Applying Ind AS 115 - Life Science entities
What you need to know

- Application of Indian Accounting Standard (Ind AS) 115 will require life sciences entities to use significant judgement and make more estimates than they do under Ind AS 18.
- The key issues for life sciences entities include determining how the new standard applies to: Collaboration arrangements, arrangements with variable consideration, licenses of intellectual property and reseller arrangements.
- Life sciences entities have to update their policies, systems and controls to meet the new requirements. Further, the standard also requires greater disclosure.
- Considering the significant judgement and estimates to be made under Ind AS 115, documentation of fact analysis and conclusion drawn becomes of the utmost importance from a corporate governance perspective.
- Implementation experience of global life science entities suggest implementation of the standard requires significantly greater effort than expected and hence a timely preparation will be the key to successful implementation of Ind AS 115.
- Ind AS 115 is effective for annual periods beginning on or after 1 April 2018.
Overview

The Ministry of Corporate Affairs (MCA) has notified Ind AS 115– Revenue from Contracts with Customers, which came into effect from 1 April 2018. This publication highlights key aspects of applying the standard to life sciences arrangements, addresses significant changes to the legacy practice and reflects the implementation insights based on experience by global life science companies. The new standard will supersede virtually all revenue recognition requirements under Ind AS that life sciences entities apply today.

The new standard provides accounting requirements for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers (unless the contracts are in the scope of other standards, such as Ind AS 17– Leases). The new standard also provides a model for the measurement and recognition of gains and losses on the sale of certain non-financial assets, such as property, plant and equipment (PP&E) and intangible assets.

The views we express in this publication may evolve as implementation continues and additional issues are identified.

Key considerations for life sciences entities

Life sciences entities may have to change their policies, systems and controls for making estimates in order to comply with Ind AS 115’s requirement for estimating variable consideration.

In addition, complex arrangements with multiple promised goods and services (e.g., a license of a product candidate combined with research and development services or a medical device combined with installation services and a maintenance agreement) will require careful consideration to determine whether there are separate performance obligations.

Collaboration agreements

Life sciences entities frequently enter into collaboration agreements with other parties in which the counterparty may be a collaborator (rather than a customer) that shares in the risks and benefits of developing a product to be marketed. An example would be two pharmaceutical companies that collaborate on the development of an experimental product candidate.

However, depending upon the facts and circumstances, these arrangements may also contain vendor-customer relationship components. Such transactions could be within the scope of Ind AS 115, at least partially, if the collaborator or partner meets the definition of customer for some, or all, aspects of the arrangement. Life sciences entities may find it
challenging to determine whether their collaboration agreements are within the scope of Ind AS 115. Therefore, all facts and circumstances will need to be considered to determine which transactions have a vendor-customer relationship that is subject to the new standard.

**How we see it**

Identifying the customer can be difficult, especially when multiple parties are involved. This evaluation may require significant judgement, but Ind AS 115 does not provide additional application guidance to assist entities in making such judgement. Furthermore, transactions among partners in collaboration arrangements are not within the scope of Ind AS 115. Therefore, life sciences entities will need to use judgement to determine whether the transactions are between parties acting in their capacity as collaborators or through vendor-customer relationship.

**Effect of termination clause on contract duration**

Life science contracts may include clauses that allow a customer to terminate a contract without a penalty, or the customer may be required to pay a termination penalty that is not substantive. The absence of a substantive termination penalty may affect an entity's determination of the contract duration, the number of performance obligations, the transaction price, the timing of revenue recognition and the required disclosures.

The standard does not explicitly address the effect of termination penalties on the length of the contractual period. However, in our view, a substantive termination penalty payable by a customer is an evidence of enforceable rights and obligations on the part of both the parties throughout the period during which the substantive termination penalty applies.

The amount, nature and purpose of the termination penalty are some of the factors to consider when determining whether the termination penalty is substantive. If the termination penalty is not substantive, the contract may be shorter than the stated contractual term. If it is accounted for a shorter-term contract, life science entities may need to evaluate whether the implicit renewal option created by the customer’s decision not to exercise its option to terminate the contract represents a material right.

Some life sciences contracts have stated terms of multiple years, but they also have provisions that allow the customer to terminate the contract without a cause. If the customer terminates the contract, it is common for any payments made under the contract prior to the termination date to be non-refundable and for all rights conveyed under the license of IP to revert to the entity, along with any ‘know-how’ developed or obtained during the contact. Entities will need to exercise significant judgement to determine whether the reversion of a license of IP is substantive termination penalty that compensate the entity for termination of the contract. This may be challenging because there could be number of uncertainties and potential contingent events that could negatively affect the value of right conveyed in the contract for termination. For example, a customer may exercise its termination rights because of the failure to obtain regulatory approval, product safety or efficacy issues.
How we see it

Life science entities should carefully evaluate the terms of their contract with customers, including all substantive termination penalties, to determine the period during which enforceable rights and obligations exist in the contract. This is critical to conclude on contract duration, which in turn can affect the identification of performance obligations, determination and allocation of transaction price.

Identifying performance obligations

Promised goods and services

When identifying performance obligations in a contract, the first step is to identify the promised goods or services. To do so, a life sciences entity should consider whether the customer has a reasonable expectation that the life sciences entity will transfer certain goods or services. If it does, the life sciences entity is likely to view those goods or services as promises that are apart of the negotiated exchange. The life sciences entity needs to distinguish between the promised goods or services that will be transferred to a customer and the activities that are more administrative in nature; i.e., the activities that a life sciences entity must undertake to fulfill a contract and that do not transfer a good or service to the customer that are not promised.

Ind AS 115 does not include explicit language to indicate an entity may disregard promised goods and services that are immaterial in the context of the contract. However, in context of International Financial Reporting Standard 15, the International Accounting Standard Board (IASB) noted that it did not intend for entities to identify every possible promised good or service in a contract and that entities should consider materiality and the overall objective of the standard when assessing promised goods or services and identifying performance obligations.

Free goods and services

Some items that are considered marketing incentives or incidental goods or services under legacy Ind AS will have to be evaluated under the standard to determine whether they represent promised goods or services in the contract. These items should be evaluated to determine whether they represent promises to a customer. The promised goods and services that are distinct should be treated as separate performance obligations. The entity would allocate a portion of the transaction price to those free goods or services and recognize it as revenue when they are transferred to the customer.
For example, a medical technology entity may provide a product and a free service in a contract with a customer. Assuming that the medical technology entity has a contract with a customer at the time when the free service is provided, and that contract is within the scope of the standard, the medical technology entity would need to allocate a portion of the transaction price to the service if that service is assessed as a promised service and is identified as a performance obligation in the context of the contract.

**Participation on a Joint Steering Committee**

Life science entities often enter into collaborative research and development (R&D) arrangements with counterparties that include multiple promised goods and services. It is common for an arrangement to include provisions that require the development of and participation on a Joint Steering Committee (JSC) to make decisions about the collaborative activities. For example, a biotechnology entity that has a revenue contract with a pharma entity could be required to provide its expertise through participation on a JSC in addition to licensing a product candidate and performing R&D services.

Assuming that such a collaborative arrangement is within the scope of Ind AS 115, the participation in a JSC should be evaluated to determine whether it is a promised service in the arrangement. This determination may require careful evaluation of facts and circumstances such as whether participation on the JSC is required or optional, can the life science entity terminate its participation at any time, etc. If participation in the JSC is determined to be a promised service in the arrangement, the life science entity will have to further consider if such participation is distinct from other promised goods or services under the contract.

**Determining whether a promise is distinct**

Under the standard, life sciences entities have to first identify the promised goods or services in the contract and determine which ones (or which bundles of goods or services) are distinct (i.e., a separate performance obligation, which is the unit of account for the purpose of applying the standard). A good or service is distinct if both: (1) The good or service is capable of being distinct; and (2) The promise to transfer the good or service is distinct within the context of the contract. The standard provides three factors that are intended to help entities identify when promises in a bundle of promised goods or services are not separately identifiable and, therefore, should be combined into a single performance obligation. These three factors include: (1) The presence of a significant integration service; (2) The presence of significant modification or customisation; or (3) Whether the promised goods or services are highly interdependent or highly interrelated. Life sciences entities may need to apply significant judgement when determining whether a promise is distinct, especially to determine whether a promised good or service is distinct in the context of the contract.

Analogy can be drawn from illustrative guidance given in IFRS 15.IE58G – IE58K which addresses a common situation for medical technology entities that sell equipment and specialized consumables for use in the equipment. In the example, the equipment does not require any significant customization or modification. The entity is the only producer...
of the consumables, but the consumables are sold separately. The entity concludes that the equipment and consumables are distinct promises because it can satisfy each of them independently of the other. Medical technology entities will need to carefully evaluate the terms of their contracts with customers to determine whether equipment and specialized consumables are distinct performance obligations. Significant judgement will likely be needed.

Application of the series of distinct goods and services provision

After identifying the distinct goods or services in a contract, life sciences entities will need to determine whether any of them represent a series of distinct goods or services that must be combined and accounted for as a single performance obligation. Life sciences entities may need to evaluate these requirements when assessing R&D, manufacturing or other services provided to customers. Determining whether an entity’s promise is a single performance obligation comprising goods or services that are not distinct from one another, or a single performance obligation comprising a series of distinct goods or services, is important because the determination can affect the allocation of variable consideration and the accounting for contract modifications and changes in the transaction price.

Distinct goods or services have to meet certain criteria in the standard in order to be accounted for as a series, including the requirement that they are substantially the same. To determine whether they are substantially the same, life sciences entities first need to determine the nature of the promised goods or services. If their nature is the delivery of a specified amount of services, the entity evaluates whether each service is distinct and they are substantially the same. If the nature of the promise is the act of standing ready or providing a single service for a period of time (i.e., because there is an unspecified amount of services to be delivered), the entity evaluates whether each time increment, rather than the underlying activities, is distinct and substantially the same.

While evaluating whether the series requirement applies to R&D services, a life sciences entity may determine that the series requirement does not apply because the daily R&D services that are provided are not distinct (i.e., the R&D services provided throughout the development period are dependent on and interrelated with the R&D services provided on other days). This would result in the R&D services being accounted for as a single performance obligation or multiple performance obligations (but not under the series requirement). In contrast, a life sciences entity may determine that the series requirement applies because the nature of the overall promise is to provide a daily R&D service that is distinct and that the performance of the overall promise to provide R&D services each day is substantially the same (assuming the other series requirement criteria are met). This could be the case even though the life sciences entity performs a number of different activities to provide R&D services throughout a day and from day to day (e.g., enrolment of patients, laboratory testing, opening/closing clinical trial sites, preparation of regulatory filings).

If promised goods or services are required to be accounted for as a series of distinct goods or services, any variable consideration received for providing the goods or performing the services (e.g., milestone payments received for completing a phase of R&D services) should be recognized as the life sciences entity provides those specific services if certain criteria are met. Consider the following example:
Illustration 1 – Accounting for R&D services that are a single performance obligation versus a single performance obligation under the series requirement

Biotech agrees to perform R&D services over a three-year period. In exchange, Pharma agrees to pay Biotech a fixed monthly payment for the R&D services and a CU5 million milestone payment upon the enrollment of 100 patients in a phase II clinical trial.

Analysis:

If Biotech concludes that all of the R&D services to be provided over the three-year period are a single performance obligation comprising non-distinct services, the milestone would be included in the transaction price (subject to the constraint on variable consideration) and recognized based on the single measure of progress determined for the entire period of performance of the R&D services. This may result in a portion of the milestone being recognized as revenue throughout the R&D services period, including during the development period after the milestone is achieved.

Conversely, if Biotech concludes that the R&D services are a single performance obligation comprising a series of distinct services, Biotech may be able to recognize the milestone payment as it enrolls patients in the clinical trial if certain criteria are met.1 Assuming those criteria are met and Biotech, after considering the constraint on variable consideration, concludes that the milestone should be included in the transaction price, the CU5 million milestone payment is allocated directly to Biotech’s efforts to perform the distinct services that led to the enrolment of the 100 patients. The entire CU5 million milestone amount is recognized as revenue during the period when Biotech performed the distinct R&D services that led to the enrolment of the 100 patients (i.e., no revenue from the milestone payment would be recognized during the development period after the milestone is achieved).

How we see it

A life sciences entity needs to first determine the nature of its promise to the customer when evaluating whether any of its promises are distinct and meet the criteria to be accounted for under the series requirement. This evaluation may require significant judgement and life sciences entities need to consider all of the facts and circumstances of the arrangement.

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1 Ind AS 115.85.
Customer options for additional goods or services

Some contracts give the customer an option to purchase additional goods or services (e.g., consumables for use with medical devices, additional R&D services and manufacturing services). These additional goods and services may be priced at a discount or may even be provided free of charge.

When a life sciences entity grants a customer the option to acquire an additional good or service, the option is a separate performance obligation, only if it provides a material right to the customer that the customer would not receive without entering into the contract (e.g., a discount that exceeds the range typically given for those goods or services to that class of customer in that geographical area or market). In those cases, the customer, in effect, pays the life sciences entity in advance for future goods or services. If an entity concludes that a customer option for additional goods or services provides a material right, the option itself is deemed to be a performance obligation in the contract. In that case, a portion of the transaction price is allocated to it at contract inception, but the underlying goods or services are not accounted for until the option is exercised or until it expires.

If a customer has the option to acquire an additional good or service at a price that would reflect the stand-alone selling price for that good or service, the option does not provide the customer with a material right. In those cases, the life sciences entity has made a marketing offer that it should account for when the customer exercises the option to purchase the additional good or service. However, if the contract includes variable consideration (rather than a customer option), a life sciences entity may need to estimate at contract inception the variable consideration expected over the life of the contract.

Determining whether a customer option is a material right will require a significant judgement. Consider the following example:

| Illustration 2 — Accounting for a customer option |
|-------------------------------------------------
| A medical device manufacturer contracts with its customer to provide a cancer-screening device, perform installation services and provide 50 consumable cartridges to be used with the device. The medical device manufacturer also offers an option to purchase up to 50 additional consumable cartridges in the future at a discount of 25% off the list price. The medical device manufacturer generally sells its products at the list price (i.e., undiscounted).

**Analysis:**

The medical device manufacturer will likely conclude that the customer option for the discounted consumable cartridges is a material right and, therefore, a separate performance obligation. This is because the medical device manufacturer does not sell the replacement cartridges at a discount on a stand-alone basis or offer discounts to new customers that have not entered into a similar contract.

Conversely, if the contract did not provide a discount for the additional consumable cartridges (i.e., the customer option to purchase up to 50 additional cartridges was at the medical device manufacturer's stand-alone selling price), the medical device manufacturer would likely determine that the customer option for additional consumable cartridges was not a material right. Therefore, would account for it as a separate contract when the customer exercises the option to purchase the additional consumable cartridges.
How we see it

Contracts in the life sciences industry often include contingent deliverables, such as manufacturing and marketing services that will be provided upon the successful development and approval of a product candidate.

Under the new standard, life sciences entities are required to evaluate whether a contingent good or service represents: (1) A customer option to purchase additional goods or services that is a material right and, therefore, a portion of the transaction price should be allocated to it at contract inception and recognized when or as the option is exercised or expires; (2) A variable quantity of goods or services that generates variable consideration that is considered in the estimation of the transaction price for the contract; or (3) A customer option to purchase additional goods or services that is not a material right and, therefore, is accounted for as a separate contract when the customer exercises the option to purchase the additional goods or services. This determination likely requires significant judgement and may result in a life sciences entity accounting for a contingency as a component of the initial contract, either in the form of the material right or variable consideration.

Variable consideration

In life sciences arrangements, a portion of the transaction price can often vary in amount and timing due to rebates, incentives, rights of return, performance bonuses, milestones, other contingencies (e.g., future royalties) or concessions.

Life science entities, which provide rebates and/or discounts on the price of goods or services they offer to customers once their specific volume thresholds are met, must determine whether to apply the requirements for variable consideration or the application guidance for customer options. If a volume rebate or discount is applied prospectively, the rebate or discount generally would be accounted for as a customer option, rather than as a variable consideration. This is because the consideration for the goods or services in the contract is not contingent upon, or affected by, any future purchases and the volume rebates or discounts affect only the price of future (optional) purchase. In this case, life science entities will need to evaluate whether the option to purchase future goods or services is a material right and, therefore, is required to be accounted for as separate performance obligation.

However, a volume rebate or discount that is applied retrospectively should be accounted for as variable consideration because the final price of each good or service sold depends on the customers’ total purchases subject to the rebate program. That is, the consideration is contingent on the occurrence or non-occurrence of future events.
Life science entities should keep in mind that the definition of variable consideration is broad and they will need to evaluate whether contract terms, other than those specific to their rebate or discount, create variable consideration that would need to be separately evaluated. For e.g., if the goods subject to a rebate program are also sold with a right of return.

**Estimating variable consideration**

Ind AS 115 requires an entity to estimate variable consideration using the method (i.e., most likely amount or expected value) that best predicts the amount to which the entity will be entitled. An entity includes in the transaction price, amounts for which it is highly probable that a significant revenue reversal will not occur (i.e., a constraint on variable consideration is applied before including it in the transaction price).

Life science entities should consider all information (e.g., historical, current and forecast) that is reasonably available to them when applying either of these methods. The requirement to estimate variable consideration will likely require life sciences entities to make changes to their accounting policies, accounting systems and/or internal controls over financial reporting. For example, life sciences entities may need to adjust their processes and controls for calculating rebates on product sales due to the requirement in Ind AS 115 to estimate variable consideration.

**How we see it**

Under Ind AS 115, life sciences entities will have to estimate the consideration to which they expect to be entitled from these bonuses and milestone payments and, after considering the constraint, may recognise some portion of these payments before they achieve the performance metric or milestone. As a result, a life sciences entity may recognize revenue related to some of these items sooner than it does today.

However, we expect life science entities to conclude, in many instances, that the variable consideration constraint prevents them from recognising certain types of bonuses and milestone payments that are contingent on regulatory approvals.

Questions will likely arise about how to apply the variable consideration constraint to specific fact patterns, including how to determine when it is highly probable that a significant revenue reversal will not occur.
Rights of return

A right of return creates variable consideration that an entity will estimate and include in the transaction price. In doing so, an entity will consider the products it expects to be returned. It then excludes the consideration associated with those products to determine the amount to which it expects to be entitled. While an entity may need to change the method it uses to make this estimate, it is unclear whether the estimate amount will change significantly under the new standard.

An entity will recognize the amount of expected returns as a refund liability, representing its obligation to return the customers’ consideration. The new standard also requires a return asset to be recognized for the right to recover the product. But this requirement is unlikely to affect pharmaceutical companies, because returns frequently have no value due to product expiration or requirements to destroy returned inventory. Entities must present the return asset (if recognized) separately from both the refund liability (i.e., on a gross basis) and inventory.

How we see it

Treating rights of return as variable consideration under the standard may not significantly change the timing of revenue recognition compared to legacy Ind AS. Separately presenting the right of return asset and the refund liability on the balance sheet will be a change in practice for some medical technology entities. For other entities in the life science industry, returns frequently have no value because of product expiration or requirements to destroy the returned inventory.

Reseller and distributor arrangements

Under Ind AS 115, life sciences entities that sell their products through distributors or resellers (collectively, resellers) may recognize the revenue sooner than under legacy Ind AS. Ind AS 18.14 required the amount of revenue to be recognized when it could be measured reliably and it was probable that the economic benefits associated with the transaction would flow to the entity. However, under Ind AS 115, entities will need to estimate variable consideration (i.e., the end-sale price) based on the information available at contract inception, taking into consideration the effect of the variable consideration constraint.

If an entity concludes that its contract with a reseller is not a consignment arrangement, deferring revenue recognition until the end-sale has occurred will no longer be acceptable if the only uncertainty is the variability in the pricing. The entity must recognize revenue upon the transfer of control of the promised goods based on its estimate of the amount of consideration (i.e., the end-sale price) to which it expects to be entitled, considering the constraint on variable consideration. Therefore, an entity may recognize revenue earlier than it does today, if it can determine that it is highly probable that a significant reversal will not occur for at least some of the variable consideration (i.e., the entity is able to estimate an amount of consideration that is not constrained).
How we see it

Under legacy Ind AS, when the sales price charged to distributors or reseller is not finalised, many life science entities wait to recognize revenue until the cash is received or known with a high degree of certainty, which is typically when the product is sold to the end-customer (e.g., upon being prescribed to a patient).

Under the standard, the practice of waiting until the product is sold to the end customer to recognise any revenue will no longer be acceptable if the uncertainty is the variability in the pricing. However, in some cases, the outcomes under the standard and legacy Ind AS could be similar if a significant portion of the estimated revenue is constrained.

Licenses of intellectual property

Life sciences entities’ arrangements frequently include licenses of intellectual property (IP) for other goods and services, such as research and development or manufacturing services. Entities need to determine if contracts involving IP are contracts with customers or are, instead, financing arrangements. For those that are contracts with customers, entities will need to consider whether such contracts include distinct licenses of IP in order to apply the new standard appropriately.

Determining whether a license is distinct

The application guidance for licenses of IP is only applicable to licenses that are distinct. When the license is the only promised item in the contract, the assessment of whether the contract includes a distinct license of IP is straightforward and the application guidance is clearly applicable to that license. However, contracts for licenses of IP frequently include explicit or implicit promises for additional goods and services and life sciences entities may have to more carefully evaluate the nature of the rights conveyed. Under the standard, an entity must first determine whether the license and additional goods and services are distinct and, therefore, separate performance obligations, by applying the requirements on identifying performance obligations. A license of IP that is not distinct is combined with other promised goods and services into a single performance obligation. Consider the following two examples.
Illustration 3 — Identifying performance obligations - license is not distinct

Pharma A licenses its patent rights to an approved, mature drug to a customer for 10 years and promises to manufacture the drug for five years, while the customer develops its own manufacturing capability. There is no expectation that Pharma A will undertake activities to change the drug (e.g., to alter its chemical composition). No other entity can perform the manufacturing service while the customer develops its manufacturing capability because of the highly specialized nature of the process. As a result, the license cannot be purchased separately from the manufacturing service.

Analysis:

Because the customer cannot benefit from the license without the manufacturing service, the license and the manufacturing service are not capable of being distinct and the promises are accounted for as a single performance obligation. The nature of the combined good or service for which the customer has contracted, is a sole source supply of the drug for the first five years.

Illustration 4 — Identifying performance obligations - license is distinct

Assume the same facts as in Illustration 6 above, except that the manufacturing process is not specialized and can be performed by other entities.

Analysis:

Pharma A concludes that the promises are capable of being distinct because the customer can benefit from: (1) The license together with other readily available resources (i.e., because other entities can provide the manufacturing service); and (2) Manufacturing services together with the license that transfers to the customer upfront.

Pharma A also concludes that the promises are distinct in the context of the contract because they: (1) Are not inputs that the entity integrates into a combined output; (2) Do not significantly modify or customize each other; and (3) Are not highly interrelated or highly interdependent (i.e., the entity would be able to fulfil its promise to transfer the license independently to manufacture the drug for the customer)

As a result, Pharma A concludes that the license and the manufacturing services should be accounted for as separate performance obligations.

There may be some situations in which, even though the license is not distinct from the good or service transferred with it, the license is the primary or dominant component (i.e., the predominant item) of the combined performance obligation. In such situations, the application guidance for licenses will still be applied.

If the license is a predominant item of a single performance obligation, a life science entity will need to consider the licensing application guidance when: (a) Determining whether the performance obligation is satisfied over time or at a point in time; and (b) Selecting an appropriate method for measuring progress of that performance obligation if it is satisfied over time. The determination of whether a license is the predominant component may be obvious in some cases, but not in others. Therefore, life sciences entities may need to exercise significant judgement and consider both qualitative and quantitative factors.
Contractual restrictions

Some licenses contain substantive contractual restrictions on how the customer may employ a licence. The standard explicitly states in Ind AS 115.B62 that restrictions of time, geography or use do not effect the licensor’s determination of whether the promise to transfer a license is satisfied over time or at a point in time. However, this type of contractual restrictions might affect the identification of the promised goods or services in the contract.

Significant judgement will be required to determine whether a contractual provision results in additional promises (e.g., additional licenses) or is an attribute that defines the scope of the license. If a life sciences entity determines that a license contains multiple promises, it will need to evaluate whether those promises represent multiple performance obligations. The requirement for contractual restrictions in Ind AS 115.B62 does not replace the requirement to appropriately identify the goods or services promised to the customer in accordance with the standard.

When analyzing contractual restrictions, a life sciences entity should consider whether a restriction requires it to grant additional rights to the customer at a future date in order to fulfill its promises under the contract. The presence of a requirement to grant additional rights to the customer indicates that there may be multiple promises that need to be accounted for.

How we see it

In many life sciences contracts, multiple distinct rights may be transferred to a customer at the same point in time (e.g., licenses for multiple rights to use product candidates or patented drug formulas) or over the same period of time (e.g., licenses for multiple rights to access brands or trade names).

Licensing contracts in the life sciences industry often restrict where and/or how a customer can use a product candidate or patented drug formula. For example, a licensing contract may provide the customer with a right to use a patented drug formula in Country A starting in year one of the contract and Country B starting in year two of the contract. These rights generally would be viewed as multiple promises that are separate performance obligations because additional distinct rights are granted to the customer in the year two.

Life sciences entities will need to apply judgement to determine whether these types of provisions represent multiple promises to the customer and, if so, whether those multiple promises are distinct.
Effect of contractual restrictions on the distinct analysis

Contractual restrictions that require a customer to obtain goods or services from a specific life sciences entity (e.g., manufacturing, R&D services) are common in contracts in the life sciences industry. A contractual restriction that requires a customer to purchase goods or services from the entity (and not from the alternate suppliers) does not change the evaluation of whether promised goods or services are distinct if the contractual restriction does not change: (1) The characteristics of the goods or services themselves; and (2) The entity’s promises to the customer.

For example, a customer may be contractually required to use a life sciences entity to manufacture a drug once it obtains regulatory approval. However, the contractual requirement does not change the characteristics of the license to the drug or the manufacturing services and it does not change the life sciences entity’s promises to the customer (i.e., the contractual requirement does not change the evaluation of whether the license to the drug and the manufacturing services are distinct).

How we see it

It is common in the life sciences industry for regulators (e.g., the US Food and Drug Administration (FDA)) to restrict manufacturing to entities with approved facilities and manufacturing processes. Determining how such restrictions affect the distinct analysis may require a significant judgement.

Careful consideration should be given to factors such as whether a third party would be able to implement the necessary processes and how long it would take them to develop those processes and obtain regulatory approval to manufacture the product. For example, certain products (e.g., some biologics) may be more complex to manufacture than others (e.g., some generic drugs) and it could take longer for a third party to develop the processes and obtain the regulatory approval to do so. This may have a significant effect on the utility of the promised goods or services in the contract (e.g., a license of IP and manufacturing services).

License arrangements that include sales-based or usage-based royalties

Life sciences entities commonly enter into arrangements that require the customer to pay a sales-based or usage-based royalty in exchange for a license of IP. For example, a licensee may be required to pay royalties based on a percentage of its drug product sales.

The standard provides application guidance on the recognition of revenue for sales-based or usage-based royalties received in exchange for licenses of IP and requires that royalties are recognized at the later of when: (1) The subsequent sale or usage occurs; or (2) The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated is satisfied (either in whole or in part). That is, an entity recognizes the royalties as revenue when (or as) the customer’s subsequent sales or usage occurs, unless that recognition pattern accelerates the revenue recognition ahead of the entity’s satisfaction of the performance obligation to which the royalty solely or partially relates, based on an appropriate measure of progress.
The application guidance addresses the recognition of sales-based or usage-based royalties received in exchange for a license of IP rather than measurement of the transaction price. As a result, this exception (the royalty recognition constraint) is a recognition constraint and the variable consideration constraint does not apply. It is important to note that this royalty constraint applies only to licenses of IP for which some or all of the consideration is in the form of a sales-based or usage-based royalty. Entities cannot analogize to it for other situations.

The standard requires the royalty recognition constraint to be applied to the overall royalty stream when the sole or predominant item to which the royalty relates is a license of IP (including when no single license is the predominant item to which the royalty relates, but the royalty predominantly relates to two or more licenses in the contract).

Life sciences entities will need to apply judgement to assess whether a license of IP is the sole or predominant item to which the royalty relates in a performance obligation that includes a license to IP or in relation to other distinct goods or services in a contract. One way for a licensor to make this determination is for it to assess whether the licensee would ascribe significantly more value to the license than to the other goods and services in the contract. For example, consider a contract that provides a license of IP and R&D services that are combined into a single performance obligation. A life sciences entity could determine whether the license is the predominant item to which the royalty relates by evaluating whether the customer would consider it significantly more valuable than the R&D services. This determination may require significant judgement based on the facts and circumstances (e.g., the remaining clinical trial studies that need to be completed, the expected size of the market).

The standard requires that a royalty stream be accounted for either entirely under the royalty recognition constraint or the variable consideration constraint. That is, an entity should not split a single royalty and apply the royalty recognition constraint to one of it's portion and the variable consideration constraint to the other's.

**Scope of the sales-based or usage-based royalty recognition constraint**

Ind AS 115 provides an exception to the variable consideration requirements for sales and usage-based royalties from licenses of IP, which generally will be recognized when the relevant sales or usage occurs. This will likely result in an accounting treatment that is consistent with the current practice.

In context of IFRS 15, the IASB discussed, but decided not to expand, the scope of the royalty exception to include sales of IP. The IASB also stated that the royalty exception is intended to apply only to the limited circumstances (i.e., those circumstances involving licenses of IP). Therefore, entities cannot apply it by analogy to other types of transactions. And we believe this guidance should apply in context of Ind AS 115 too.

**Estimating a sales-based or usage-based royalty where there is a lag in reporting**

Life science entities have questioned whether they can recognize revenue for sales-based or usage-based royalties for licenses of IP on a lag if actual sales or usage data is not available at the end of the reporting period. If the sales or usage has occurred and the performance obligation to which the royalties relate has been satisfied (or partially satisfied), we believe the licensors that lack sales or usage data from the licenses will need to estimate the
royalties earned in the current reporting period. This would include application of the constraint on variable consideration.

**How we see it**

Estimating royalties earned in the current reporting period will be a significant change in the practice for entities that do not have actual sales or usage data from the licensee and report on a lag under legacy practice. Significant judgement will be likely required for these estimates. Licensors without this data will need to implement processes and controls to collect data and develop assumptions to make reasonable estimate.

**Recognition of revenue from a license of IP**

Ind AS 115 states that revenue from a right-to-use license cannot be recognised before the beginning of the period during which “the customer is able to use and benefit from the licence”.\(^2\) If the customer cannot use and benefit from the licensed IP then, by definition, it does not control the license. Assuming that all the other criteria have been met, a life sciences entity will recognize revenue from a right-to-use license at the point in time when the customer is able to use and benefit from the product or product candidate (i.e., the start of the license period).

**Consideration paid or payable to a customer**

The standard requires an entity to account for payments made to a customer or another party that purchases the entity’s goods or services from the customer, regardless of whether the purchaser receiving the consideration is a direct or indirect customer of the entity. This requirement applies to consideration payable to any purchasers of an entity’s products or services at any point along the distribution chain, including customers of resellers or distributors that purchase directly from a life sciences entity (e.g., retail pharmacies, governmental agencies).

Common forms of consideration paid or payable by a life sciences entity to its direct or indirect customers include:

- Rebates paid to government entities, managed care entities or other health insurers
- Fee-for-service amounts paid to wholesalers or other resellers
- Charge-backs paid to wholesalers
- Prompt payment discounts to wholesalers and specialty pharmaceutical companies
- Patient assistance and co-payment programs

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\(^2\) Ind AS 115.B61.
Questions have arisen as to whether a contribution to a not-for-profit or other organization that funds co-payment assistance programs is a form of a consideration paid or payable to an indirect customer because the contribution funds may be used by a patient to obtain the entity's products.

Life sciences entities that contribute to not-for-profit or other organizations that may fund co-payment assistance programs should carefully evaluate the facts and circumstances of each contribution to determine whether it represents consideration paid or payable to an indirect customer (i.e., whether it should be accounted for as a reduction of the transaction price from a contract with a customer because the amount is not provided in exchange for a distinct good or service). Life sciences entities will need to apply significant judgement while making this determination.

To determine the appropriate accounting treatment for the consideration paid or payable to a customer, a life sciences entity must first determine whether the consideration is a payment for a distinct good or service, a reduction of the transaction price or a combination of both. The payment is treated as something other than a reduction of the transaction price only if the entity receives a distinct good or service from the customer in its exchange. However, if the payment is in excess of the fair value of the distinct good or service received, the entity must account for such an excess as a reduction of the transaction price.

**How we see it**

Questions have arisen as to whether a contribution to a not-for-profit or other organization that funds co-payment assistance programs is a form of a consideration paid or payable to an indirect customer because the contribution funds may be used by a patient to obtain the entity's products.

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**Transition**

Ind AS 115 requires either a full retrospective adoption in which the standard is applied to all the periods presented or a modified retrospective adoption. Certain practical expedients are available under both the methods.

The standard considers a contract to be completed when the entity has transferred all the goods or services identified in accordance with legacy Ind AS. Depending on the manner in which life science entities elect to transition to Ind AS 115, they may not need to apply Ind AS 115 to contracts if they have completed performance before the date of initial application, even if they have not yet received the consideration and the same is still subject to variability (e.g., royalties, milestones). One may argue that for this purpose, “transfer of goods or services” refers to the performance in accordance with legacy Ind AS requirements, instead as per notion in Ind AS 115. This determination requires life science entities to apply judgement in some cases.
Presentation and disclosure

Presentation
When either party to a contract has performed, an entity must present the contract in the balance sheet as a contract asset or a contract liability, depending on the relationship between the entity’s performance and the customer’s payment. Contract assets and liabilities are determined at the contract level and not at the performance obligation level i.e., an entity would not separately recognize an asset or liability for each performance obligation within a contract, but would aggregate them into a single contract asset or liability.

Under the standard, entities are not required to use the terms ‘contract asset’ or ‘contract liability’, but must disclose sufficient information so that the users of the financial statements can clearly distinguish between unconditional rights to consideration (receivables) and conditional rights to receive consideration (contract assets).

When a life sciences entity expects to refund some or all of the consideration received (or receivable) from a customer, it records a refund liability. A refund liability will not typically meet the definition of a contract liability because the former generally does not represent an obligation to transfer goods or services in the future. However, an entity should determine whether it should be characterized as a contract liability based on the specific facts of circumstances of the arrangement. When a life sciences entity concludes that a refund liability is not a contract liability, it must present the refund liability separately from any contract liability (or asset) and it would not be subject to the disclosure requirements for contract assets and liabilities included in Ind AS 115.116-118.

Disclosure
Disclosures will include qualitative and quantitative information about contracts with customers, significant judgements are made to apply the standard and any assets recognized for the costs to obtain or fulfill a contract.

The required qualitative and quantitative disclosures about contracts with customers include information about disaggregation of revenue, performance obligations, contract assets and contract liabilities.

The standard also requires disclosure of significant accounting estimates and judgements made in determining the transaction price, allocating the transaction price to performance obligations and determining when performance obligations are satisfied. In case of life sciences entities, this may include information about estimating the stand-alone selling price of promised goods or services, estimating variable consideration and allocating variable consideration to a specific part of a contract. These disclosures exceed the requirements for significant judgements and accounting estimates under Ind AS 1 Presentation of Financial Statements.
The transition disclosure requirements will differ for life science entities depending on the transition method selected (i.e., full retrospective or modified retrospective).

Ind AS 34 Interim Financial Reporting requires disclosure of disaggregated revenue information, consistent with the requirement included in Ind AS 115 for annual financial statements. Although none of the other annual Ind AS 115 disclosure requirements apply to interim condensed financial statements, life sciences entities will need to comply with the general requirements in Ind AS 34 (e.g., to include sufficient information to explain events and transactions that are significant to an understanding of the changes in the entity’s financial position and performance since the end of the last annual reporting period).

Prior to adoption, entities are required to make certain disclosures about the potential effects of the standard. This includes disclosure of a life sciences entity’s expected transition method once the decision is made.

Some of the specific disclosure requirements in the standard that may affect life sciences entities are discussed below, further in detail.

**Disclosure of disaggregated revenue**

The requirement to disclose disaggregated revenue information is intended to illustrate how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. When determining how to disaggregate revenue, a life sciences entity should consider how the information is presented for other purposes, including the way it is presented outside the financial statements (e.g., investor presentations), reviewed by the chief operating decision maker to evaluate operating segments and used to evaluate the life sciences entity’s financial performance. The categories may include type of services, type of customer, type of contract and geographical location.

The standard states that an entity does not have to duplicate disclosures required by another standard. For example, a life sciences entity that provides disaggregated revenue disclosures as a part of its segment disclosures does not have to separately provide disaggregated revenue disclosures if the segment-related disclosures are sufficient to illustrate how the nature, amount, timing and uncertainty of revenue and cash flows from contracts with customers are affected by economic factors. However, segment revenue disclosures may not always provide the users of financial statements with enough information to help them understand the composition of revenue recognized in the period. If a life sciences entity provides disaggregated revenue disclosures in addition to segment disclosures, the standard requires an entity to explain the relationship between the disclosures.

**Disclosure of revenue related to satisfied performance obligations**

The standard requires entities to disclose the amount of revenue recognized in the period that relates to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods (e.g., due to a change in transaction price or in estimates, related to the variable consideration constraint).

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3 Ind AS 8.30.
Disclosure of remaining performance obligations

Entities are required to disclose information about the remaining performance obligations, including the amount of the transaction price allocated to performance obligations that are unsatisfied (or partially unsatisfied) as of the end of the reporting period and when they expect to recognize those amounts. The standard provides a practical expedient that allows an entity not to disclose information about the remaining performance obligations in certain situations, including situations when contracts have an original expected duration of less than one year, as well as situations that meet the requirements of the right to invoice practical expedient in Ind AS 115.B16.

Disclosure of reconciliation of revenue recognized duly reconciled with contracted price

Entities are required to disclose a reconciliation between the amount of revenue recognized in the statement of profit and loss with the contracted price showing separately each of the adjustments made to the contract price, for example, on account of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, etc., specifying the nature and amount of each such adjustment separately.

How we see it

Disclosing the revenue recognized from performance obligations satisfied in previous periods will likely be a change in practice for life sciences entities. Life sciences entities will need to make sure they have appropriate systems, policies and procedures and internal controls.
Next steps

- Entities should perform an assessment of how they will be affected as soon as possible so they can determine how to prepare to implement the new standards. While the effect on entities will vary, some may face significant changes in revenue recognition. All entities will need to evaluate the requirements of the new standard to determine the effects.

- Entities also should consider their communication plans with investors and other stakeholders, including their plan for disclosures about the effects of new accounting standards, as required by Ind AS 8 Accounting Policies, Changes in Accounting Estimates and Errors.
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