Financial Reporting & Ind AS Issues in Pharmaceutical Sector

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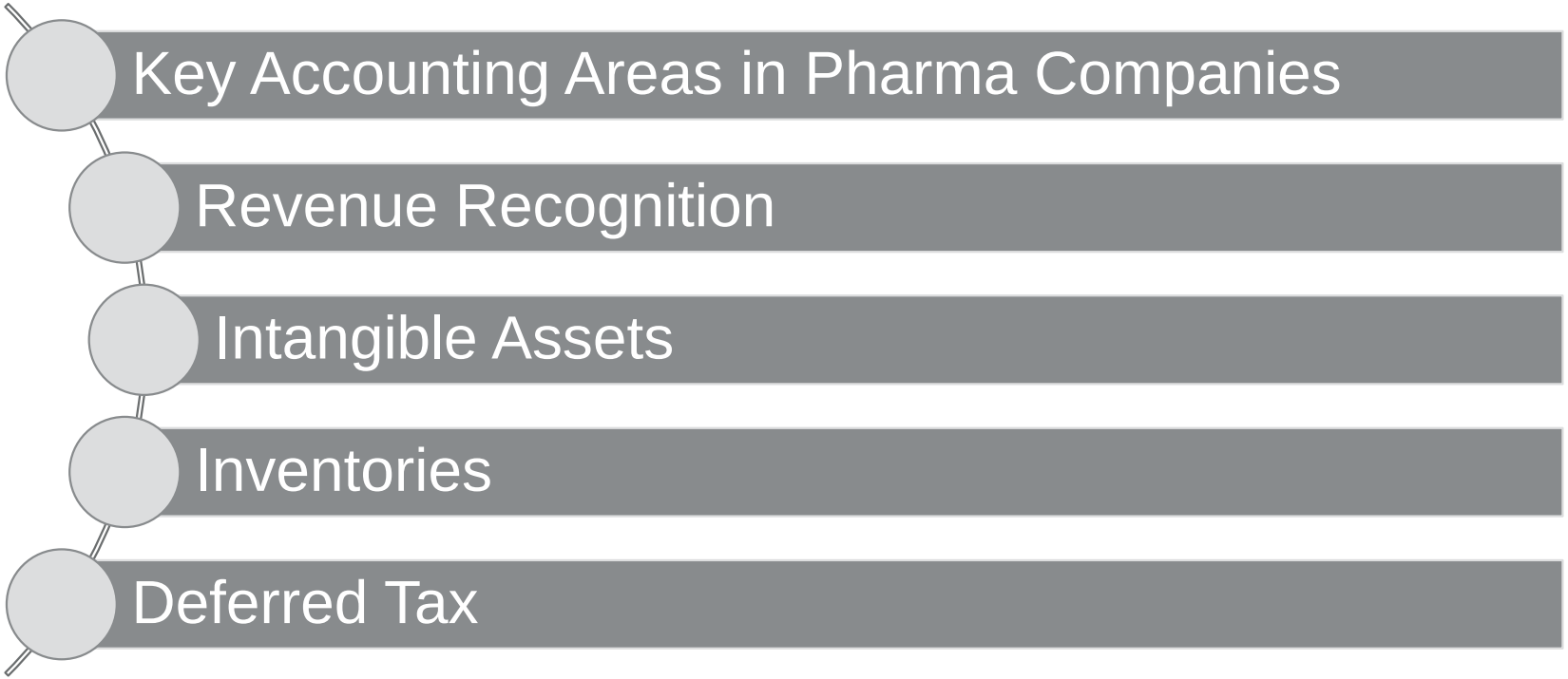
Content


Key Accounting Areas in Pharma Companies
Revenue Recognition
Intangible Assets
Inventories
Deferred Tax

Key Accounting Issues in Pharma Companies in India

Whether Reported as Key Audit Matters by Auditor in FY19?	Lupin	Aurobindo	Sun Pharma	GSK Pharma	Cipla	Torrent	Glenmark	DRL	Biocon	Divi's Lab	Novartis	Abbott	Alkem	Ipca Lab
Revenue Recognition														
Licensing & collaborative arrangements	✓								✓					
Customer rebate, returns, allowances, etc	✓	✓			✓	✓	✓	✓				✓	✓	
Point of sales recognition								✓			✓			✓
Capitalisation of In-process R&D cost		✓												
Provision towards litigations & claims	✓	✓	✓	✓	✓			✓						
Impairment of Intangible assets incl. Goodwill	✓	✓			✓	✓	✓	✓					✓	
Income Taxes														
Uncertain tax positions	✓		✓	✓					✓					
Recognition of Def Tax Assets						✓	✓						✓	
Business combinations & mergers		✓	✓											
Other Matters			✓							✓				✓

Key Accounting Issues: Revenue

Revenue Recognition under Ind AS 115

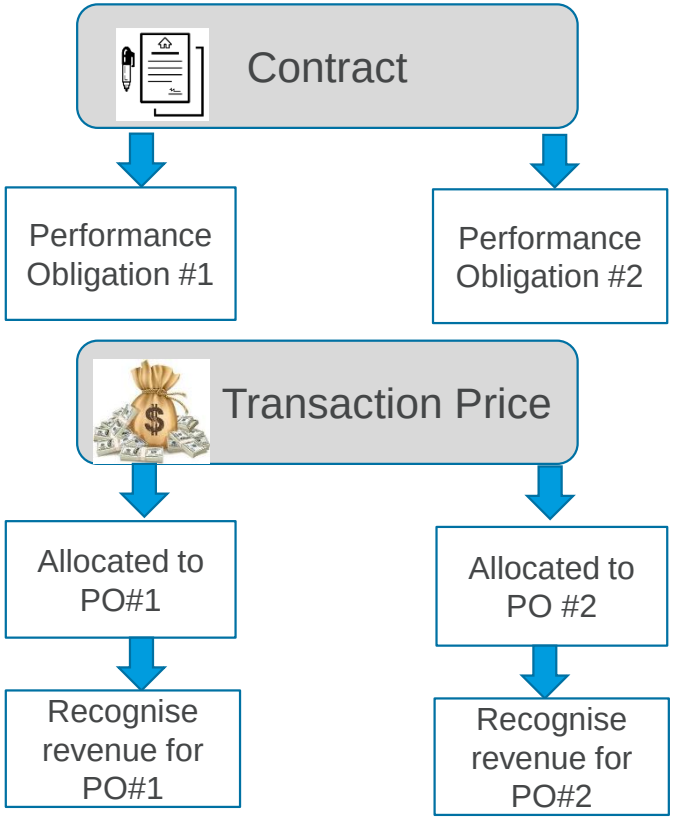
Step 1
- Identify the contract(s) with a customer (written, verbal or implied)

Step 2
- Identify the performance obligations in the contract

Step 3
- Determine the transaction price

Step 4
- Allocate the transaction price to the performance obligations in the contract

Step 5
- Recognise revenue when performance obligation is satisfied



Revenue –Deferral of revenue - Examples

Company	Impact in financial results (Rs. Crores)
Cipla	*Deferment of revenue recognition on customer contracts 9.90 (YE March 2016), 1.5 (QE June 2016)*
Biocon	*Difference on account of revenue recognition net of related costs* 23 (YE March 2016)
GSK Pharma	Provision for expected sales returns 30.95 (YE March 2016)
Lupin	Revenue recognition – linked arrangements,, measurement of revenue, etc. 159.6 (YE March 2016)

Revenue: Key impact areas for Pharma Companies

- Licensing/ Collaborative arrangements
- Accounting for Sales Returns Provision
- Accounting for Customer Rebates/ Incentives
- Timing of recognition of revenue can be different that that under Indian GAAP (for example, dispatch vs. delivery)
- Accounting for Contract Manufacturing (Tolling arrangements)

Illustrative Example: Point of Sales Recognition

- **Dr. Reddy's Lab** Limited (Extracts from Annual Financial Statements FY 2018-19)

Presented below are the points of recognition of revenue with respect to the Company's sale of goods:

Particulars	Point of recognition of revenue
Sales of generic products in India	Upon delivery of products to distributors by clearing and forwarding agents of the Company. Control over the generic products is transferred by the Company when the goods are delivered to distributors from clearing and forwarding agents.
Sales of active pharmaceutical ingredients and intermediates in India	Upon delivery of products to customers (generally formulation manufacturers), from the factories of the Company.
Export sales and other sales outside of India	Upon delivery of the products to the customers unless the terms of the applicable contract provide for specific revenue generating activities to be completed, in which case revenue is recognised once all such activities are completed.

Example 1: Revenue from Contract for Development Services

- Alpha, a small pharmaceutical company, contracts with a much larger pharmaceutical company, BetaX, to develop a new medical treatment for migraine over a five-year period.
- Alpha is engaged only to provide development services, and it will periodically have to update BetaX with the results of its work.
- BetaX owns the underlying product IP, and it has exclusive rights over the development results. Beta X owns Alpha's work-in-progress at all points in the contract.
- BetaX will make 20 equal quarterly non-refundable payments of US$250,000 (totalling $5 million). Payments do not depend on the achievement of a particular outcome, but Alpha is required to demonstrate compliance with the development programme. Alpha's management estimates that the total cost will be $4 million.
- Alpha has completed many similar contracts, and it has a track record of reliably estimating costs to complete. Alpha incurs costs of $400,000 in the first quarter of year 1, in line with its original estimate. Alpha is in compliance with the research agreement, including the provision of updates from the results of its work.
- *How should Alpha recognise the payments that it receives from BetaX to conduct development?*

Solution 1: Revenue from Contract for Development Services

- Revenue is recognised over time if any of the following criteria is met: 1) the customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs; 2) **the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced;** or 3) the entity's performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date. [Ind AS 115 para 35].
- Revenue should be recognised, for a performance obligation satisfied over time, only if the entity can reasonably measure its progress towards complete satisfaction of the performance obligation (this requires reliable information). [Ind AS 115 para 44].
- Alpha identifies that it has promised to supply development services to BetaX. Alpha concludes that the control of development services is transferred over time. This is because BetaX controls an asset (that is, the work-in-progress) at any stage during the contract. Alpha is enhancing that asset through its development services.
- Alpha determines that an appropriate measure of progress is an input method, based on an estimate of total costs. Alpha can reasonably measure its progress towards completion. Alpha recognises revenue of $ 500,000, costs of $ 400,000 and profit of $100,000 for the first quarter. The unbilled $ 250,000 of revenue should be recognised as a contract asset on Alpha's balance sheet.

Example 2: Development services with up-front and contingent payments

- CareB has appointed Devox to develop an existing compound on its behalf. Devox will have no further involvement in the compound after regulatory approval.
- CareB will retain full ownership of the compound (including intellectual rights) at all stages during the development contract and after regulatory approval is obtained.
- Devox will not participate in any further marketing or production arrangements. A milestone plan is included in the contract. CareB agrees to make the following non-refundable payments to Devox:

  a. $3 million on signing of the agreement;

  b. $1 million upon successful completion of Phase III clinical trial approval; and

  c. $2 million on securing regulatory approval.
- Devox expects to incur costs totalling $3 million up to the point of securing regulatory approval. Devox management has concluded that it is not probable that the compound will obtain Phase III clinical trial approval or regulatory approval.

How should Devox recognise revenue for this contract?

Solution 2: Development services with up-front and contingent payments

- Management has reviewed the contract and concluded that it has contracted to supply development services, which is a single performance obligation, the control of which is transferred over time.
- The consideration that Devox receives includes a fixed amount (the up-front payment) and two contingent amounts (dependent on clinical trial and regulatory approval). The contingent amounts are variable consideration. Devox uses the most likely outcome to estimate variable consideration and concludes that the most likely amount is zero. Therefore, it is unlikely that Devox can include these amounts in the transaction price until the contingencies are resolved.
- The nature of the contingencies are such that the resolution is outside Devox's control and thus, in most cases, it would not be possible for Devox to conclude that no reversal is highly probable.
- The up-front payment is initially deferred. This amount has been received, but Devox has not transferred any goods or services to the customer.
- Revenue for the services provided is recognised using an appropriate measure of progress; that is, the percentage of completion at the reporting date is applied to the total transaction price at that date (including the fixed up-front fee and any element of variable consideration that is no longer constrained). At the end of each reporting period, the company would re-assess its estimate of the variable consideration that is no longer constrained. For example, if it is highly probable that the milestone payments will be received, these amounts are included in the transaction price. This could result in a cumulative catch-up of revenue for the performance to date.

Illustrative Examples: Development services with Up-front and Contingent Payments

- **Dr. Reddy's Lab** Limited (Extracts from Annual Financial Statements FY 2018-19)

Out-licensing agreement with CHD Biosciences Inc.:

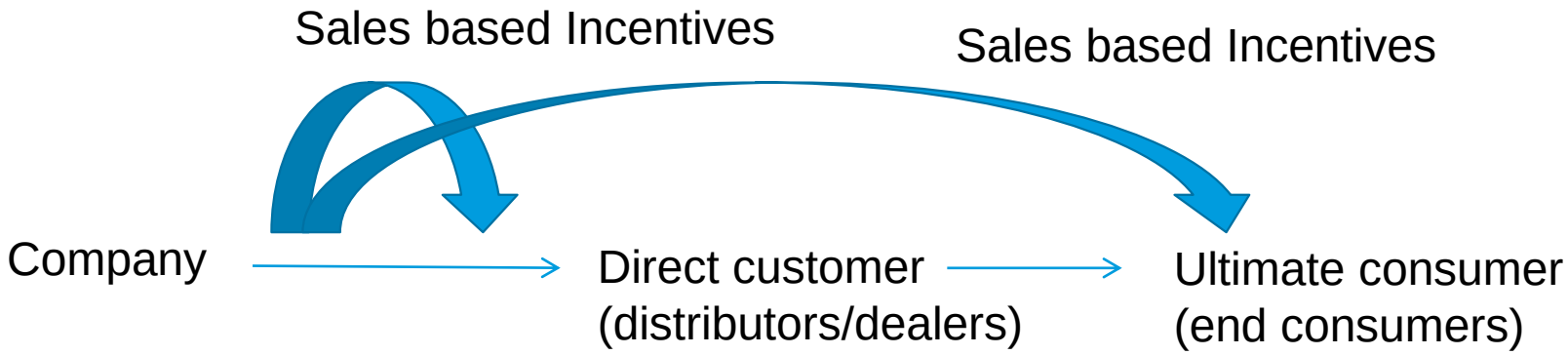
In July 2017, the Company entered into an agreement with CHD Biosciences Inc for out-licensing the Phase III clinical trial candidate, DFA-02. As part of the agreement, the Company is entitled to receive equity shares in CHD valued at US$ 30 million upon an initial public offering of CHD or, if no initial public offering occurs within 18 months of execution of the agreement, a cash payment of US$ 30 million.

The Company will also receive additional milestone payments of US$ 40 million upon U.S. FDA approval. In addition, the Company is entitled to royalties on sales and certain other commercial milestone payments with respect to the product. At the time of execution, as the arrangement did not meet all of the revenue recognition criteria, no revenue has been recognised for the transaction during the year ended 31 March 2018.

- **Glenmark Pharma** Limited (Extracts from Annual Financial Statements FY 2018-19)

Company enters into development and marketing collaborations and out-licences of the Company's compounds or products to other parties. These contracts give rise to fixed and variable consideration from upfront payments, development milestones, sales-based milestones and royalties. Income dependent on the achievement of a development milestone is recognised when it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur, which is usually when the related event occurs. Sales-based milestone income is recognised when it is highly probable that the sales threshold will be reached.

Customer Incentives



Indian GAAP	Reduced from revenue	Sales promotion cost
Ind AS	Reduced from revenue	***Reduced from revenue***

Example 3: Rebates on Volume Purchases

- Alpha has a multi-year contract with Delta to sell pharmaceutical drugs, and it agrees to pay Delta an annual rebate if Delta completes a specified cumulative level of purchases during any year of the contract period.
- The contract specifies that the amount of rebate will vary based on a tiered structure agreed to in the contract as follows (note that the rebate earned is not retroactive to prior purchases):

Purchases	Rebate	Probability
1-1000 units	NIL	15%
1,001-2,000 units	2%	60%
> 2,000 units	5%	25%

- The unit price for each product is Rs.100. Based on historical experience of rebates due to Delta, Alpha has assigned probabilities to each possible outcome.

How should Alpha account for the rebate expected to be paid to the customer at the end of the year?

Solution 3: Rebates on Volume Purchases

- Alpha determines that the ‘expected value’ method best predicts the amount of consideration to which it will be entitled. Alpha concludes that it is probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty is resolved.
- Under the expected value approach, Alpha estimates the rebate to be 2.45% ((0% rebate x 15% likelihood) + (2% rebate x 60% likelihood) + (5% rebate x 25% likelihood)), based on a probability-weighted assessment of each possible scenario.
- Therefore, as each unit is shipped during the year, Alpha will recognise a rebate accrual of Rs.2.45 and revenue of Rs.97.55.
- At the end of each reporting period, Alpha should revise the estimate of sales and true up the calculation and rebate that will be due at the end of the arrangement.
- This true-up would include a cumulative adjustment on shipments throughout that reporting period.

Example 4: Revenue from Contract Manufacturing

- Vendor is hired by Customer to manufacture a batch of 100,000 units of a drug with specific package labelling.
- The initial contract term is six months.
- Once bottled and labelled, there are significant practical limitations that preclude Vendor from redirecting the product to another customer.
- Vendor also has an enforceable right to payment for performance completed to date if the contract is cancelled for any reason other than a breach or non-performance.

- *When and how should Vendor recognise revenue?*

Solution 4: Revenue from Contract Manufacturing

- Revenue is recognised over time if any of the following criteria is met: 1) the customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs; 2) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or 3) **the entity's performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date**. [Ind AS 115 para 35].
- A practical limitation on an entity's ability to direct an asset for another use exists if an entity would incur significant economic losses to direct the asset for another use. A significant economic loss could arise because either the entity would incur significant costs to rework the asset, or it would only be able to sell the asset at a significant loss. For example, an entity might be practically limited from redirecting assets that have design specifications that are unique to a customer or are located in remote areas. [Ind AS 115 para B8]
- Vendor should recognise revenue on transfer of control of the product to the distributor, which in this scenario would be over time as the units are being manufactured.
- Management has concluded that the drug to be manufactured by Vendor has no alternative use to Vendor (that is, the bottled and labelled product imposes a practical limitation that precludes Vendor from redirecting it to another customer).
- A practical limitation on an entity's ability to direct an asset for another use exists if the entity would incur significant economic losses to direct the asset for another use. Vendor has an enforceable right to demand payment if Customer cancels the contract.
- Therefore, Vendor should record revenue over time as the units are being manufactured.

Accounting for Sale with Customer’s Right of Returns

- Pharmaceutical, biotechnology, and certain medical technology entities may sell products with a right of return.
- The right of return often permits customers to return product within a few months prior to and following product expiration. Return rights may also take on various other forms, such as trade-in agreements.
- These rights generally result from the buyer's desire to mitigate the risk related to the products purchased and the seller's desire to promote goodwill with its customers. The sale of goods with a right of return will be accounted for only when the entity concludes it is highly probable that there is not a risk of significant revenue reversal in future periods.
- Pharmaceutical entities usually destroy returned inventory, but certain medical technology entities can resell returned product.
- Transition to Ind AS 115 has resulted the balance sheet being grossed up to include the refund obligation and the asset for the right to the returned goods.
- The asset is required to be assessed for impairment if indicators of impairment exist.

Example 5: **Customers' Right of Returns**

- A Ltd. sells 1,000 product units to a customer for Rs.50 each. Customer has the right to return the product for a full refund for any reason within 180 days of purchase.
- A's cost of each product is Rs.10.
- A estimates, based on the expected value method, that 6% of sales of the video games will be returned and it is highly probable that returns will not be higher than 6%.
- A has no further obligations after transferring control of the products.

How should A Ltd record this transaction?

Solution 5: **Customers' Right of Returns**

- A should recognize revenue of Rs.47,000 (Rs.50 x 940 product units) and cost of sales of Rs.9,400 (Rs.10 x 940 units) when control of the goods transfers to Customer.
- A should also recognize an asset of Rs.600 (Rs.10 x 60 units) for expected returns, and a liability of Rs.3,000 (6% of the sales price) for the refund obligation.
- The return asset will be presented and assessed for impairment separately from the refund liability.
- A will need to assess the return asset for impairment, and adjust the value of the asset if it becomes impaired.

Illustrative Example: Accounting for Sale with Customer's Right of Returns

- **Cipla Ltd.** (Extracts from Annual Financial Statements FY 2018-19)

The Company accounts for sales returns accrual by recording an allowance for sales returns concurrent with the recognition of revenue at the time of a product sale. This allowance is based on the Company's estimate of expected sales returns. The Company deals in various products and operates in various markets. Accordingly, the estimate of sales returns is determined primarily by the Company's historical experience in the markets in which the Company operates. With respect to established products, the Company considers its historical experience of sales returns, levels of inventory in the distribution channel, estimated shelf life, product discontinuances, price changes of competitive products, and the introduction of competitive new products, to the extent each of these factors impact the Company's business and markets.

Illustrative Example: Accounting for Sale with Customer's Right of Returns

- **Dr Reddy's Lab** (Extracts from Annual Financial Statements FY 2018-19)

Revenue from the sale of goods is measured at the transaction price which is the consideration received or receivable, net of returns, taxes and applicable trade discounts and allowances. Revenue includes shipping and handling costs billed to the customer. In arriving at the transaction price, the Company considers the terms of the contract with the customers and its customary business practices. The transaction price is the amount of consideration the Company is entitled to receive in exchange for transferring promised goods or services, excluding amounts collected on behalf of third parties. The amount of consideration varies because of estimated rebates, returns and chargebacks, which are considered to be key estimates. Any amount of variable consideration is recognised as revenue only to the extent that it is highly probable that a significant reversal will not occur. The Company estimates the amount of variable consideration using the expected value method.

Illustrative Example: Accounting for Sale with Customer's Right of Returns

- **Abbott India Ltd.** (Extracts from Audit Report FY 2018-19)

Key audit matter	How our audit addressed the key audit matter
Provision for Non-Saleable returns (as described in Note 24 of the Ind AS financial statements)	
The Company makes sales to stockists who further sells products in the market. Stockists have a right of return in case goods are not sold further during shelf lives of the products. Return of these expired goods, result in deductions to gross amounts invoiced in arriving at revenue and creation of obligations for the Company to give credit for sales returns. The amounts pertaining to such sales return are estimated at the time of sale and deducted from gross sales and recorded as provisions for sales returns. These estimates are based on analysis of historical trends of sales return and shelf life of the products. The management has determined provision for sales returns amounting to ₹ 129,17.77 Lakhs which have been recorded at March 31, 2019 (including reimbursable provision for sales return amounting to ₹ 60,09.65 Lakhs) We focused on this area because establishing an appropriate year-end position requires significant judgement and estimation by the management. The assumptions required for estimating provisions for sales returns are complex in nature, the estimates may not be appropriate and, as a result, provisions and revenue may be incorrectly recorded.	Our audit procedures included, amongst others, • Obtained an understanding of management process for making provision for non-saleable returns including related controls. • Tested the Company's key controls relating to the deductions made to gross sales for sales returns, including those controls over booking of sales and sales return process. • We obtained management's calculations for provisions, recalculated the amounts and validated the assumptions used by reference to historical sales returns levels and current trends. • We considered the management's estimates in previous years by comparing historical accrued provisions and revenue deductions recorded to the actual amounts. • We tested the working of discounting of non-current provisions for sales return prepared by the management. • We understood and assessed the Company's revenue recognition accounting policies, including the recognition and measurement of deductions to gross sales relating to sales returns and related disclosures.

Key Accounting Issues: Intangible Assets

Intangible Assets: Capitalisation of R&D Costs

Development costs are capitalised as an intangible asset if all of the following criteria are met [Ind AS 38 para 57 and AS 26 para 44]:

a. the **technical feasibility** of completing the asset so that it will be available for use or sale;

b. the **intention to complete** the asset and **use or sell** it;

c. the **ability to use or sell** the asset;

d. the asset will **generate probable future economic benefits** and **demonstrate the existence of a market or the usefulness** of the asset if it is to be used internally;

e. the availability of **adequate technical, financial and other resources** to complete the development and to use or sell it; and

f. the ability to **measure reliably** the expenditure attributable to the intangible asset.

Example 6: Capitalisation of R&D Costs

Arts Pharma markets a drug approved for use as a painkiller.

Recent information shows that the drug might also be effective in the treatment of cancer.

Arts has commenced additional development procedures necessary to gain approval for this indication.

When should management start capitalising the development costs relating to alternative indications?

Solution 6: Capitalisation of R&D Costs

- Arts should begin capitalisation of development costs as soon as the criteria are met. Entities involved in developing new drugs or vaccines usually expense development expenditure before regulatory approval. There is no definitive starting point for capitalising development costs of alternative indications. Management must use its judgement, based on the facts and circumstances of each project.
- Arts must determine whether the existing approval indicates that technical feasibility has been achieved, to assess if capitalisation is required earlier than achieving regulatory approval for the alternative indication.
- Management should consider, amongst other factors:
    - the risks associated with demonstrating effectiveness of the new indication;
    - whether a significantly different dosage might be needed for the other indication (potentially requiring new side effect studies); and
    - whether the new indication will target a different group of patients (for example, children versus adults).
- If these considerations indicate that the uncertainties are comparable to a new drug, and that commercialisation is substantially dependent on regulatory approval, the entity should not begin to capitalise development costs prior to achieving regulatory approval.

Example 7: Capitalisation of development costs for generics

- A pharmaceutical entity is developing a generic version of a painkiller that has been sold in the market by another company for many years.
- The technical feasibility of the asset has already been established, because it is a generic version of a product that has already been approved, and its chemical equivalence has been demonstrated.
- The lawyers advising the entity do not anticipate that any significant difficulties will delay the process of obtaining commercial regulatory approval.
- Assume for the purpose of this example that the other conditions in para 57 of Ind AS 38 and para 44 of AS 26 are satisfied.

Can management capitalise the development costs at this point?

Solution 7: Capitalisation of development costs for generics

- There is no definitive starting point for capitalisation; management should use its judgement, based on the facts and circumstances of each development project.
- Regulatory approval is deemed probable in this scenario, so management can start capitalising internal development costs.
- It might still be appropriate to expense the costs if there are uncertainties about whether the product will be commercially successful.

Illustrative Example: Capitalisation of development costs for generics

- **Aurobindo Pharma** (Extracts from Audit Report FY2018-19)

Capitalisation of in-process development expenditure - The matter relates to the audit of Aurobindo Pharma USA, Inc. (subsidiary of the Holding Company)

Intangible assets under development as at 31 March 2019 includes amounts aggregating to ₹ 2,393.1 million (31 March 2018: ₹ 1,206.1 million) representing the product development cost capitalised by the Group during the year ended 31 March 2019 on its various molecules under development. The Group capitalises qualifying development expenditure on the basis of its products being generic alternatives to already proven and regulator approved, in-market original medical therapies. Where these criteria are not met, the Group expenses its research and development cost.

The capitalisation of development expenditure was considered a key audit matter as development activities are subject to uncertainties and judgmental assumptions as to the probability of scientific success, the timing of regulatory approval processes, as well as the ongoing future market viability of the relevant products from project initiation date to approved product launch date.

Capitalised development costs are amortised once the product is available for use; normally from when regulatory approval is obtained.

In view of the significance of the matter the auditor of Aurobindo Pharma USA, Inc. has reported that the following audit procedures in this area were applied, among others to obtain sufficient appropriate audit evidence:

Tested the mathematical accuracy of the Group's capitalised development expenditure model and evaluated the key assumptions and methodologies used by the Group. Performed the following procedures in respect of the development expenditure capitalised:

- Assessed the nature and appropriateness of the costs incurred that have been assessed by Group as directly attributable to the development activities of the relevant projects, and tested the consistency of the capitalisation approach taken across the portfolio during the year and in previous periods;
- Agreed a sample of costs capitalised and assessed whether these met the capitalization criteria set out in accordance group accounting policies;
- Carried out a series of discussions with the Group's Quality and Product Development heads to understand the status of various products under development and to test the criteria applied by them for capitalisation of the costs incurred for consistency with the group accounting policies;
- In respect of projects that are no longer considered viable, determined whether any carrying amount had been appropriately written off.

Example 8: Capitalisation of development costs for biosimilars

- A pharmaceutical manufacturer is developing a biosimilar product and has submitted its application to the FDA, which included robust analytical studies and data comparing the proposed product to the existing FDA-approved reference product to demonstrate biosimilarity.
- The FDA has reviewed the product's structural and functional characterisations and requested the manufacturer to move forward with comparative Phase I clinical studies.
- Management does not anticipate any significant difficulties with clinical trials.

Should management start capitalising development costs at this point?

Solution 8: Capitalisation of development costs for biosimilars

- No, management should not capitalise additional development expenditure, because the product has not met all of the capitalisation criteria. It cannot demonstrate that it has met the criterion of technical feasibility. The abbreviated pathway for biological products does not mean that a lower approval standard is applied to biosimilar or interchangeable products.
- The manufacturer must still demonstrate that the product is biosimilar to the reference product, and it must complete the requested Phase I, and later Phase III, clinical trials to support approval.
- There is no definitive starting point for the capitalisation of internal development costs. Management must use its judgement, based on the facts and circumstances of each product.
- However, a strong indication that an entity has met all of the above criteria arises when it obtains regulatory approval of the biosimilar product. It is the clearest point at which the technical feasibility of completing the asset is proven, and this is the most difficult criterion to demonstrate.

Example 9: Accounting for marketing expenditure once development criteria are met

- Pharmaceutical entity MagicCure has obtained regulatory approval for a new respiratory drug.
- MagicCure determined that the development criteria were met when it received regulatory approval.
- MagicCure is now incurring expenditure to educate its sales force and perform market research.

Should the management of MagicCure capitalise these costs?

Solution 9: Accounting for marketing expenditure once development criteria are met

- MagicCure should expense sales and marketing expenditure, such as training a sales force or performing market research.
- This type of expenditure does not create, produce or prepare the asset for its intended use.
- Expenditure on training staff, selling and administration should not be capitalised.

Example 10:Accounting for development expenditure once capitalisation criteria are met

- Pharmaceutical entity Delta has determined that it has met the six criteria for capitalisation for a vaccine delivery device.
- It is continuing expenditure on the device to add new functionality.
- The development of this device will require new regulatory approval.

Should the management of Delta capitalise these costs?

Solution

- Delta should not capitalise the expenditure that it incurs to add new functionality, because new functionality will require filing for new regulatory approval.
- This requirement implies that technical feasibility of the modified device has not been achieved.

Key Accounting Issues: Inventory

Example 11:Validation Cost of Inventory

- Delacroix SA scrapped the first validation batch produced by its new plant, because it did not meet pre-determined criteria.
- The subsequent batch met all requirements and was used to successfully validate the plant with the regulatory authorities.

How should Delacroix account for the first validation batch?

Solution

- Delacroix should expense the first validation batch as validation cost.
- This cost should be recognised as a component of R&D expense.

Example 12:Recognition of raw materials as inventory

- Altdorfer Pharma Corp buys bulk materials used for manufacturing a variety of drugs. The material is used for marketed drugs, samples and drugs in development.
- The material is warehoused in a common facility, and it is released to production based on orders from the manufacturing and development departments.

How should purchased materials be accounted for when their ultimate use is not known?

Solution

Inventories are assets that are: a. held for sale in the ordinary course of business;

b. in the process of production for such sale; or c. in the form of materials or supplies to be consumed in the production process or in the rendering of services.

Altdorfer should account for raw materials that can be used in the production of marketed drugs as inventory.

The material should be accounted for as a marketing expense at the point at which it is packaged for use as a sample.

The material should be accounted for consistently with the treatment of other R&D expense related to the product, when the material is released to production for use in manufacturing of drugs in development.

Example 13:Prelaunch Inventory produced before regulatory approval

- Van Eyck Ltd has an asthma drug in development. Management has determined that the drug has not yet met the criteria in paragraph 57 of Ind AS 38 to allow capitalisation of development costs.
- Management believes that there is a 40% likelihood that development will succeed and that final regulatory approval will occur in the short term.
- Van Eyck takes the risk of building inventories of the finished product in order to facilitate immediate launch after regulatory approval.
- The inventory has no alternative use.
- The inventory building begins with small production runs prior to final regulatory approval, and it continues after the approval.

What is the carrying amount of pre-launch inventory?

Solution 13:Prelaunch Inventory produced before regulatory approval

- Van Eyck's management does not believe that the asthma drug has achieved technological feasibility prior to final regulatory approval.
- Inventory manufactured prior to this approval is immediately provided for and written down to zero (that is, the probable amount expected to be realised from its sale at the time of production).
- The write-down should be recognised in cost of goods sold or as R&D expense, according to its policy.
- Van Eyck has demonstrated the probability of the technological feasibility of the drug, by obtaining final regulatory approval. It begins to capitalise the inventory costs.
- The provision recognised prior to approval should also be reversed, up to no more than the original cost.
- The reversal should also be recognised through cost of goods sold or as R&D expense, as applicable.

Key Accounting Issues: Deferred Tax

Deferred tax – Key Ind AS impact areas

- Deferred tax on inter-company eliminations in consolidated financial statements of unrealised profits
- Deferred tax based on ‘reasonable certainty’ rather than ‘virtual certainty’

Deferred tax on inter company eliminations- Examples

Company	Impact of intercompany eliminations of unrealised profits	
	Extracts from financial results	**P&L impact (Rs. Crores)**
Cadila	*Deferred tax on Ind AS adjustments and on unrealised profits on intra group transactions*	170 ↑ (H1 2015)
Sun Pharma	*Tax impact on Ind AS adjustments (including on unrealised intragroup profits on inventories)*	155 ↑ (H1 2015)
UPL	*Deferred tax on unrealised profits*	47 ↑ (H1 2015)
Cipla	*Impact on deferred tax*	149 ↑ (H1 2015)

Illustrative Example: Uncertain Tax Position

- **GSK Pharma** (Extracts from Audit Report FY 2018-19)

Uncertain tax positions	Principal audit procedures performed:
The Company operates in a complex tax environment and is subject to a range of tax risks during the normal course of business. The arrangements for multi-national transactions entered into by the Company are complex, judgmental and subject to challenge by the Tax Authorities. Further, the allowability of certain expenses and admission of additional supporting documents by the Company is also a matter of ongoing dispute with the authorities. **Refer notes 40A(ii)(a) and 40A(iii) to the standalone financial statements**	• We evaluated and tested the design and operating effectiveness of the Company's controls over provisions for uncertain tax positions to ensure that they operate effectively. • With the assistance of our tax specialists, we evaluated management's judgements in respect of estimates of tax exposures and contingencies in order to assess the adequacy of the Company's tax provisions. • In understanding and evaluating management's judgements, we considered the status of recent and current tax authority audits and enquiries, judgmental positions taken in tax returns and current year estimates and developments in the tax environment.

Illustrative Example: Uncertain Tax Position

- **Lupin** (Extracts from Audit Report FY 2018-19)

4. Uncertain tax positions: (UTPs)

The Group operates in numerous tax jurisdictions with various tax exemptions available across regions which are subject to periodic challenges by local tax authorities leading to protracted litigations. There are a number of open tax and transfer pricing matters under litigation with tax authorities over a number of years and tax exposures with overseas tax authorities giving risk to uncertain tax provisions.

The range of possible outcomes for provisions and contingencies can be wide and management is required to make certain judgement in respect of estimates of tax exposures and contingencies in order to assess the adequacy of tax provision.

The group also carries deferred tax assets aggregating to ₹ 7,340.0 million arising from temporary differences in various jurisdictions. These assets are tested for realisability based on projections of taxable profits prepared by management. These projections involves judgement with respect to growth rates, new product launches and cost escalations.

Provision for current tax, valuation of UTPs and recognition of deferred assets/liabilities have been identified as a key audit matter due to the inherent level of complexity in the underlying tax laws and the extent of management judgement involved in developing these estimates. These matters are disclosed in note 46 to the consolidated financial statements. Refer note 1A(k) in significant accounting policies.

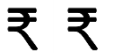
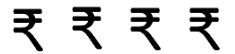
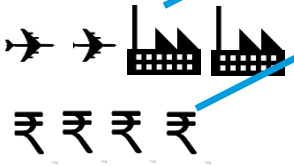
Total tax related liabilities carried in the books aggregate to ₹ 2,882.8 (Deferred tax liabilities) and ₹ 442.1 (Current tax liabilities).

With the support of tax specialists, we assessed the appropriateness of the provisions for UTPs and carrying value of deferred tax assets by performing the following audit procedures;

- Testing the design and operating effectiveness of the Group's controls over provisions for current tax, deferred tax and uncertain tax positions;
- Assessing and challenging the completeness of UTPs in conjunction with our internal tax specialists by considering changes to business and tax legislation in key jurisdictions by having discussions with management and review of correspondence with authorities where relevant;
- Assessing and challenging the calculation for current tax provisions and the procedures performed to analyse movements including the rationale for any release, increase or continued provision in the year;
- Assessing and challenging management's judgements regarding the recoverability of temporary differences pertaining to deferred tax balances by obtaining and critically examining the forecasts and demonstrating the expected utilization of key temporary differences in order to assess their recoverability;
- Assessing and challenging management's judgments with respect to probability of outflow arising out of litigation after considering the status of recent tax assessments, audits and enquiries, recent judicial pronouncements and judgments in similar matters, developments in the tax environment and outcome of past litigations. We focused our work on the jurisdictions with greatest potential exposure involving higher level of judgements;
- Involving transfer pricing specialists to review the transfer pricing methodology of the group and associated approach to provisioning; and
- Evaluating adequacy of disclosures given in Note 46 to consolidated financial statements.

Key Accounting Issues: Leases

ICAI Exposure Draft: Ind AS 116 *Leases*

	Current Ind AS 17		Proposed Ind AS 116
	Finance leases	**Operating leases**	**All leases**
Assets		-	
Liabilities		-	
Off-balance sheet disclosures	-		-

- Exemptions for short-term leases (i.e. leases < 12 months) and low value assets
- Effective for Financial year ending 2019-20 onwards

Ind AS 116 *Leases:* Impact on Profit and Loss

	Current Ind AS 17		Ind AS 116
	Finance leases	**Operating leases**	**All leases**
Revenue	**X**	**X**	**X**
Operating Expenses (excluding depreciation and interest cost)	--	Single Expense	
EBITDA		- -	
Depreciation	Depreciation	- -	Depreciation
Operating profit			
Interest Cost	Interest	- -	Interest
Profit before tax			No impact

Thank You!