Issues in Accounting, Tax and Compliances for Pharma Companies

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Setting the context

Setting the context

COVID-19 pandemic has affected the global economy adversely, and the ripple effect could continue for some time.

Multinational enterprises (MNEs) are now starting to rethink both internal and external business arrangements - cost calibrations, revising expenditure budgets, revisiting customer/vendor contracts, etc.

Immediate focus for MNEs during this crisis has been to conserve liquidity and direct cash flows effectively from a group perspective.

Present economic outlook, subsequent financial consequences, as well as any measures that MNEs may take to deal with the COVID-19 crisis, could have a significant impact on existing TP structures.

Building trust and solving important problems of society

Aligning TP policies with economic realities can help businesses ease their financial burden.

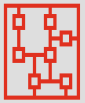
Common issues that many organisations are facing

Workforce

Lower productivity especially those living in affected territories.

Supply chain

Re-routing, delays, disputes and knock-on impact on customers



Decline in sales

Leading to cash flow and covenant issues

Operations

Reduced resilience in key functions, infrastructure and services, or locations become unavailable

Liquidity crisis

Reduced revenue with proportionate higher expenses burning up cash

Audits

Impact on margins poses an increased tax audit risk

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Specific impact areas

Navigating the Turbulence

- Limited Risk Distributor
- Contract R&D / Manufacturing
- Financing Arrangements
- Intangibles
- Intra-group services
- Advance Pricing Agreements (APAs)
- Business Restructuring

Specific impact areas

Stoppage in services – force majeure

- Temporary suspension of contracts, without any support payment
- Continue arrangement, but considering utility, fund with cost recovery or a lower mark-up
- Continue the arrangement, and extend credit periods for payments

- Unavailability of workforce who are either stranded or have migrated
- Underutilised workforce capacity due to restricted operations
- Additional costs for operations due to social distancing and safety concerns
- Significant people function, DEMPE,* permanent establishment risks
- Personal tax exposures, residency issues of workforce

Workforce and business/cost impact

Re-negotiating TP

- Justifying lower margins on the basis of comparability analysis
- Treatment of bad debts
- Building an economic rationale for sharing certain costs
- Zero margins and economic rationale for low-risk entities
- Justification of losses
- Whether modification/waiver/moratorium of royalty (or like payments) is warranted?

Specific impact areas

- Falling INR against major currencies – embedded impact on margins and payments
- Treatment as operating or non-operating?
- Renegotiation of contracts?

Rupee depreciation impact

Comparability analysis

- Recent business, tested party and transaction stresses
- Impact on comparability and comparability adjustment
- Revision of benchmarks for low(er) margins/markups
- Finding alternatives to support absence of current data
- Selection of appropriate time frames for realigning TP policies
- Potential losses
- Strain in ‘limited risk’ models
- Tax authority challenges in case of losses.

- Economic adjustments – idle capacity or reduced productivity
- Challenges due to non-availability of comparable data
- Working capital adjustment
- Treatment of interest costs on additional funding arrangements owing to COVID-19
- Increased cost for healthcare of employees
- Increased cost of upgrading IT infrastructure
- Any performance guarantees that exist may be triggered
- Any other extraordinary costs

Economic adjustments

Specific impact areas

Liquidity and financial transactions

- Liquidity crisis within the group
- Impact on credit rating and borrowings – related renegotiation of terms of inter-company financing arrangements
- Local thin cap rules may restrict interest deduction
- Impact on cash pooling arrangements
- Additional guarantees may be sought for by external lenders
- Cash repatriation to group
- Risk of delayed payments

- Business disruption
- Movement of functions, assets, risk and profit potential– need to evaluate exit charge implications
- Certain functions to be replaced by technology
- Changes in inter-company agreements

Business restructuring

Asset valuations and impairment

- Assumptions about values (e.g. of IP) may be out of date
- Impact of accounting norms – inventories may be written down
- It may be necessary to decide which entities bear the costs

Specific impact areas

Indirect taxes

- Disputes in classification of pharma products (such as sanitizers)
- Treatment of discounts given during lockdown and post lockdown periods
- Treatment of bad debts and issuance of credit notes especially in case of sales returns
- Impact on valuation of goods in case of subsequent price subsidies provided to customer especially in case of pricing ceiling by Government Agencies
- Allocation of large amounts of R&D cost incurred globally

Input tax credit

- Eligibility of ITC on face masks, sanitizers, personal protective equipment to employees, mandatory insurance taken for employees, etc.
- ITC on expenditure incurred towards CSR activities
- Treatment of ITC on goods destroyed/disposed
- Reversal of ITC on account of expired stocks
- Availability / reversal of ITC on invoices not uploaded by suppliers due to lockdown

Customs

- Interplay of Customs and TP on prices such as impact of moratorium on royalty payments, allocation of R&D costs, etc.
- Impact of number of restrictions placed on imports and exports of essential pharma products
- Upward/ downward revision of export price of goods considering change in the quantum of incentives
- Changes to supply chain may change indirect tax that vary considerably between countries and may be irrecoverable.

Specific impact areas

COVID related cost

- Cost for healthcare
- Cost of upgrading IT infrastructure
- Any performance guarantees that exist may be triggered
- Other costs that can be termed extraordinary and kept outside the cost base while computing the mark-ups in the normal course of business

Disclosure/ documentation/audit

- Appropriate disclosure of impact on financial results
- Documentation of impact
- Increase in audit risk

Disputes, advance pricing agreements (APAs) and mutual agreement procedures (MAPs)

- APAs/enquiries/MAPs may be delayed
- 'Critical assumptions' of existing APAs may be broken If not, business may be required to adhere to APA terms
- Litigation/audits may increase
- Actions this year may contradict (or support) past positions

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Dealing with the tax impact – next steps

Dealing with the TP impact – next steps

Analysis needs to be fact specific and the following may need a detailed evaluation:

- Inter-company agreements
- Revisiting invoicing terms, including credit terms
- BCP of the organisation – internal communications and relevant management data
- Group's overall impact analysis due to COVID-19
- Group response while dealing with third parties
- Historical conduct of parties
- Industry analysis and competitive landscape
- Quarterly results of comparable companies, wherever /whenever available
- Way forward on APAs

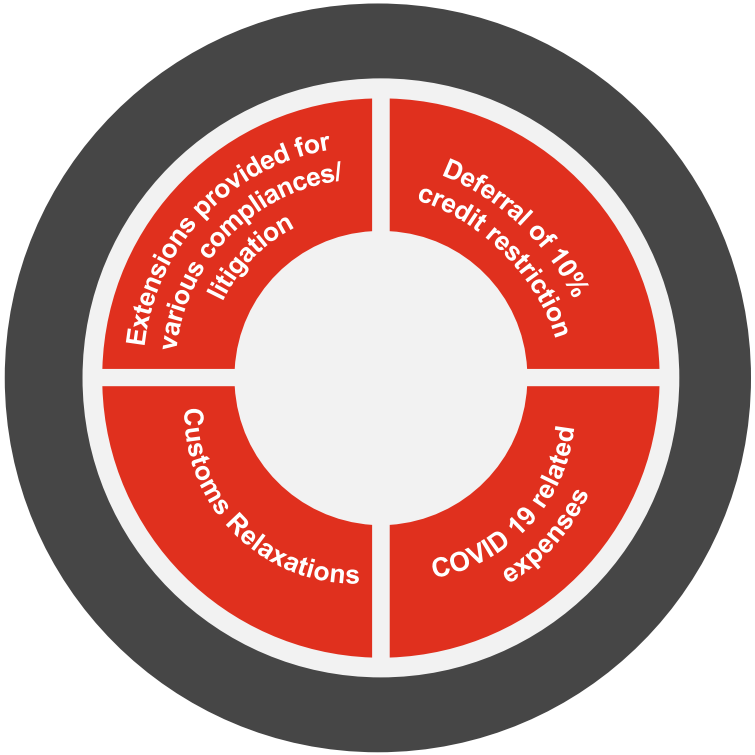
- ✓ **Actual liquidity position of the group?**
- ✓ **Fit case? – Considering commercial expediency**
- ✓ **Need for counsel opinion?**
- ✓ **Business restructuring on the cards?**
- ✓ **Potential exit charge implications**
- ✓ **Impact on APAs? – Past and ongoing, or consider fresh application**
- ✓ **Need for additional documentation to be maintained in future?**
- ✓ **Tax impact analysis**

The timing of analysis and executing the remedial actions is the key!

The strategy should also take into consideration the impact under Corporate Tax, Goods and Service Tax and other tax or regulatory laws.

Note: This list is suggestive and indicates a starting point

Reliefs provided in view of COVID-19



Extensions provided for various compliances/litigation

- All due dates falling between 20 March–30 August 2020 extended to 31 August 2020 (under the GST Act)
- Certain due dates under allied laws extended to 30 September 2020
- These events include issue of notices, furnishing of returns/statements/applications, filing of appeals, refunds, etc.
- Specific exclusions provided to which extension will not apply (such as issuance of invoices, time of supply, registration, penalty, seizure of goods)

Deferral of 10% credit restriction

- Relaxed for the months of February to August 2020
- Adjustment to be taken cumulatively in GSTR-3B for September 2020

COVID 19 related expenses

- Ministry of Home Affairs (MHA) issued an order under the Disaster Management Act 2005 wherein it mandated provision of thermal scanner, hand wash and sanitizers
- In view of judicial precedents, the company can claim credits on such expenditure since the same is mandatory and used in the course of business

Customs Relaxations

- Extension of IGST and Compensation Cess exemption on imports by EOUs/STP/BHTP/ EHTP or under AA/EPCG scheme till March 31, 2021
- Waiver of Detention charges / Demurrage Charges, relaxed requirement to submit bonds prescribed for provisional assessment, warehousing and specific clearances

Dealing with the impact from IDT perspective – next steps

- **Focus on reconciliations – both output and input**
- **Evaluate tax positions and apply for Advance Rulings / Counsel opinions wherever necessary**
- **Keep a check on vendor compliances (to ensure timely credits) and follow up on regular basis**
- **Expedite refund claim filing and follow up for processing**
- **Evaluate use of technology in current process and create roadmap on how to minimize manual efforts and maximize technology usage for efficiency**
- **Realignment or renegotiation of contracts with vendors**
- **Prepare for GST audits and investigations – Data collation**

Life after COVID-19: E-invoicing under GST

Initial updates

- E-invoicing initially proposed from 1 April 2020 for B2B transactions for businesses with turnover > Rs. 100 crore
- Self generated QR code required for B2C transactions for businesses with turnover > Rs. 500 crore
- Schema and APIs issued - Multiple changes
- Concept notes and FAQs issued
- Sandbox provided for testing

March 2020

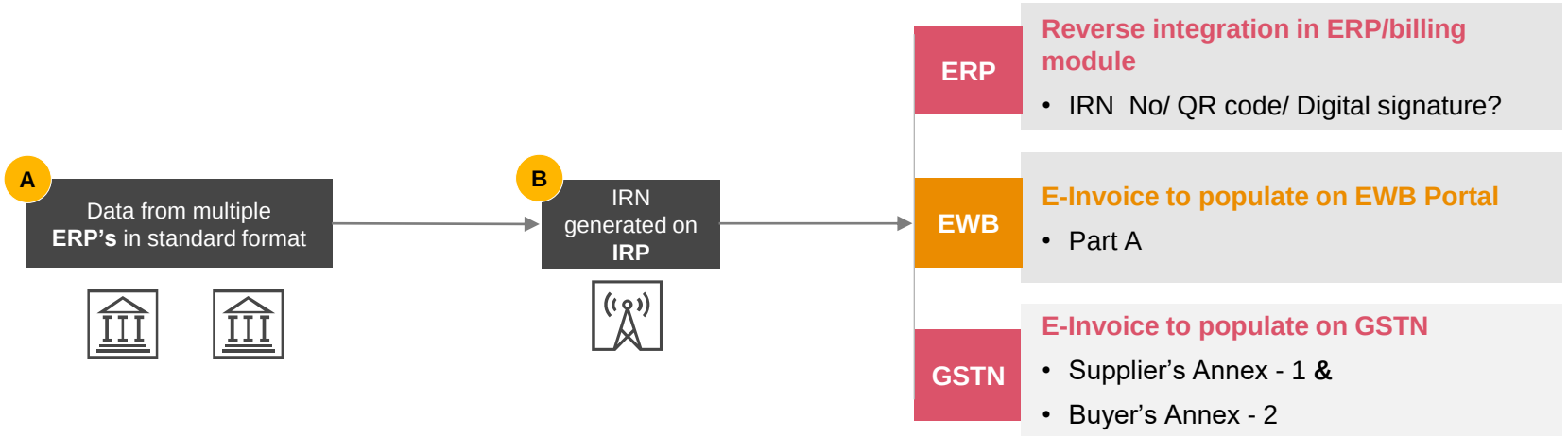
- Updated API and validations released in sandbox (V 1.01)
- **E-invoicing date extended to 1 October 2020**
- E-commerce operators allowed to generate IRN on behalf of suppliers

April 2020 - July 2020

- Updated API released (V 1.02)
- Changes in data template and validations
- Single API to generate IRN & EWB together provided

Possibility of phase wise implementation – Initial rollout maybe only for businesses more than Rs. 500 crore – Clarity awaited
Updated API and FAQs also expected

E-Invoicing demystified



* Recent FAQ clarifies that IRP will not e-mail invoice to buyer/seller

Documents liable to IRN

- Invoice (Including ISD invoice ?)
- Debit Note
- Credit Note (Including ISD credit note ?)

[Delivery challan, Bill of supply not liable to IRN]

Transactions liable to IRN

- Business to business (B2B)
- Business to government (B2G)
- Exports

[Job work, B2C transactions not liable to IRN]

- Reverse Charge?
- Supply through e-com operator

* Above is based on FAQs released by GSTN/NIC

Assessments, Audits and Investigation framework

Assessments and audits under GST

- Routine Inquiry
- Scrutiny assessments
- Audit by GST authorities
- Special audit by Commissioner

Investigation and other audits

- DGGSTI- Directorate General of GST Intelligence investigation
- DRI- Directorate of Revenue Intelligence investigation
- NAA- National Anti Profiteering Authority
- DGAP- Director General of Anti-Profiteering
- DGFTR- Anti-dumping and Countervailing Duty investigation
- Customs Audit
- EA 2000 and VAT audit for previous period under Excise and Service Tax
- CAG Audit- Comptroller and Auditor General Audit

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Pharma sector – Regulatory overview

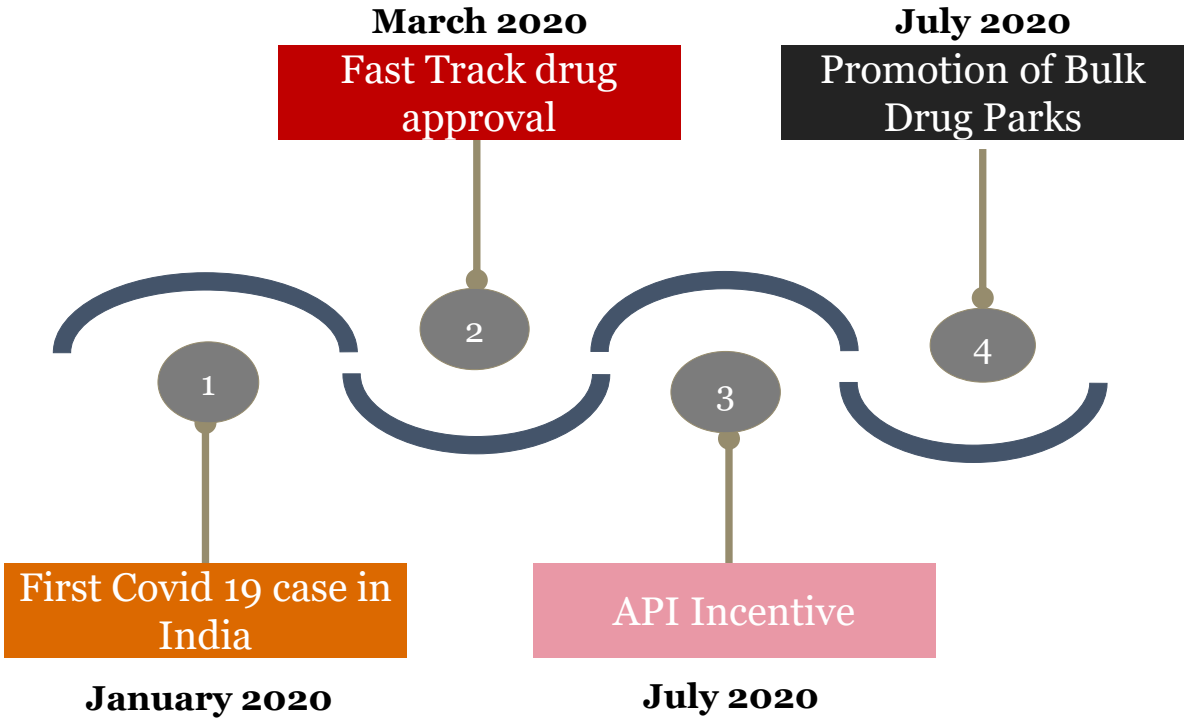
Pharma – Legal and Regulatory Landscape

Domain	Import, manufacture, distribution and sale of drugs	List of essential drugs and it's pricing	Marketing laws	Patents and Trade marks	Competition
Regulations	• Drugs and Cosmetics Act, 1940 and Rules, 1945 • NDPS Act, 1985;	• Essential Commodities Act, 1955 • Drugs (Price Control) Order, 2013	• The Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955 • UCPMP • MCI guidelines	• Patents Act, 1970 • Trade Marks Act, 1999	• Competition Act, 2002
Authority	CDSCO headed by DCGI; Central and State Government	NPPA	Central and State Government; Department of Pharmaceuticals; MCI	Controller General of patents; Controller General of trademark	Competition Commission of India

NDPS - Narcotic Drugs and Psychotropic Substances Act
UCPMP – Uniform Code for Pharmaceuticals Marketing Practices
MCI – Medical Council of India
CDSCO - Central Drugs Standard Control Organization (CDSCO)
DCGI – Drug Controller General of India (DCGI)
NPPA – National Pharmaceutical Pricing Authority

Recent regulatory development/changes

Following are the key regulatory development post COVID-19 impacting Pharma industry:



Recent regulatory development/changes

Fast track drug approval *Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services has released a fast track pathway for COVID-19 drugs on March 19, 2020.*

Why?

- During COVID-19 pandemic, there was a need to develop a **process** to expedite the development and approval of **drugs** which may demonstrate potential cure/substantial improvement over current therapy for COVID-19.
- Fast track approval process to encourage R&D of COVID-19 drug or vaccine

Content

- Requirement for animal toxicity study, clinical study, stability study etc. may be abbreviated, deferred or waive off on case to case basis.
- Fast track approval for drugs already approved outside India.

Fact track drug approval

Key Guidelines and updates

- Drug/vaccine under development for COVID-19 can directly approach CDSCO
- Key guidelines for Import, Manufacture and Clinical trials
- Protocol for repurposing of existing drugs/vaccines will be given priority
- Processing of COVID-19 drugs/vaccines application within 7 days.

Benefits

- Accelerated process enabling quick launch of COVID-19 drugs
- Several Indian companies benefited from the fast track approval

Recent regulatory development/changes

API incentives

Ministry of Chemicals and fertilizers (Department of Pharmaceuticals) issued notification dated July 21, 2020 on incentives schemes for manufacturing API locally.

Why?

- ~70% of APIs in India is imported from a single country
- To reduce dependency on import and to further strengthen "Atmanirbhar Bharat" principles, government has came out with notification to provide incentives for local API manufacturing

Objectives

- Optimization of resources and economies of scale
- Reduce dependency on imports for identified KSMs, DIs and APIs.

Key Guidelines & financial assistance

- Incentives provided to manufacturers of critical KSMs/DIs and APIs, subject to defined threshold
- Financial Incentive for sale of identified 41 products for six years
- For Fermentation based products incentive ranges from 5% to 20 % and for Chemical synthesis products it is 10%
- Tenure of the scheme is FY 2020-21 to FY 2029-30 and expected total financial outlay is Rs 6,940 crores

Benefits

- Large scale investments in the Pharma sector
- Boost local manufacturing of identified key APIs, KSMs and DIs
- Reduction in imports

KSM – Key Starting materials
DI – Drug Intermediaries

Recent regulatory development/changes

Promotion and bulk Drugs parks *Ministry of Chemicals and fertilizers (Department of Pharmaceuticals) issued notification on July 21, 2020 for promotion of Bulk drug parks.*

Why?

- Bring down overall manufacturing costs of bulk drugs
- High cost of common infrastructure facilities such as waste management, testing, logistics and power
- Providing easy access to standard testing and infrastructure facilities

Objectives

- Help industry to meet environment standards at a reduced cost through innovative methods of common waste management system
- Optimization of resources and economies of scale
- Strengthen existing infrastructure facilities

Key Guidelines & financial assistance

- Financial assistance for creation of common infrastructure facilities (such as central effluent plant, solvent recovery and distillation plant, logistics, laboratory testing, etc.) in bulk drug parks
- Financial assistance to be 90% of project cost for North Eastern & Hilly states and 70% for other states
- Tenure of the scheme is FY 2020-21 to FY 2024-25 and expected total financial outlay is Rs 3,000 crores

Benefits

- Reducing cost of production by 20-25%
- Easy access to world class common infrastructure facilities

Other Key update that may impact Indian Pharma industry

4 Executive orders passed by US President

Notified on July 24, 2020:

- 1st order: Access to affordable life-saving medications
- 2nd order: Allows for individual state plans for the safe importation of certain drugs and re-importation of insulin products made in the US.
- 3rd order: Prohibits secret deals between drug manufacturers and pharmacy, ensuring patients directly benefit from available discounts
- 4th order: Lowest medicine prices in economically comparable countries.

Impact :

- India exported drugs of about $6 billion in 2019 to US.
- These orders provide opportunity as well as threat for Indian Pharma industry.
- Opportunity: Increased market access and possibility of increased market share
- Threat: Pricing pressure in US market

USA to restrict import of pharmaceutical drugs (Import Alert 66-40)

Notified on July 21, 2020 by US FDA:

- Usually, FDA physically audits pharma companies and incase of any adverse reporting, import from a particular pharma company maybe restricted.
- Through this order, FDA can restrict import from particular pharma company, without physically visiting it in case of any of the following:
  - A pharma company is not operating in conformity with current good manufacturing practices (GMP's).
  - FDA receives information concerning inspections conducted by other government authorities under a Memorandum of Understanding.
- FDA has provided a list of pharma companies and products subject to DWPE (Detention without physical examination)

Impact:

- List also includes Indian Pharma companies

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Pharma sector – Key Accounting and Auditing issues

Pharma sector – Key Accounting and Auditing issues

Capitalization of internal development costs (IndAS 38):

Scenario	Guidance
A pharmaceutical entity is developing a vaccine for Covid-19 that has successfully completed Phases I and II of clinical testing. The drug is now in Phase III of clinical testing. Management still has significant concerns about securing regulatory approval, and it has not started manufacturing or marketing the vaccine. Should management start capitalizing development costs at this point?	Development costs are capitalized as an intangible asset if all of the criteria given in para 57 of IndAS 38 are met (technical feasibility, intention, ability, future economic benefits, measure reliably) Obtaining regulatory approval is considered to be a strong indication that entity has met all criteria as it is the most difficult criteria to be met. Significant Management judgement involved - auditor to ensure compliance with SA 540. When to stop capitalizing the development cost?

Pharma sector – Key Accounting and Auditing issues

Examples of development costs that can be capitalized:

Scenario	Guidance
A laboratory is developing a drug to cure SARS. Management has determined that it meets the criteria in paragraph 57 of IndAS 38, and that certain development costs must therefore be capitalized, because regulatory approval has been obtained. Management is unsure about what costs to include and exclude.	Following directly attributable cost: • employee benefits for personnel involved in the investigation and trials • overheads that are directly attributable to developing the asset and that can be allocated on a reasonable and consistent basis; • allocation of depreciation of property, plant and equipment or rent; • legal costs incurred in presentations to authorities; • design, construction and testing of pre-production prototypes and models Expenditure such as training a sales force or performing market research should not be capitalized as this type of expenditure does not create, produce or prepare the asset for its intended use. Auditor to obtain 'sufficient' and 'appropriate' audit evidence – SA 500.

Pharma sector – Key Accounting and Auditing issues

Accounting for promotional campaigns / free samples:

Scenario	Guidance
A pharmaceutical company has developed a new drug that simplifies the long-term treatment of kidney disease. The company's commercial department has incurred significant costs with a promotional campaign, including TV commercials and presentations in conferences and seminars for doctors.	An intangible asset is an identifiable non-monetary asset without physical substance. An asset is a resource that is controlled by the entity as a result of past events and from which future economic benefits are expected to flow to the entity. The company should not recognize its advertising and promotional costs as an intangible asset, even though the expenditure incurred might provide future economic benefits; it should charge all promotional costs to the income statement as it does not meet the definition of intangible asset. Expenditure on advertising and promotional activities should be expensed when incurred. Similarly, free samples distributed to Doctors should be recognized as marketing expense when the cost is incurred.

Pharma sector – Key Accounting and Auditing issues

Accounting for right to return:

Scenario	Guidance
As per the terms of contract, the company has given its customers the right to return the goods within a specified period of time. How should this be recognized in the financial statements?	An entity shall recognize a refund liability if the entity receives consideration from a customer and expects to refund some or all of that consideration to the customer (para 55 of IndAS 115). This involves the estimation of expected refund liability based on the past trend and other relevant information. Refund liability is disclosed as non-financial liability (current or non-current based on the expected timing of outflow). Corresponding non-financial asset should be recognized towards the expected value of inventory to be returned. Significant Management judgement involved - auditor to ensure compliance with SA 540.

Pharma sector – Key Accounting and Auditing issues

Right to return in case of completely new product launch:

Scenario	Guidance
A pharmaceutical company has launched a completely new product for which there is no past history. How should company recognized refund liability in the financial statements?	An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 53 only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved (para 56 of IndAS 115). Para 57 of IndAS 115 gives list of factors that could increase the likelihood or the magnitude of a revenue reversal include. Significant Management judgement involved - auditor to ensure compliance with SA 540.

Pharma sector – Key Accounting and Auditing issues

Revenue recognition for sales to customers with a history of long delays in payment:

Scenario	Guidance
A pharmaceutical sell products to hospitals / institutional customers. The Company has historically experienced long delays in payment but it continues to sell products to these customers at its normal market price. How should company recognized revenue to such customers?	Revenue should be recognized only when it is probable that the entity will collect the consideration to which it is entitled. Slow payment does not, on its own, preclude revenue recognition. However, it might affect the amount of revenue that can be recognized. This is because the receivable will be discounted at initial recognition if there is a significant financing component. If the entity concludes that it will receive an amount which is less than the invoiced amount (by giving price concessions) , it has to evaluate whether it granted an implicit price concession or whether the receivable is impaired. Auditor to obtain 'sufficient' and 'appropriate' audit evidence – SA 500.

Pharma sector – Key Accounting and Auditing issues

Compliance with Laws and Regulations (SA 250):

Scenario	Guidance
Compliance with requirement of Drug Price Control Order (DPCO) / National List of Essential Medicines (NLEM)	Responsibilities of the Management and those charged with governance Responsibilities of Auditor

Pharma sector – Key Accounting and Auditing issues

Impact of Covid-19 on Pharmaceutical companies:

- **Going concern assessment**
- **Impairment assessment of tangible and intangible assets**
- **Inventory Count**
- **Authenticity of audit evidence (original documents)**
- **Reporting Considerations**
- **Disclosures in the financial statements**

Questions & Answers

Thank you

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