E-Book

Indian Accounting Standards And Pharmaceutical Industry

The Institute of Chartered Accountants of India

(Set up by an Act of Parliament)

Southern India Regional Council

Chennai

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First Edition : December 2021

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Published by : Southern India Regional Council
The Institute of Chartered Accountants of India
ICAI Bhawan
122, Mahatma Gandhi Road
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FOREWORD

Every accounting function has its own independent features, methodologies and significance. Chartered Accountants having been exposed to all areas of accounting principles and procedures play an important role while offering their expert professional services to any sector they associate.

One such sector where the Chartered Accountants make an imprint is the pharmaceutical sector which is a specialized area that requires expertise and an understanding of the sector. This e-book serves as a reference where the reader can access a wide range of aspects that govern the audit of transactions in the pharmaceutical industry and understand the nuances involved in this field of activity.

SIRC is pleased to present an e-book on Indian Accounting Standards and Pharmaceutical Industry giving in a concise and candid manner would enlighten, sharpen and enhance the level of the knowledge of the readers in the ambit of pharmaceutical industry from the point of view of various concepts envisaged and in tune with the Indian Accounting Standards with reference to pharmaceutical sector and accordingly comply the requirements of the regulators and the stakeholders.

The author had made a sincere attempt to express his views to educate the readers with inputs on the relevant issues which are faced in the pharmaceutical industry with relevant examples and references to provisions / interpretations for easy and better understanding.

This e-book, yet another publication in the series of member-centric publications brought out by SIRC, aims to serve as a Handbook and Guide for the professionals who intend to look into the general issues in the accounting and reporting areas connected with the pharmaceutical industry and understand how the same could be interpreted considering the Indian Accounting Standards with specific references to US Generally Accepted Accounting Principles (GAAP).

On behalf of SIRC and on my own behalf I place on record our sincere and grateful thanks and appreciation to CA. G V Naga Durga Sudhakar for sparing his precious time to share with our elite professional fraternity his insightful thoughts and invaluable experience on the Indian Accounting Standards vis-à-vis the pharmaceutical industry. I also take the privilege of expressing our grateful thanks to CA. Gangesh K Shrinivas for reviewing the basic draft of this e-book and for adding immense value to the substance of the e-book.

In a publication meant for professional accountants like this there is also a scope for improvement of contents, presentation and coverage. Accordingly comments and suggestions on the e-book are welcome at sirc@icai.in

CA.K.JALAPATHI
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CONTENT

Capitalization of development costs – A question

The first thing that comes into the listener's mind when one talks about pharmaceutical industry is – development costs.

As per the April 2021 "Research and development in Pharmaceutical industry" report issued by Congressional Budget Office:

- In 2019, the pharmaceutical industry spent $83 billion dollars on R&D. Adjusted for inflation, that amount is about 10 times what the industry spent per year in the 1980s.
- Also, the expected cost to develop a new drug—including capital costs and expenditures on drugs that fail to reach the market—has been estimated to range from less than $1 billion to more than $2 billion.

With this backdrop, for an accounting mind, the immediate question that comes is – What happens to these development costs? While the answer is seemingly simple and straight, it definitely requires some discussion and deliberation.

As far as research costs are concerned, Paragraph 54 of Ind AS 38 very clearly specifies that expenditure on research (or on the research phase of the internal project) shall be recognized as an expense when it is incurred.

When it comes to development costs, the position of the standard is little different. While it does not directly require an entity to charge off all the development costs, it lays down conditions (under paragraph 57) that must be satisfied, if an intangible assetwere to be recognized in the books. In other words, Standard gives us conditions for capitalization of development costs

Of all the conditions specified in paragraph 57, it is the demonstration of technical feasibility (first condition) that assumes greater importance - The technical feasibility of completing the intangible asset so that it will be available for use or sale. The recognition criterion of technical feasibility is very subjective and relies also on management's intent.

What is technical feasibility?

The word is neither defined nor interpreted by the accounting standard. In the absence of such explanation, if one were to take a colloquial meaning of the word, it simply means - *proving that the concept is technically possible*. In other words, the objective of technical feasibility is to ensure that the product will perform and that there would not be any production barriers.

Let us take an example – A pharmaceutical Company is developing the product for commercialization in the United States. So, it has to go through all the rigor of meeting the regulatory requirements of the US FDA and obtain its approval to launch and sell the product in the US.

In such circumstances, if one were to interpret the word technical feasibility, when do we say that the product will perform? When can an entity say there will not be any production barriers? The uniqueness of the pharmaceutical industry that

distinguishes it from most of the other industries is the regulatory oversight. With this novelty, when can a pharmaceutical industry demonstrate technical feasibility?

Should this be considered as achieved when once the Company receives approval of the US FDA? Or should this be considered as achieved once the company reached the stage of filing?

Although there is no direct answer, given the stringent regulatory oversight of the US FDA, considering the risks of development, success ratio in the pharmaceutical industry, it appears that for *innovator companies*, substantial portion of the development costs would be recognized in the profit and loss account.

Then what about companies that are into development and marketing of generic drugs?

Although *Generics* are approved copies of small molecule drugs that contain the same amount of active ingredients, dosage form, safety, strength etc., of originally marketed products, most of the times they also require significant amount of time and money to get the approval of the US FDA by establishing bio-equivalence.

So can a generic company capitalize the development costs merely because these are approved copies? Is it easier for the generic drug manufacturers to establish technical feasibility? Is establishing bio-equivalence and achieving the desired results an easy task?

The Accounting Standard is one and the same for innovators and for generic companies. This implies, the requirement of technical feasibility equally applies even tothe generic manufacturers.

Let us look at the numbers and try to understand. One **crude** way to understand the probability is to compare the submissions made and approvals received.

Tabulated below are the details of Abbreviated New Drug Applications made by Indian Pharmaceutical companies and the approvals obtained:

ANDA Submissions to USFDA

Year	Count
FY16	852
FY17	1,306
FY18	1,044
FY19	909
6MFY20	467

ANDA approvals received

Company / Year	FY20	FY19
Alembic	31	15
Alkem	23	21
Aurobindo	16	49
Cipla	35	77
Cadila Healthcare	14	32
DRL	21	20

Glenmark	14	25
Lupin	15	33
Sun Pharma	45	37
Torrent Pharma	3	20
Wockhardt	2	2
Total Approvals	**219**	**331**

(Source: Article from Business Standard published in May 31, 2020)

https://www.business-standard.com/article/companies/fda-new-drug-approval-run-rate-down-in-fy20-for-most-indian-pharma-majors-120053100360_1.html

Even if one were to take an average of 1,000 filings per year and 250 approvals per annum, and consider a reasonable gap of 24 months from the ANDA submission to approval, the success percentage would be around 25%. Although this a crude of wayof evaluating the probability of a success, one cannot definitely undermine the stated fact as one of the arguments against the capitalization.

What do the Big 4 Audit firms say?

We understood in the foregoing paragraphs that the word technical feasibility was neither defined nor interpreted by the Standard setters. Hence, it is pretty common to look up to the interpretation drawn by the Big 4 accounting firms. Although it was notexplicitly mentioned anywhere in their publications, these firms tend to take a conservative stance and oscillate towards believing the position that technical feasibility is not achieved unless the product receives the approval of the regulator.

What am I trying to say? (Concluding remarks):

Although there seems to be a conservative stance taken by the companies and accounting firms, one should definitely take the objective of the accounting standard before taking a position and merely concluding that all the development costs shall be charged off. As a matter of fact, the Standard is not against capitalization. It only gave conditions for capitalization. So definitely there is an argument possible for capitalization provided a clear demonstration is made by the Company.

Just to cite a reference from Global companies, Companies like Celtrion Healthcare and Samsung Biologics do capitalize their development costs for **certain projects** (emphasis supplied). Although these companies are guided by Korean IFRS, the said framework is completely aligned to the IFRS as issued by the IASB. How could these companies do it?

Connect the dots:

Readers are requested to go through the financial statements of these two companies for better clarity.

Project by project or product by product, if the companies (with the help of their scientific teams) can evaluate the technical feasibility by considering the factors such as:

- the stage of the development of the project / product;
- complexity associated with the development;
- Regulatory framework;

- Costs incurred and yet to be incurred till approval;
- Number of years till approval

There seems to be a possibility, however meek, for capitalizing the development costs as an internally generated intangible asset.

Capitalization of development costs – Less regulated markets

In the previous section, the entire analysis revolved around company's effort to develop and launch the product in a highly regulated environment such as the United States.

As it stands today, the United States and the Europe have the toughest drug approval regulations and standards in the world. Before a new drug can be sold, pharmaceutical companies are required to produce large amounts of clinical data demonstrating that products are both safe and effective. In addition, safety and efficacy have to be proven through rigorous, well-controlled clinical trials, investigations that are scientifically demanding and expensive to conduct.

Given such highly regulated framework, we understood that the accounting tends to be little conservative and gives us a little scope for capitalization of development costs.

Now, what about semi regulated or less regulated markets - Africa, Latin American Countries, Association of Southeast Asian Nations (ASEAN) and Commonwealth of Independent States (CIS). Not only these, even countries like Australia and New Zealand tend to accept the data generated for filing in a highly regulated market such as the US and the UK for the purpose of filing in those countries.

(Note: the above list is only illustrative in nature and the Companies are requested to use their judgment in deciding the geographies that fall under this category. This needs to be done after thorough deliberations with the regulatory team and after obtaining a sound understanding of work to be done in the second geography. Say for example, China and Russia – although the regulatory affairs in these countries are not as stringent as those in the US or the UK, these countries require pivotal studies to be carried out using the local RLD (reference listed drug) and on the local population or might require certain tests to be done at the local laboratories. In such circumstances these geographies may not fall under less-regulated markets)

In such circumstances, an opportunity seems exist for the pharmaceutical companies for capitalization of development costs in those geographies.

These countries accept the clinical data that is used for filing with the US FDA and generally do not have a restriction that bio-equivalence needs to be established on the local population. Hence, if a company has successfully obtained and approval for a drug in the United States and planning obtain approval in another geography where the data from the United States filing can be used to establish the bio-equivalence in the second geography, it appears that the company can demonstrate technical feasibility for the second geography and hence capitalize the development costs.

What types of costs can be considered for capitalization?

1) Costs incurred for conduction additional tests, if any;
2) Costs of filing

An excerpt from PWC's issues and solutions in the pharmaceutical industry has beenpresented that supports this view:

Background

A pharmaceutical entity has obtained regulatory approval for a new respiratory drug in one country, Agara. It is now progressing through the additional development procedures and clinical trials necessary to gain approval in another country Belan.

Management believes that achieving regulatory approval in this secondary market is a formality. Mutual recognition treaties and past experience show that Belan's authorities rarely refuse approval for a new drug that has been approved in Agara.

Relevant guidance

Development costs are capitalized as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

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 completethe development and to use or sell it; and
f. The ability to measure reliably the expenditure attributable to the intangible asset.

Can the development costs be capitalized?

Solution

The company can capitalize any additional development costs if it judges that the development criteria have been met. The company has judged that registration is highly probable, and there are likely to be low barriers to obtaining regulatory approval, so it is likely to be technically feasible.

New launch inventory – Is it an asset??

We understood from the previous two sections that the path for product development and manufacturing in the life sciences industry is not that easy.

Consequent to the inherent complexities relating to product development, a pharmaceutical company typically starts producing a product before the product launch date so that sufficient quantities are available to meet the anticipated demand.

In other words, the stocks are accumulated or piled up even before the product receives an approval from the regulatory authority. Consider the following three scenarios where filings have been made by a pharmaceutical company for three different types of products with the US FDA:

Branded product	An NDA (New Drug Application) has been filed by the Company to the FDA for review
Generic product	An ANDA (Abbreviated New Drug Application) has been submitted to and accepted by the US FDA for review
Medical device	A 510(K) premarket approval application has been filed with the US FDA

Also consider that the Company has incurred significant costs to manufacture the product in advance of the US FDA's approval. In such circumstances, a question arises – whether the pre-launch inventory should be capitalized or expensed as incurred? To qualify for capitalization as an inventory, an item must first satisfy thecriteria of asset.

Let us evaluate the scenario from an accounting point of view:Firstly,

let us understand what an *asset* is.

Paragraphs 4.3 and 4.4 of the Conceptual Framework for Financial Reporting under Ind AS explain the word ***asset*** as under:

4.3 An asset is a present economic resource controlled by the entity as a result of past events;

4.4 An economic resource is a right that has the potential to produce economic benefits.

Combining the above two paragraphs, one can decipher that the word asset should have the following characteristics:

a) Right - the transaction or other event giving rise to the entity's right to or control of the benefit;
b) Potential to produce economic benefits - it embodies a probable future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows; and
c) Control - a particular entity can obtain the benefit and control others' access to it.

Having understood what an asset is and the characteristics of an asset, can we say that the pre-launch inventory accumulated by a pharmaceutical company, an asset?

Yes or No, whatever may be the answer, it is definitely not straight forward and isundoubtedly debatable.

Let me present an excerpt from the financial statements of one of the innovator

14. Inventories

(USD millions)	2020	2019
Raw material, consumables	967	751
Work in progress	3 324	3 024
Finished products	2 840	2 207
Total inventories	**7 131**	5 982

The following table shows the amount of inventory recognized as an expense in "Cost of goods sold" in the consolidated income statements from continuing operations:

(USD billions)	2020	2019	2018
Cost of goods sold	– 8.5	– 8.5	– 8.3

The following table shows the recognized amount of inventory provision and reversals of inventory provision recorded in the consolidated income statements from continuing operations:

(USD millions)	2020	2019	2018
Inventory provisions	– 702	– 752	– 603
Reversals of inventory provisions	255	218	216

The reversals mainly result from the release of products initially requiring additional quality control inspections and from the reassessment of inventory values manufactured prior to regulatory approval but for which approval was subsequently received.

*Novartis prepares and presents financial statements under IFRS as issued by IASB. As Ind AS is more closely aligned with IFRS, considered this example for our analysis.

From the above presentation, especially the note highlighted in red circle, we can understand that Novartis **charges off** the entire inventory accumulated for launch before the approval and reinstates back in to the balance sheet once the product receives the approval – Appears conservative but a very strong and bold stance, right!!

Frankly, in my personal view, the method adopted by Novartis is a thorough application of accounting standards.

Connect the dots:

Then how should companies approach this situation? In my view, Pharmaceutical companies need to maintain proper and sound documentation with respect to the new launch inventories by considering the following aspects especially while establishing probable economic benefits:

- The entity's prior history with approvals of similar products.
- The estimated timing of obtaining regulatory approval.
- Threatened or anticipated litigation challenges (e.g., patent infringement lawsuits).
- FDA correspondence (or other appropriate regulatory agencies) regarding the safety and efficacy of the product.
- Current market factors, including the competitive landscape and pricing.

Basis the above analysis, if the Company deems capitalization is possible, it can do so by maintaining such thorough documentation and by evaluating the position regularly.

(Refer 2021 Life Sciences Guide published by Deloitte for further reference. Although the said document is under US GAAP, it definitely provides sufficient guidance and perspectives)

Funding for research and development (R&D Financing)

One of the most sought-after topics in the recent times in pharmaceutical industry is to obtain the financing for research and development. What does it mean by obtaining finance for research and development? Is it that difficult?

In the previous sections, we have understood that most of the pharmaceutical companies are R&D intensive and the impact of the same is very significant. There are a few pharmaceutical companies who will spend an average of 15-17% of its revenues as research and development and substantial portion of such cost ends up in profit and loss account.

From the very nature of R&D expenses, if one were to put it crudely, it could be termed as a "bet" taken by the company as the outcome of the same is uncertain.

With this backdrop, one of the most sought-after asks by the pharmaceutical companies is – How can I get an investor who can invest in my R&D project by sharingthe risk of development so that I can minimize the burden **on profit and loss account**(emphasis supplied)?

As the need for new ways of capital in pharmaceutical industry increasing, companies are exploring innovative funding arrangements with variety of terms and conditions. They plan to enter into arrangements with passive investors who often provide funding for R&D Programmes in exchange for various success based milestones. Typically in these arrangements, the investor does not receive any repayment if the whole program or the product is unsuccessful.

From a logic standpoint, it appears reasonable that if there is an investor who is willing to take part in the R&D activity of a product, say by 50%, there shall be a reduction in the company's R&D costs by 50%.

Let us examine whether the so called reasonable and logical stance is also endorsed by the Accounting Standards. Do accounting standards also oscillate towards reduction in R&D costs? Let us try to find an answer.

To understand the concept better, consider the following simple example scenario:

Company C is a pharmaceutical company which is currently developing a product P. As development of P is a cost intensive project, C approached Bank B and agreed for the following terms:

1) The total development cost (yet to be incurred) is Rs.200 crore;
2) The remaining development period is 3 years;
3) Bank B will pay Rs. 100 crore and will take part in 50% of the results;
4) If the development is a failure (no approval is received from regulatory authorities), nothing is required to be paid by the company to bank;
5) If the development is successful (approval is received for commercialization), Rs. 150 crore shall be paid by the Company to B.

<u>Accounting analysis:</u>

A plain reading alludes us to believe that Rs. 100 crore received from B is *contingently* payable (because it is payable only after the successful development, the outcome of which is not under the control of either party) and hence immediately draws our attention to *Ind AS 37, Provisions, contingent liabilities and contingent assets.*

Paragraph 27 of Ind AS 37 states that contingent liability shall not be recognized in the books of account.

Also, paragraph 53 of Ind AS 37 states that if there is a reimbursement right available, such reimbursement right shall be recognized only if it is virtually certain that such reimbursement would be received.

In the example considered, because B agreed to reimburse 50% of the total development costs, it is virtually certain that as and when C incurs the cost, 50% of thesame is virtually certain to be recovered.

With these two paragraphs, it **APPEARS** that the ask of the company is easily met.

Is it so? Are we referring to the right accounting standard? Is it Ind AS 37 that shouldbe referred to or is there any other accounting standard that shall be referred to here?

Paragraph 2 of Ind AS 37 states that the standard does not apply to financial instruments.

So, our first responsibility is to see whether the transaction with B is covered by Standards that cover financial instruments – Ind AS 32 and Ind AS 109.

Being a lending arrangement, the agreement between C and B is a financial instrument. So, the most appropriate accounting standards that need to be applied here are Ind AS 32 and Ind AS 109.

Let us understand what does Ind AS 32 has to offer in this regard.

I am presenting some of the paragraphs from Ind AS 32, so that the scenario on hand can be better analyzed.

Paragraph 19 of Ind AS 32 states that - *If an entity* ***does not have an unconditional right to avoid delivering cash*** *or another financial asset to settle a contractual obligation, the obligation meets the definition of a financial liability.*

Paragraph 25 of Ind AS 32 states that - *A financial instrument may require the entity to deliver cash or another financial asset, or otherwise to settle it in such a way that it would be a financial liability, in the event of the occurrence or non-occurrence of uncertainfuture events (or on the outcome of uncertain circumstances) that are beyond the control of both the issuer and the holder of the instrument, such as a change in a stock market index, consumer price index, interest rate or taxation requirements, or the issuer's future revenues, net income or debt-to-equity ratio.*

The issuer of such an instrument does not have the unconditional right to avoid deliveringcash or another financial asset (or otherwise to settle it in such a way that it would be a financial liability).

A combined reading of both the paragraphs gives us the following inputs:

- Company C does not have an **unconditional** right to avoid payment. The right to avoid payment is only conditional. In other words, only if the development fails, the payment can be avoided by C.
- Also the arrangement has contingent settlement provisions. The amount received by C is contingently payable.

Accordingly, the money received from B is not a reimbursement right but rather a financial liability.

The following are the sequence of journal entries

When the money is received from B:

Bank account Debit Rs. 100 crore
Loan from B Credit Rs. 100 crore

(Position remains the same even if the money is received progressively throughout the development period)

At the end of years 1 and 2:

Depending on the stage of development, evaluate the position. If the outcome is still uncertain continue to present the liability in the books.

During the year 3:

Let us assume that during the middle of third year, regulator accepted the company's filing and the company believes that it is highly probable that the approvalwould be obtained by the end of year 3.

Recognize the share of borrowing cost in the period in which such an assessment was made. What is this borrowing cost – Nothing but interest cost which is the difference between Rs. 150 crore and Rs. 100 crore. In other word, cost for sharing the R&D risk with B is Rs. 50 crore over 3 years.

Interest cost account Debit Rs. 50 croreTo
Loan account Credit Rs. 50 crore

With this, by end of year 3, the liability account will become Rs. 150 crore and will be settled by the company by paying such sum to B.

What if the development is a failure?

Continue presenting the money received as a financial liability and when it is formally agreed by the parties (B and C) that the development of P will be discontinued as the probability of obtaining the approval is less likely, on the day such agreement is entered into by both the parties, such arrangement triggers DE recognition of financial liability under Ind AS 109.

Consequently, when B absolves C from paying the Rs.100 crore amount, the following shall be the entry:

Loan account Debit Rs. 100 crore
To Other income Rs. 100 crore

(Including the amount of interest, if any, recognized in the books)

How to understand the whole scenario from an accounting point of view?

If we keenly look at the whole accounting above, although the company could successfully share the risk of development with B from an *economics* point of view or from a *cash flow* point of view, somehow *accounting* does not seem to go alongside *economics* here.

Accounting appears to take a conservative stance and requires the entity to continue to present the amount received as a liability unless it is clearly established that it is not payable under any circumstances.

Let us tweak the given example and understand if that would make any difference?

Scenario 2:

Same facts of scenario 1 continue except that instead of Rs. 150 crore payment uponapproval, royalty @ 4% is payable to B on the sales of P throughout its life.

Analysis:

The position remains the same. Paragraph 25 fits in here and the royalty payable tantamount contingently payable position and hence, financial liability

Scenario 3:

Would it make any difference if the whole arrangement is carved out in a separate entity? Let us assume that Company A is incorporated wherein Company C and Bank B will subscribe to the nominal share capital (Say Rs. 1 lakh each) and the cost of development of Rs. 200 crore is invested as under:

Rs. 100 crore by C as share capital;

Rs. 100 crore by B as loan Analysis:

First, evaluate the transaction under Ind AS 110. Which entity will consolidate entity? A? Going by the guidance of special purpose entities, it is all the more likely that Company C would consolidate entity A. Once consolidated by C, the situation is similar to scenario 1. For consolidated financial statements, the position remains thesame whether the loan is taken by subsidiary company or by the holding company.
Hence, even under this scenario, it would end up as a financial liability.

Scenario 4:

Same facts as Scenario 3, except as under:

The cost of development of Rs. 200 crore is invested as under:

Rs. 100 crore by C as share capital;

Rs. 100 crore by B as **share capital**

Analysis:

First, evaluate the transaction under Ind AS 110. Which entity will consolidate entity A? Going by the guidance of special purpose entities, it is all the more likely that Company C would consolidate entity A.

Now, in this scenario the money is contributed by B as subscription to share capital. In such circumstances does B become an NCI? This depends on how the repayment would happen to B? If it is bullet payment of Rs. 150 crore by way of redemption of Shares of B, it has greater possibility of being classified as a liability rather than an NCI shareholder. (Readers are requested to read the guidance – Put and call options relating to NCI shareholding).

It appears little strange that how come share capital is presented as liability? Honestly, it is not that strange or illogical either. Take for example, accounting for convertible debt. If the terms of the debt instrument are not on par with market, a portion of the liability is presented as equity. Similarly, if the terms equity instrument are not as per the requirements of Ind AS 32 and if they do not meet the equity characteristics, such instrument is presented as a liability eather than as equity

May be this is what is called – substance over form!!!

Then under what circumstances is R&D financing possible (credit to R&D)? Is it possible at all?

In my personal view, and based on my experience, it is possible but in limited circumstances.

Simply put, it is possible when the transaction is brought outside the scope of Ind AS 32 and Ind AS 109. As per the scope paragraph of Ind AS 32, an arrangement that falls under Ind AS 111, Joint arrangements is excluded from Ind AS 32.

So, if the entity can establish a joint venture wherein the said arrangement can be incorporated, there is an argument possible for the R&D credit. Even under this option, there is one significant challenge. It appears that the JV for the said accountingpurpose is possible only with another pharmaceutical partner.

Can't a JV be established with a banker / Venture capital or any other financial investor?

Although there is no direct theoretical answer, the practical position seems to be a little different.

As financial investors such as banks and VCs, although share R&D risk, tend to play a dormant role in decisions relating to product development. Although they come on board with people from pharmaceutical background, definitely their role would not be as authoritative as that of another pharmaceutical company. Just to cite an example - JV between Pfizer and Novartis is viewed differently from JV between Pfizer and Citibank or Novartis and Royalty Pharma.

Also, one of the fundamental traits of a financial investor is "exit" – In line with its business model, generally, a financial investor will try to find a way to exit from the venture once the desired objective is met (i.e., successful product development).

Reference to "***exit strategies***" from Ind AS 110 provides some guidance in this regard. Although it is a guidance for consolidation, it is definitely worth referring here to bring some insight and guidance on the attributes of financial investors.

An entity's investment plans also provide evidence of its business purpose. One feature that differentiates an investment entity from other entities is that an investment entity

Does not plan to hold its investments indefinitely; it holds them for a limited period. Because equity investments and non-financial asset investments have the potential to be held indefinitely, ***an investment entity shall have an exit strategy documenting how the entity plans to realize capital appreciation from substantially all of its equity investments and non-financial asset investments****. An investment entity shallalso have an exit strategy for any debt instruments that have the potential to be held indefinitely, for example perpetual debt investments. The entity need not document specific exit strategies for each individual investment but shall identify different potentialstrategies for different types or portfolios of investments, including a substantive time frame for exiting the investments. Exit mechanisms that are only put in place for default events, such as a breach of contract or non-performance, are not considered exit strategies for the purpose of this assessment.*

Connecting the dots:

So, if there is a JV with a financial partner, there is a perceived difficulty in accepting the position of a joint venture by the accounting community and it appears that the possibility of R&D credit is little weak and the probability of such investment being presented as financial liability is very high.

So, in all my reading and experience, the said R&D credit is possible only in a situation where a JV is established with another pharmaceutical partner who participates in development and commercialization activity **throughout the product's lifecycle.**

In-licensing of development phase compound

It is pretty common for pharmaceutical companies to enter into various deals in which one company will in-license or acquire semi-developed drug compound from another company. These assets are termed as "in-process research and development assets (IPR&D)"

Consider the following example:

Entity A acquired an in-process compound (Phase I complete) from Entity B for a consideration of INR 10 crore. The rest of the phases (II and III) are extremely complex and not many players in the market succeeded in completing the balance drug development process. The balance development costs are expected to be Rs. 90 crore.

What should be the accounting treatment for Rs. 10 crore paid by A? Should this be charged off as the balance development of the compound is complex and the outcomeis uncertain?

Let us examine the accounting with the following analysis:

Firstly, let us understand what an *asset* is.

Paragraphs 4.3 and 4.4 of the Conceptual Framework for Financial Reporting under Ind AS explain the word ***asset*** as under:

4.3 An asset is a present economic resource controlled by the entity as a result of past events;

4.4 An economic resource is a right that has the potential to produce economic benefits.

Combining the above two paragraphs, one can decipher that the word asset should have the following characteristics:

a) Right - the transaction or other event giving rise to the entity's right to or control of the benefit;
b) Potential to produce economic benefits - it embodies a **probable** future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows; and
c) Control - a particular entity can obtain the benefit and control others' access to it.

The word probable under Ind AS is – more likely than not = chances of occurring are greater than those not = greater than 50%.

With this understanding, if one were to look at the scenario on hand, the more possible conclusion would be – Rs. 10 crore does not qualify to be an asset. This is because, if the rest of the development activity is extremely complex and the outcome is uncertain,it would be difficult to say the probability of future economic benefits (in the form of sales and profits) is greater than 50%.

However, there is an interesting paragraph in Ind AS 38, *Intangible assets* – Paragraph 25

Paragraph 25 of Ind AS 38

Normally, the price an entity pays to acquire separately an intangible asset will reflect expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. In other words, the entity expects there to be an inflow of economic benefits, ***even if there is uncertainty about the timing or the amount of the inflow****.* ***Therefore, the probability recognition criterion in paragraph 21(a) is always considered to be satisfied for separately acquired intangible assets***

From the above paragraph, it is abundantly clear that whenever an entity acquires an intangible asset, there is no requirement for an entity to demonstrate the satisfaction of economic benefits criterion. As per this paragraph, the entity expects there to be an inflow of economic benefits, even if there is uncertainty about the timing or the amount of the inflow. In other words, Paragraph 25 of Ind AS 38 is an exception to the probability criterion of the word asset.

But for this paragraph 25 of Ind AS 38, many entities would have charged off majority (if not all) of the acquired in process research and development assets.

Let us continue the example and consider the following scenario to understand the accounting for subsequent development costs.

To complete the balance development activity, assume that the Entity A entered into anagreement with Entity B itself in the following two ways:

Scenario 1	**Scenario 2**
Entity A appointed Entity B as the development partner and entity B continues the development activity. Entity A compensates B for the efforts incurred towards development. The compensation structure is as under: - Upon completion of testing on 100 patients during phase II – Rs. 30 crore; - Upon completion of testing on 1000 patients during phase III – Rs. 50 crore - Upon completion of filing – Rs. 10 crore	After the completion of phase 1, entity A entered into an agreement with entity B for the purchase of marketing rights for the compound. Entity A pays Rs. 10 crore as an upfront consideration and the balance payments are as under: - Successful completion of Phase II – Rs. 30 crore; - Successful completion of Phase III – Rs. 50 crore; - Receipt of regulatory approval for the product – Rs. 10 crore

In both the scenarios above, total out flow is Rs. 100 crore. Rs. 10 crore qualifies for capitalization under both the cases. But as far as the accounting for balance Rs. 90 crore is concerned, accounting will be completely different.

Under Scenario 1, the structure gives us a feeling that the development risk lies with entity A. the compensation agreed is, in substance, a consideration for ***efforts incurred*** by B. B is just carrying out the development activity as agreed and planned and is compensated for his work done irrespective of the outcome of the efforts. Consequently, B is likely to be a CRO (Contract Research Organization) for A and it is A who takes the whole responsibility for development. Hence, in the absence of technical feasibility to complete the asset (condition 1 for capitalization under paragraph 57), the entire Rs. 90 crore is more likely will be charged off.

Now let us analyses scenario 2. In this scenario, the milestones are structured in such a way that they reflect the compensation for success made by B and not the efforts. Let

us assume hypothetically, to complete phase III, B had to test on 3000 volunteers instead of 1000. B might have incurred 3 times the estimated cost for phase III. However, contractually, A is obligated to pay only upon successful completion of phase III. This means, the development risk is still with B. Also, if one were to closely observe, the nature of the intangible asset is also different in both the scenarios. Under scenario 1, it is a product-related intangible and under scenario 2, it is a marketing right. In scenario 2, every milestone payment is a payment for accretion in the value of such right and hence, can be argued as qualifying for capitalization underparagraph 25 of IAS 38.

Connecting the dots:

Readers are requested to understand and appreciate the difference between compensation for work done (efforts made) and compensation for success. Arrangements that reflect compensation for work done will be considered as "self-generated intangible asset" whereas compensations for success would be assessed as "purchase of intangibles". As the purchase of intangibles is guided by paragraph 25, which presumes the satisfaction of the economic benefits criterion, it qualifies for capitalization. In case of self-generated intangible assets, the capitalization criteria are laid down in paragraph 57, which emphasizes on technical feasibility and probability of cash flows, the compensation work done would be charged off.

Material used for development activities – definition of "*incurred*"

The objective of this section is to examine when a company should recognize as an expense, the cost of raw material acquired to carry out research or development activities. In other words, it is about the timing of recognizing such costs into the profit and loss account.

We all know that expenditure is recognized in the books of account when it is incurred. But in this situation, what does the word incurred mean?

Should the cost of raw material be recognized as an expense?

- At the time of purchase of material itself? or
- At the time of consuming such material in the development activity?

Let us examine both scenarios independently.

Charge off as and when purchased

One school of thought believes that such raw material shall be charged off as and when they are procured. Their basis for such conclusion is because of the following points:

As the intention of the management at the time of procuring such raw materials is to use them in either research or development activity, the outcome of which is uncertain and hence, there is no possibility that such raw-material would meet the future economic benefits criterion. In other words, the value-in-use* (the value that would be generated by using the material for the intended activity of development) of raw material is almost zero.

**Although the word,* value-in-use *is used to determine the recoverable amount of a non-current asset as per Ind AS 36, for better understanding of the concept, I have taken the academic liberty to use the word here to explain the concept better.*

Also, proponents of this thought process believe in immediate charge off due to another reason – What would be the classification of such raw material on the balance sheet, if the same were to be capitalized? Can that be classified as inventory? This school of thought tends to disagree that such raw-material does not meet the definition of inventories as per Ind AS 2. As this material is used in the development of a compound, it is neither held for sale, nor in the process of production for sale, nor in the form of materials or consumables used in the production process. Hence, shall be charged off as and when acquired.

All in all, this school of thought takes a conservative stance and disregard completely the recoverable amount of such raw-material if sold in the market or the alternative useof such material in another R&D project.

Charge off at the time of consuming such raw material in the research or development activity

Another school of thought believes that a lenient view can be taken and believes that such charge off can be taken in the books only when such material is consumed in the development activity. However, entities need to pass through one litmus test if at all

such practice needs to be embraced. They have to demonstrate the recoverable amount either by way of their ability to use such material in alternative projects or theamount that would be fetched if they can be sold in an open market (resale value).

In other words, even though the *value-in-use* is zero, if there is a *fair-value less costs to sell*, till the time such material is consumed, this school believes that it can be recognized in the balance sheet either as inventories or as other assets.

Connecting the dots:

There is no accounting challenge in Approach one. It is fairly simple, straight, and of course conservative. Those who wish to apply Approach two have to face the practical difficulty of establishing and demonstrating the existence of a recoverable amount. Even if salvage value exists, can that be established to the extent of 100%? Let us assume that the resale value is 40% and hence the entity decided to capitalize 40% of the total purchase value. An associated challenge would be how to deal with such partvalue in ERP environment. Would this approach stand the test of audit?

Although there seems to be a lenient view and possibility of capitalizing, such option comes with numerous practical difficulties.

Revenue – Out-licensing transactions

Today, pharmaceutical companies in India earn decent revenues from licensing their original molecules to foreign drug majors. Since 2004, companies such as Glenmark Pharma earned about $210 million in cash through seven out-licensing deals.

Indian pharmaceutical companies have since realized the potential of the out-licensing business ---through which molecules are out-licensed during the first or the second phases. Phase-III trial costs, which account for about 60 per cent of the total expenditure on drug trials, remain unaffordable for Indian companies.

A typical out-licensing transaction generally encompasses the following:

- out-licensing of the semi-finished compound supplemented by development agreement where the licensor participates the development activity; or
- Out-licensing of a fully developed or approved drug compound supplemented by supply agreement.

Taking these example circumstances, by taking the following examples let us examine how the accounting works under Ind-AS framework for various sub-scenarios.

Collaborative arrangements Vs Ind AS 115

Example:

Company A grants an IP license to a drug compound to Company B and will perform manufacturing services on the compound. Company A receives an upfront payment of $40 million, per-unit payments for manufacturing services performed, and a milestone payment of $150 million upon regulatory approval. Consideration payable under this arrangement is at market rates and all payments received by Company a are non-refundable.

Analysis:

First of all, is this transaction a revenue transaction?

Why did even this question arise? This is because, in the given example parties A and B can be argued even as collaborating partners as they are collaborating in the commercialization of the product. Then in such circumstances, is the revenue standard applicable?

Paragraph 6 of Ind AS 115 states as under:

An entity shall apply this Standard to a contract (other than a contract listed in paragraph 5) only if the counterparty to the contract is a customer. A customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. A counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity's ordinary activities.

Hence, the first step is to determine whether the revenue accounting standard is applicable. For this, one needs to assess the relationship between the parties – Is the relationship that of collaborating partners or that of vendor and customer? An associated catch is a contract with a collaborator or a partner is in the scope of the revenue standard if the counterparty meets the definition of a customer for part or all of the arrangement. Accordingly, a contract with a customer may be part of an overall collaborative arrangement and the revenue standard is applied to that part.

From the given set of facts, the arrangement appears to be in the scope of the revenue standard as Company A and Company B appear to have a vendor-customer relationship. Company A is providing a license and manufacturing services to Company B and those goods and services are the outputs of Company A's ordinary activities. The fees paid are at market rates and payments received are non-refundable. Also, the two companies do not appear to share in the risks and rewards that result from the activities under the arrangement.

In this regard definition given by US GAAP for collaborative arrangements gives us some additional practical insight:

ASC 808-10-20: Collaborative arrangement: A contractual arrangement that involves a joint operating activity (see paragraph 808-10-15-7). These arrangements involve two (or more) parties that meet both of the following requirements:

- They are active participants in the activity (see paragraphs 808-10-15-8 through 15-9).
- They are exposed to significant risks and rewards dependent on the commercial success of the activity (see paragraphs 808-10-15-10 through 15-13).

Receipts for out-licensing of IP

Scenario

Company A and Company B enter into an agreement in which Company A will license Company B's IP related to a compound for HIV. Company B will not undertake any other activities under the contract. Company A will use Company B's IP for a period ofthree years. Company B obtains a non-refundable upfront payment of $30 million for access to the IP. Company B will also receive a royalty of 20% from sales of the HIV compound if Company A successfully develops a marketable drug.

Question: How should Company B account for the receipts for the out-license of its IP?Analysis:

In the given case, as per step 2, there is only one performance obligation – out-licensing of HIV compound. The arrangement very clearly stipulates that the Company B will not undertake any other activities under the contract. Accordingly, the entire amount of consideration becomes the revenue on the date of out-licensing as the transfer constitutes a right-to-use license.

Company B applies the exception for variable consideration related to sales- or usage-based royalties received in exchange for licenses of IP, therefore the royalties would not be included in the transaction price until Company A sells the product, regardless of whether or not Company B has predictive experience with similar arrangements. (Paragraph B63 of Ind AS 115)

Assessing distinct promises (license and R&D services) / multiple deliverables

To meet their customers' needs, vendors often provide multiple products, services, rights to use assets, or any combination thereof (hereinafter referred to as "deliverables"). These vendors transfer the deliverables to the customer and performance may occur at different times or over different periods of time and the customer's payments for these deliverables may be fixed, variable, or a combination offixed and variable.

Background

Company A, a biotechnology company, enters into an arrangement to provide Company B with a license to manufacture and commercialize an early-stage drug compound as well as perform ongoing R&D services on Company B's behalf to continue to developthe compound. The compound is currently in Phase II clinical trials. The license is delivered to Company B in the first quarter and the R&D services will be provided overtime.

Question: What factors should Company A consider when assessing whether the license is a separate performance obligation in this arrangement?

Significant judgment is required when identifying the number of performance obligations in an arrangement that includes a license to IP as well as R&D services performed by the licensor. In determining whether the license is distinct, Company A should consider whether the license is capable of being distinct and whether the promise to transfer the license is distinct in the context of the contract.

Capable of being distinct

This criterion is met if Company B can benefit from the license on its own or with other readily available resources. The license may not be capable of being distinct if the R&D services are so specialized that the services could only be performed by Company A as opposed to Company B or another qualified third party.

Another way to look at the situation is – Does the delivered item(s) has value to the customer on a standalone basis. That item(s) has value on a standalone basis if it issold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for that deliverable(s).

Generally, in pharmaceutical industry be it consequent to the novelty associated with the product under development, or be it due to the rigor in evaluating the process for approving the product by the regulator, generally the licensee would involve the licensor either in manufacturing the product or for participation in subsequent development activity.

Distinct in the context of the contract

This criterion is met if the promise to transfer the license is separately identifiable from the R&D services. The license may be separately identifiable from the R&D services if the R&D services are not expected to significantly modify or customize the initial IP.

This is often the case with clinical trials when the purpose is to validate the usage and efficacy of a drug versus significantly modifying or customizing the initial IP (e.g., the drug compound).

Conversely, in the case of very early stage IP (e.g., within the drug discovery cycle) whereby the R&D services are expected to involve significant further development of the drug formula or biological compound, Company A might conclude that the license is not separately identifiable from the R&D services.

Company A should also evaluate if the R&D services are optional; that is, could the customer decide to cancel at any time with no penalty or hire another vendor or biotech to perform the services. Optional services may indicate that the only enforceable rights and obligations relate to the license of IP. In that circumstance, Company A would need to assess if a material right exists with regard to future optional R&D services, which may be the case, for example, if the R&D services were priced at an amount below standalone selling price.

Connecting the dots

If one were to talk from an economic point of view, is it that nobody in the world would be able to replace the licensor in providing such services (manufacturing or development services)? No, definitely such services would be obtained by another market player. But the most cardinal question is – can the market player **readily** provide those services? Can the supplementary services be obtained by the licensee from day 1 itself?

Answer is a definite No, again because of the strong regulatory framework. Even if there is a ready market player available, to change the place of manufacturing it has to go through the rigor of regulatory requirements and sometimes approval by the regulator.

So, in the instances of license and R&D services or license and supply services, there is a perceived notion that, in the pharmaceutical industry, these two promises are not two distinct performance obligations or there is a single "unit of accounting". In other words, there is a "rebuttable presumption" that these two promises are not separable.
Entities have to demonstrate the economic and regulatory possibilities, if they choose to rebut the presumption.

Assessing distinct promises (license and manufacturing)

Background

Company A, a pharmaceutical company, enters into an agreement with Company B to provide them with a license related to a mature product for a period of 10 years. For the first 5 years, Company A will continue to manufacture the drug while Company B is developing their manufacturing facilities. As the license is related to a mature product, it is not expected that the underlying product will change over the license period.

Question: What factors should Company A consider when assessing whether the license is a separate performance obligation in this arrangement?

Solution

Determining whether the license is distinct in this scenario will depend upon the facts and circumstances surrounding the license and the related manufacturing services. Company A will need to determine whether the customer can benefit from the license on its own, as well as whether the license is separately identifiable from the manufacturing services. For example, if the manufacturing process is highly specialized and only Company A has the knowledge and expertise to perform the manufacturing services, the license may not be distinct as Company B cannot benefit from the license on its own but rather requires the ongoing involvement of Company A to continue the manufacturing. If that were the case, the license may not be separately identifiable as Company B has contracted with Company A for the license as well as the manufacturing of the product for the first 5 years. In other words, Company B can only benefit from the license in conjunction with the related manufacturing services and therefore the license is not considered distinct and the license and manufacturing services would be accounted for as a single performance obligation.

Conversely, if Company B could contract with another company to perform the manufacturing services (for example, a contract manufacturing organization), the license may be distinct as the customer can benefit from the license on its own without Company A's ongoing involvement. This would be the case even if Company B is contractually required to use Company A to manufacture the product for the defined period. Additionally, the license may be separately identifiable as Company B is not contracting for the combined output of the license and manufacture of product, and Company A could fulfill its promise to deliver the license independent of fulfilling the promise to provide manufacturing services. In this instance, the entity may be able to conclude that the license is distinct.

Finally, in a scenario in which the license Company B obtained was solely limited to a right to distribute Company A's product, the arrangement may not constitute a distinct license to use IP under Ind AS 115 and would function only as a mechanism for Company B to sell what they purchased from Company A.

(Refer example provided from IFRS 15 in the next section – License of intellectual property)

Non-refundable upfront fee – Revenue recognition

Most of the out-licensing deals in pharmaceutical industry will feature non-refundable upfront fee. One common argument we keep seeing generally from the management point of view is why can't this be recognized immediately as the whole amount is non-refundable.. It is non-refundable even if the contract is terminated. How should we look at this argument?

Paragraphs B48 and B49 of Ind AS 115 provide complete clarity and guidance regarding this.

Presenting those paragraphs for immediate reference:

B48 In some contracts, an entity charges a customer a non-refundable upfront fee at or near contract inception. Examples include joining fees in health club membership contracts, activation fees in telecommunication contracts, setup fees in some services contracts and initial fees in some supply contracts.

B49 to identify performance obligations in such contracts, an entity shall assess whether the fee relates to the transfer of a promised good or service. In many cases, even though a non-refundable upfront fee relates to an activity that the entity is required to undertake at or near contract inception to fulfil the contract that activity does not result in the transfer of a promised good or service to the customer (see paragraph 25). Instead, the upfront fee is an advance payment for future goods or services and, therefore, would be recognized as revenue when those future goods or services are provided. The revenue recognition period would extend beyond the initial contractual period if the entity grants the customer the option to renew the contract and that option provides the customer with a material right as described in paragraph B40.

B50 If the non-refundable upfront fee relates to a good or service, the entity shall evaluate whether to account for the good or service as a separate performance obligation in accordance with paragraphs 22–30.

B51 an entity may charge a non-refundable fee in part as compensation for costs incurred in setting up a contract (or other administrative tasks as described in paragraph 25). If those setup activities do not satisfy a performance obligation, the entity shall disregard those activities (and related costs) when measuring progress in accordance with paragraph B19. That is because the costs of setup activities do not depict the transfer of services to the customer. The entity shall assess whether costs incurred in setting up a contract have resulted in an asset that shall be recognized in accordance with paragraph 95.

Connecting the dots

Readers are requested to focus more on the highlighted portion in the aforementioned paragraphs. What do these highlighted lines mean – simply put, revenue recognition presupposes the existence of earning activity. Entity must have rendered some serviceto the customer either by way of supplying the goods or rendering services. Without revenue earning activity, there is no revenue recognition possible. In a crude way – Nopain (service to the customer), No gain (revenue to the customer).

Revenue is recognized as the performance obligations are satisfied. Even if the upfront amount represents the value for the past efforts of the vendor and economically they represent the compensation for the efforts and sacrifices thus far made, there will not be any change in the conclusion to be reached if there are any pending performance obligations relating to the promise made.

Revenue – consideration paid back to customer

One of the most interesting aspects under revenue recognition topic for pharmaceutical industry is when a portion of consideration paid back to customer. How should those amounts be classified in the income statement? If the consideration received from customer is revenue, by design, does this mean that any consideration paid back to the customer is reduction from revenue? May be yes, or maybe not.

Let us examine the accounting considerations.

It is pretty common for a pharmaceutical company, especially for the one having operations in the US to have the challenges on the said matter. Be it chargebacks, rebates (direct and indirect) or discounts in the US or advertising contracts with the customers in the European region, considerable amounts are paid to the customer back by the vendors. (Commonly referred to as *gross to net* items in the industry)

If one looks at the accounting for those transactions, most of the items would get accounted for as "net" of revenue rather than getting accounted for "gross" as expenses.

What drives such net accounting? Let us understand

Paragraphs 70 to 72 of Ind AS 115 address the topic.

An entity shall account for consideration payable to a customer as a reduction of the transaction price and, therefore, of revenue ***unless*** *the payment to the customer is in exchange for a* ***distinct good or service*** *(as described in paragraphs 26–30) that the customer transfers to the entity.*

Simply put, if the vendor pays the consideration back to the customer due to a distinct (rather separate) service, then such payment is accounted for as expense rather than reduction from revenue.

Let us take an example – Company A sells pharmaceutical products to company B and company B runs a co-operative advertising campaign in which Company A also takes part. Company a received Rs. 10 lakh as a consideration for sale of goods and paid Rs. 2 lakh for the advertising cost.

Prima facie, from a logic and economics standpoints, it appears that sale of pharmaceuticals and availing of advertising services are distinct and separate. But is it so, from an accounting lens? Is it what the crux of paragraph 70 when it means distinct or does it have any deeper inner meaning?

The subsequent analysis looks little elongated and establishes links to different accounting frameworks. Hence, readers are requested to be little patient.

Paragraph 70 of Ind AS 115 does not seem to further explain the word – *distinct service* apart from linking it to step 2. Hence, it would be reasonable to refer parent accounting standard IFRS 15 for further research. Here is what one of the paragraphs from the basis for conclusions of IFRS 15 has to offer:

To help an entity distinguish between those types of payments, the boards decided that the only circumstance in which an entity should account for any good or service received in the same way as for other purchases from suppliers is if the good or service is distinct. Previous requirements in US GAAP on the consideration that a vendor gives to a customer

used the term 'identifiable benefit', which was described as a good or service that is 'sufficiently separable from the recipient's purchase of the vendor's products such that the vendor could have entered into an exchange transaction with a party other than a purchaser of its products or services in order to receive that benefit'. ***The boards concluded that the principle in IFRS 15 for assessing whether a good or service is distinct is similar to the previous requirements in US GAAP.***

(Emphasis supplied)

From the basis of conclusions paragraph, we can reasonably ascertain that the word distinct means – identifiable benefit sufficiently separable from the original sale transaction.

Also, readers are requested to note that the IFRS Standard gives reference to US GAAPin this regard and states that the *principle* behind assessing the distinct nature of service is similar to that under the previous requirements of US GAAP.

What are these previous requirements of US GAAP?

There is one literature under US GAAP – EITF 01-9 (Emerging Issues Task Force 01-9) which provides guidance for this topic.

While it is not practically feasible to reproduce the entire literature of US GAAP, I would attempt to present the guidance in crisp and brief way. However, those who intend to obtain complete grasp of the topic are requested to refer to the complete EITF.

As per the EITF, firstly, one simple question that need to be put to determine the separately identifiable benefit is – Can such service be obtained by any party other thanthe customer (including the reseller) of the product?

Applying the question to our example, can Company A obtain the advertising services from any party other than Company B, or is it so that such contract can be entered into only with the customer?

If the answer is YES, meaning such services can be obtained from anybody and not justthe customer, then it is a separate benefit. If the answer is NO, then it is not a distinct benefit even though from logic point of view, such services appears to be distinct.

Take an example of a big Pharma that entered into an agreement with one of its distributors. As per the agreement, the big Pharma's branded products are required to be put on display at a particular slot in the distributor's stores in consideration for X amount of money to be paid as slotting fee.

Applying the question – can the display services be availed from anybody other than the customer (distributor)? Answer is a clear NO. One can obtain the services of slotonly from its customers. Hence, the slotting fee paid would end up as reduction of revenue.

Connecting the dots

Taking the last example as a base, a prudent mind tends to believe and oscillate towards the conclusion that the slotting fee is a distinct service. Because, from logic and economics standpoint, it appears that it is an evidently clear and separate service. However, it is not the case when one connects his/her thoughts with the principle available under previous guidance of US GAAP. Readers are requested to pay lot of attention to this area as this constitutes a slippery ground in the revenue recognition area.

Revenue - Licenses of intellectual property

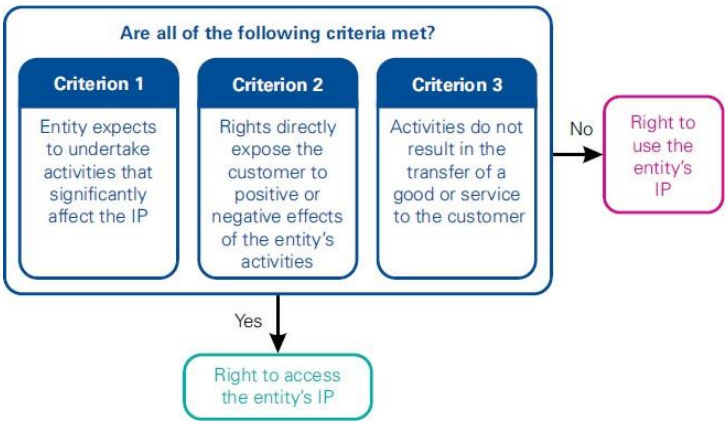
Generally, a license granted by a company (the licensor) provides the customer (the licensee) with the right to use, but not own, the licensor's IP. A common example in the pharmaceutical and life sciences industry is a company that "out licenses" to a customer the IP it developed related to a drug that has not yet received regulatory approval. Often, under the terms of the license, the licensee can further develop the IP, and manufacture and/or sell the resulting commercialized product. The licensor typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based royalties as consideration for the license. Some arrangements also include ongoing involvement by the licensor, who might provide R&D and/or manufacturing services relating to the licensed IP.

Accounting for licenses could be challenging under the revised revenue standard. Determining whether a license is distinct from other goods and services in an arrangement is a key part of applying the model. Licenses coupled with other services, such as R&D, must be assessed to determine if the license is distinct (that is, both "capable of being distinct" and "distinct in the context of the contract,"). If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is recognized as the licensor satisfies the combined performance obligation.

In determining whether to recognize revenue from a license of IP over time or at a point in time, an entity needs to determine the nature of the licensing arrangement. The nature of the arrangement is determined on the basis of the entity's promise to the customer and whether that promise (1) provides access to the IP throughout the licenseterm (i.e., "right to access") or (2) provides a right to use the IP as it exists at the point in time when control of the license is transferred to the customer (i.e., "right to use").
Revenue from a license that grants a right to access an entity's IP is recognized over time since the customer simultaneously receives and consumes the benefits of the entity's IP throughout the license periods

How to decide whether a license is right-to-access license or right-to-use license. For that purpose, Ind AS 115 itself gives guidance to the readers in such determination.

The Following table from KPMG's handbook on revenue provides an easier glimpse into such determination:



Although the Standard seems to attribute residuary position (if the said conditions do not meet, then it is right-to use license), for a reader it would be more appropriate and easier to understand when a license becomes right-to-use license.

Whether the license is functional at the time of transfer?

The license is said to be functional if at the time of transferring the license, customer can direct the use of, and obtain substantially all of the remaining benefits from, the product/drug compound/IP when the license is transferred to the customer.

Furthermore, the entity concludes that because the software is functional when it transfers to the customer, the customer does not reasonably expect the entity to undertake activities that significantly affect the intellectual property to which the license relates. This is because at the point in time that the license is transferred to thecustomer, the intellectual property will not change throughout the license period.

May be this is the reason why US GAAP terms these words as Functional license (Right-to-use the license) and symbolic license (Right-to-access the license)

One crude way of identifying whether the license is functional is from the step 2 itself – identify the performance obligations. If the license is a distinct performance obligation (where the customer has standalone value from the license granted), predominantly, such license tends to become a right-t0-use the-license.

In this regard, presenting the following example from IFRS 15 for better reference

Example 56—identifying a distinct license

An entity, a pharmaceutical company, licenses to a customer its patent rights to an approved drug compound for 10 years and also promises to manufacture the drug for the customer. The drug is a mature product; therefore the entity will not undertake any activities to support the drug, which is consistent with its customary business practices.

Case A—License is not distinct

In this case, no other entity can manufacture this drug because of the highly specialized nature of the manufacturing process. As a result, the license cannot be purchased separately from the manufacturing services.

The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 27 of IFRS 15. The entity determines that the customer cannot benefit from the license without the manufacturing service; therefore, the criterion in paragraph 27(a) of IFRS 15 is not met.Consequently, the license and the manufacturing service are not distinct and the entity accounts for the license and the manufacturing service as a single performance obligation.

The entity applies paragraphs 31–38 of IFRS 15 to determine whether the performance obligation (i.e. the bundle of the license and the manufacturing services) is a performance obligation satisfied at a point in time or over time.

Case B—License is distinct

In this case, the manufacturing process used to produce the drug is not unique or specialized and several other entities can also manufacture the drug for the customer.

The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 27 of IFRS 15. Because the manufacturing process can be provided by other entities, the entity concludes that the customer can benefit from the license on its own (i.e. without the manufacturing service) and that the license is separately identifiable from the manufacturing process (i.e. the criteria in paragraph 27 of IFRS 15 are met). Consequently, the entity concludes that the license and the manufacturing service are distinct and the entity has two performance obligations:

(a) license of patent rights; and

(b) Manufacturing service.

The entity assesses, in accordance with paragraph B58 of IFRS 15, the nature of the entity's promise to grant the license. The drug is a mature product (i.e. it has been approved, is currently being manufactured and has been sold commercially for the last several years). For these types of mature products, the entity's customary business practices are not to undertake any activities to support the drug. Consequently, the entity concludes that the criteria in paragraph B58 of IFRS 15 are not met because the contract does not require, and the customer does not reasonably expect, the entity to undertake activities that significantly affect the intellectual property to which the customer has rights.

In its assessment of the criteria in paragraph B58 of IFRS 15, the entity does not take into consideration the separate performance obligation of promising to provide a manufacturing service. Consequently, the nature of the entity's promise in transferring the license is to provide a right to use the entity's intellectual property in the form and the functionality with which it exists at the point in time that it is granted to the customer. Consequently, the entity accounts for the license as a performance obligation satisfied at a point in time.

The entity applies paragraphs 31–38 of IFRS 15 to determine whether the manufacturing service is a performance obligation satisfied at a point in time or over time

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