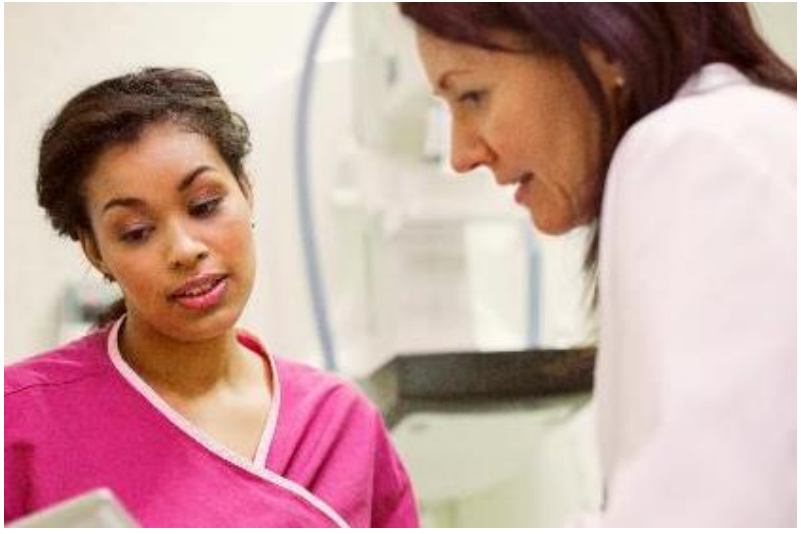
- **Viability gap funding for empaneling hospitals:** Proposal to set up viability gap funding window for setting up hospitals in the public-private partnership mode to increase the number of empaneled hospitals in Tier-2 and Tier-3 cities covered under PMJAY. In the first phase, 112 aspirational districts, where there are no Ayushman-empaneled hospitals, have been identified.
- **Reaching immunisation goals:** Mission Indradhanush, which aims to achieve 90% immunisation against vaccine-preventable diseases, expanded to cover 12 diseases from 8.
- **Use of machine learning and artificial intelligence (AI):** Using machine learning and AI in the Ayushman Bharat scheme, health authorities and the medical fraternity

- **Holistic view on women's health:**
  - A task force to be appointed to study and provide recommendations related to women's welfare
  - Under the 'Poshan Abhiyan', more than six lakh anganwadi workers equipped with smartphones to upload the nutritional status of more than 10 crore households



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- **Swatch Bharat Mission**: INR 12,300 crore allocated towards Swatch Bharat Mission
- **Clean water**: INR 3.6 lakh crore allocated to Jal Jeevan Mission to provide piped water to all households
- **Skill improvement for nurses, para-medical staff and care givers abroad:** The Ministry of Health will design a special course to improve the employment opportunities for nurses, para-medical staff and care-givers abroad

Our view

Corporates should evaluate tax strategies in light of the Union Budget 2020:

01 Effective tax outflow by opting for revised corporate tax rates vs Special Economic Zone (SEZ) scheme and other existing benefits

02 Race to the March 2020 deadline for setting up a new SEZ unit per the SEZ sunset clause, considering the indirect tax benefits that remain

03 Investment opportunities in medical devices as the government pushes 'Make in India'

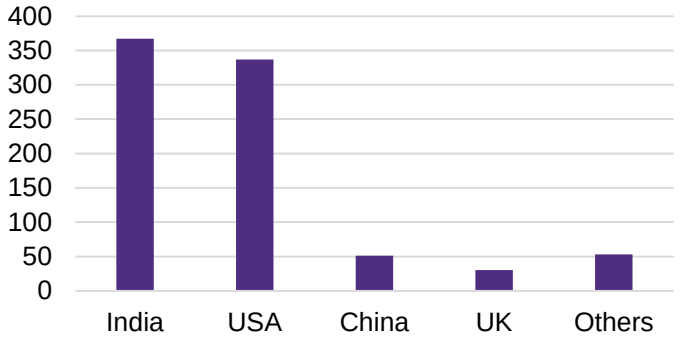
04 Benefits of going under the amnesty scheme, Vivad Se Vishwas to clear pending tax litigation

05 Gear up for e-invoicing under GST across the distribution network

New drug approvals

Investment in R&D paying off

India was the **largest receiver of generic drug approvals by USFDA in 2019,** with 43% of approvals. The US received 41% of generic drug approvals.



* ANDA: Abbreviated New Drug Application

In India, DCGI approved 26 new drugs in India in 2019, 11 of which were in the last quarter.

This year, neuro/mental health, dermatology, and cancer drugs together received 50% of approvals in India.

A deeper analysis of drug approvals of Indian pharma companies indicates that most of the **expertise lies in oral dosage forms** wherein seven out of the nine top-listed pharma companies have over 75% of their approvals.

Oral	Injectable (incl. IV/ IM)	Topical	Others	Total	Orals %
1,267	161	95	58	**1,581**	80%

Cipla and Glenmark, being the exceptions, obtained 24% and 30% of their approvals from injectibles and topical dosage forms, respectively.

Our view

To maximise return on R&D, companies need to closely monitor three major factors:

Drug quality and success of approval: Recent impairment losses were on account of ANDA rejections

Time to file: First to market has a natural advantage in garnering market share

Project budget management: R&D activities are cash-intensive with a long gestation period

Challenges in quality management

Challenges in quality management

The USFDA performs annual site inspections of approved manufacturing facilities with 3 outcomes:
NAI: No Action Initiated (clean report); **VAI**: Voluntary Action Initiated (minor audit observations); **OAI**: Official Action Initiated (serious audit observations)

While India is a significant contributor to drugs sold in the US, compliance to the USFDA's stringent quality management norms remains one of its key challenges. Quality-related observations were found in 64% of inspections concluded in India in 2019 on drug quality assurance

Under the lens

Region	Inspection outcome			% of inspections with no observations
	No observations	Minor observations	Serious observations	
US	220	276	33	42%
India	75	109	24	36%
China	23	72	13	21%
Canada	24	37	2	38%
Japan	17	29	-	37%
Germany	17	27	1	38%
Others	71	149	13	30%
Total	**447**	**699**	**86**	

23 warning letters were issued to Indian pharma companies in 2019. The top six countries completed 35% of their inspections with no observations on an average

In 2019, 17 recall events by Indian pharma companies were mostly due to impurities seen in drugs. Major recalls by Indian companies were: Losartan (Q1 FY20), Valsartan (Q2) and Ranitidine (Q3).

The major risk with receiving warning letters is delay in approval of other drug applications, which increases the pay back period on R&D investments.

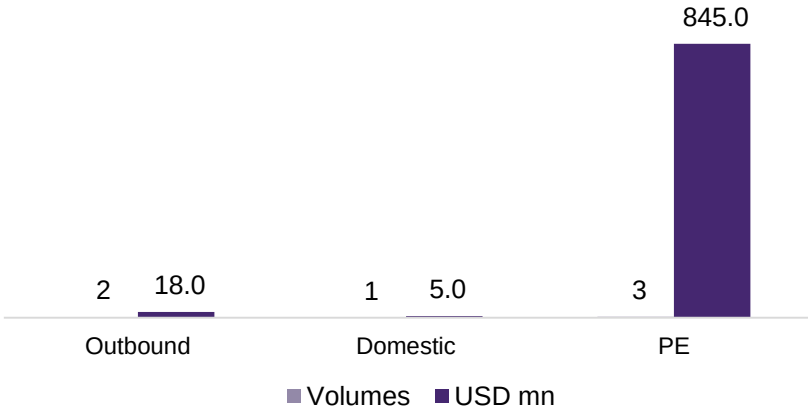
It is safe to assume that scrutiny by the USFDA will only increase, and companies should relook at their plans for:

- Pre-inspection audits; and
- A culture change or metamorphosis from compliance to integral ethics of the organisation

Transaction update

Mergers and acquisitions (M&A), Private equity (PE)

Deal summary



Q4 2019	Volumes	USD million
Outbound	2	18.0
Domestic	1	5.0
PE	3	845.0

Note: Deals where in reliable data for transaction value is not available, we have assumed the transaction value as USD 5 million

- The sector witnessed subdued activity during Q3 FY20, with only six deals. Only a couple of them were high-value transactions.
- The critical drivers for the high-value transactions has are either a) increasing pricing pressure leading to some markets being unattractive and thereby companies exiting such markets or b) players aiming to add product pipeline/newer markets seeking capital to achieve such objective.
- We see increased deals in this space driven by factors such as price controls across markets, mandatory genericisation in India, increasing healthcare spending and better accessibility in India and increasing exports to large and traditionally under penetrated markets such as China, Africa, Indonesia, and Latin America.

Top deals

M&A deals

Acquirer	Target	USD million	Deal type	% Stake
Eris Lifesciences Ltd	Novartis AG- Zomelis Trademark	13	Outbound	100%
Cipla Ltd	Venus Remedies Ltd- Elores anti infective drug	N.A.	Domestic	100%
Cipla Ltd	Novartis AG- Vysov and Vysov M Trademark rights in india	N.A.	Outbound	100%

PE deals

Acquirer	Target	USD mn	% Stake
Unison Capital Partners	Lupin Ltd- Kyowa Pharmaceutical Industry Co. Ltd	525.00	99.8%
Quadria Capital	Akums Drugs & Pharmaceuticals Ltd	70.00	N.A.
Advent International	Bharat Serums and Vaccines Limited	250.00	N.A.

Source: Compiled from public domain like VC Circle, Mint etc.

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