



Applying IFRS

How the new revenue standard
will affect life sciences entities

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Building a better
working world

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What you need to know

- ▶ Life sciences entities may need to use significant judgement and make more estimates under IFRS 15 than they do under legacy IFRS.
- ▶ Life sciences entities have to update their policies, systems and controls to meet the new requirements, although their pattern of revenue recognition may not change. The standard also requires greater disclosure.
- ▶ We do not anticipate significant changes to the recognition and measurement principles in the standard and, therefore, life sciences entities should focus on implementation. Many entities are finding that implementation requires significantly greater effort than expected.

Overview

The mandatory effective date of the new revenue recognition standard, IFRS 15 *Revenue from Contracts with Customers* (the standard) issued by the International Accounting Standards Board (IASB or the Board), is fast approaching.¹ As life sciences entities work on implementation, they need to consider all developments. For example, the IASB issued amendments to IFRS 15 to address implementation questions on identifying performance obligations, principal versus agent considerations, licences of intellectual property (IP) and transition. In addition, the Joint Transition Resource Group for Revenue Recognition (TRG) generally agreed on several issues that may affect the life sciences industry.

This publication highlights key aspects of applying the standard to life sciences arrangements, addresses significant changes to legacy practice and reflects the latest implementation insights.

This publication supplements our *Applying IFRS: A closer look at the new revenue standard* (October 2017) (general publication) and should be read in conjunction with it.² The views we express in this publication may evolve as implementation continues and additional issues are identified.

Collaborative arrangements

In certain life sciences arrangements, a counterparty may not be 'a customer' of the entity, as defined in IFRS 15. Instead, the counterparty may be a collaborator or partner that shares in the risks and benefits of developing a product to be marketed, for example, when two pharmaceutical (pharma) companies enter into a collaborative arrangement to develop a product candidate. However, depending on the facts and circumstances, these arrangements may also contain vendor-customer relationship components. Such transactions could be within the scope of IFRS 15, at least partially, if the collaborator or partner meets the definition of a customer for some, or all, aspects of the arrangement. Life sciences entities may find it challenging to determine whether their collaborative arrangements are within the scope of IFRS 15. 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.

The IASB decided not to provide additional application guidance for determining whether certain revenue-generating collaborative arrangements are within the scope of IFRS 15. In the Basis for Conclusions, the IASB explained that it would not be possible to provide application guidance that applies to all collaborative arrangements.³ Therefore, the parties to such arrangements need to consider all of the facts and circumstances to determine whether a vendor-customer relationship exists that is subject to the standard. However, the IASB did determine that, in some circumstances, it may be appropriate for an entity to apply the principles of IFRS 15 to collaborative arrangements (e.g., when there are no applicable, or more relevant, requirements that could be applied).⁴

¹ Effective for annual reporting periods beginning on or after 1 January 2018.

² The most up-to-date version of this publication is available at www.ey.com/IFRS.

³ IFRS 15.BC54.

⁴ IFRS 15.BC56.

How we see it

Under legacy IFRS, identifying the customer can be difficult, especially when multiple parties are involved in a transaction.⁵ This evaluation may require significant judgement and the new standard does not provide additional factors to consider.

Furthermore, transactions among partners in collaboration arrangements are not within the scope of IFRS 15. Therefore, life science entities will need to use judgement to determine whether transactions are between parties acting in their capacity as collaborators or through a vendor-customer relationship.

Effect of termination clauses on contract duration

Life sciences contracts may include clauses that allow a customer to terminate a contract without 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, the TRG generally agreed that a substantive termination penalty payable by a customer is evidence of enforceable rights and obligations on the part of both parties throughout the period during which the substantive termination penalty applies.⁶

The amount, nature and purpose of the termination penalty are factors to consider when determining whether the termination penalty is substantive. TRG members observed that the determination of whether a termination penalty is substantive, and what the enforceable rights and obligations are under a contract, requires judgement and consideration of the facts and circumstances. If the termination penalty is not substantive, the contract may be shorter than the stated contractual term. For example, entities may be required to account for contracts with stated terms as shorter-term contracts, e.g., month-to-month, if the parties to the contracts can terminate them without paying a substantive penalty, although the stated terms may be for multiple years.

If a contract is accounted for as a shorter-term contract, life sciences 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.

⁵ IAS 11 *Construction Contracts*, IAS 18 *Revenue* and related Interpretations.

⁶ TRG Agenda paper no. 48, *Customer options for additional goods and services*, 9 November 2015.

Illustration 1 – Determining contract duration for a contract without a substantive termination penalty

Biotech enters into an arrangement with Pharma to provide Pharma with a research, development and commercialisation licence to a phase I product candidate and perform R&D services. Biotech determines that it is licensing a right to use the IP. In exchange, Pharma agrees to pay Biotech a non-refundable, upfront fee and market rates for the R&D services. The stated contract term extends through commercialisation, but Pharma can terminate the contract without paying Biotech a monetary penalty at any time with six months' notice.

Analysis:

Biotech would determine the legally enforceable contract period by evaluating Pharma's right to terminate the contract without penalty if it provides six months' notice. If Biotech concludes that the enforceable rights and obligations in the contract exist for six months (i.e., there is no substantive termination penalty), Biotech effectively would have a rolling six-month contract, and the contract duration would extend to the first available cancellation date, which is six months after the contract begins. Biotech would evaluate whether Pharma's ability to renew the contract after the initial six-month period (i.e., the effective renewal each day Pharma does not exercise its option to terminate the contract) constitutes a material right because Pharma is not obligated to pay any consideration (beyond the upfront fee) each time it renews the contract.

Accounting when the licence and R&D services are not distinct

If Biotech concludes that the licence is not distinct from the R&D services, Biotech allocates the transaction price to the separate performance obligations: (1) a six-month term licence with related R&D services; and (2) the material right associated with the daily renewal options. Biotech recognises the portion of the transaction price allocated to the six-month term licence and R&D services as revenue over the six-month contract term using a single measure of progress (e.g., following the pattern of performance of the R&D services). Biotech recognises the portion of the transaction price allocated to the material right as revenue as Pharma exercises its renewal options over the expected renewal period of the contract (see section 6.1.5 in our general publication for further discussion on allocating the transaction price to a material right).

Accounting when the licence and R&D services are distinct

If Biotech concludes that the licence is distinct from the R&D services, Biotech allocates the transaction price to: (1) the six-month licence right; (2) the six months of R&D services; and (3) the material right associated with the daily renewal options. Biotech recognises the portion of the transaction price allocated to the six-month licence as revenue on the date that control of the licence is transferred to Pharma and it recognises the portion of the transaction price allocated to six months of R&D services as revenue as the services are performed. Biotech recognises the amount allocated to the material right as revenue as Pharma exercises its renewal options over the expected renewal period of the contract (see section 6.1.5 in our general publication for further discussion on allocating the transaction price to 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 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 licence of IP to revert back to the entity, along with any 'know-how' developed or obtained during the contract, upon (or shortly after) termination. The requirement for the customer to forgo all rights under the licence should be evaluated as a factor to consider when determining contract duration. In particular, if the customer decides to terminate the contract, the return of rights to the IP to the entity may represent a substantive non-monetary penalty that would compensate the entity for termination of the contract (i.e., the surrender of the licensed rights). This could indicate that the contract duration aligns with the period for which the penalty would be incurred (rather than only through to the date that the customer can terminate the contract).

Entities will need to exercise significant judgement to determine whether the reversion of a licence of IP is a substantive termination penalty that compensates the entity for termination of a contract. Entities may find this assessment challenging because there are often a number of uncertainties and potential contingent events, many of which are outside of the control of the parties to the contract that could negatively affect the value of the rights conveyed in the contract at the termination date. For example, a customer may exercise its termination rights because of a failure to obtain regulatory approval, product safety or efficacy issues or other market factors. The payment terms associated with the licence of IP are also important to consider (e.g., surrendering rights to IP that have been fully or significantly prepaid would be viewed differently than surrendering rights to IP and avoiding ongoing licensing payments).

At contract inception, entities likely will have estimated the probability of success of the contracted-for activities and both parties will be committed to perform under the terms of the contract, but they may not be able to assert with a high degree of certainty that the rights to the IP will have substantive value at any future termination date. Instead, the customer may decide to terminate the contract because there is a significant decline in the value of the rights and continuation under the contract is not viable. In such cases, an entity may determine that the reversion of the rights to the IP may not be a substantive termination penalty.

In other cases, an entity may evaluate the nature of the IP (e.g., the stage of development), together with any payment terms in the contract and other relevant factors, and determine that the reversion of the rights to the IP represents a substantive termination penalty. For example, an entity may license the IP for an approved drug formula to a customer for development and commercialisation by the licensee in a different market. The licensee pays a non-refundable upfront fee for the licence that is consistent with market terms for an approved drug and will pay royalties if the drug is approved and sold in the new market. The contract permits the licensee to terminate the contract with six months' notice, and the rights conveyed by the licence revert back to the entity after the contract is terminated. In this fact pattern, the entity might conclude that the upfront fee is compensation for providing the licensee with the right to use the IP. It may also conclude that any subsequent reversion of the rights to the IP is a substantive non-monetary penalty that provides compensation for termination of the contract. This means the licensee's ability to terminate the contract does not affect the contract term.

How we see it

Life sciences entities should carefully evaluate the terms of their contracts with customers, including all substantive termination penalties, to determine the period during which enforceable rights and obligations exist in the contract. The evaluation of substantive termination penalties requires significant judgement and is critical because the conclusions on the enforceable rights and obligations in a contract, including contract duration, can affect the identification of performance obligations and determination and allocation of the transaction price.

Questions an entity may consider when assessing whether a reversion of licensed rights represents a substantive termination penalty include:

- ▶ Is the licensee receiving a right to use an 'unproven' or 'early stage' drug formula (such that there is likely greater uncertainty about the value of the rights to the IP during the licence term) or is the licence for rights to an approved drug (such that the value of the licensed rights is more certain at contract inception)?
- ▶ Is the licensee required to pay an amount at contract inception that is consistent with or greater than market terms for similar technologies at a similar development stage or is the licensee primarily making payments as the IP is developed or is commercialised?

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 part of the negotiated exchange. The life sciences entity needs to distinguish between the promised goods or services that transfer to a customer and the activities that are more administrative in nature; that is, the activities that a life sciences entity must undertake to fulfil a contract and that do not transfer a good or service to the customer are not promised goods or services.

IFRS 15 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 the Basis for Conclusions, the 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 IFRS 15 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 IFRS will have to be evaluated under the standard to determine whether they represent promised goods or services in the contract. Although an entity might not consider them to be the 'main' items that the customer contracts to receive, or might consider them as perfunctory or inconsequential, the IASB concluded that they are goods or services for which the customer pays and, therefore, should not be disregarded, subject

to materiality assessment.⁷ These items should be evaluated to determine whether they represent promises to a customer and which of those should be treated as separate performance obligations. Those promised goods and services that are distinct represent separate performance obligations and the entity would allocate a portion of the transaction price to those free goods or services and recognise it as revenue when those goods or services 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 that it provides the free service, 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 identified as a performance obligation in the context of the contract.

Government vaccine stockpile programmes

Life sciences entities may participate in government vaccine stockpile programmes under which they produce vaccines and bill the government, but hold the goods until requested. IFRS preparers will need to assess carefully their stockpile arrangements to determine the performance obligation(s) and determine the appropriate timing of revenue recognition.

Under updated US Securities and Exchange Commission (SEC or Commission) guidance specific to certain types of vaccine stockpile programmes, entities reporting under US GAAP and participating in these programmes should recognise revenue and provide the disclosures required by the revenue standard when vaccines subject to the guidance are placed into US federal government stockpile programmes.⁸ This guidance is not applicable for IFRS.

Participation on a joint steering committee

Life sciences 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 (biotech) 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 contains a vendor-customer relationship component and, at least partially, is within the scope of IFRS 15 (refer to the section, "Collaboration Arrangements" above), the participation in a JSC should be evaluated to determine whether it is a promised service in the arrangement. This determination may require judgement based on a careful evaluation of the facts and circumstances (e.g., is participation on the JSC required or optional, can the life sciences entity terminate its participation at

⁷ IFRS 15.BC90.

⁸ The SEC issued Interpretive Release, Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile, in response to public policy concerns and, therefore, this guidance should not be used by analogy for other bill-and-hold arrangements, issued on 5 December 2005. The release says the exception is limited to a specific list of 'enumerated vaccines' related to federal governmental stockpile programs. In August 2017, the SEC issued a release to update the guidance in the previous release (SEC Release Nos. 33-8642, 34-52885 and IC-27178). The updated guidance applies to the same vaccines as the previous guidance.

any time). If participation in the JSC is determined to be a promised service in the arrangement, the life sciences entity will have to consider whether its participation in the JSC is distinct from other promised goods or services (e.g., whether other parties could perform the service, or whether participation in the JSC requires unique skills or expertise that result in a significant integration of goods and services).

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.

Example 11, Case E, in the standard addresses a common situation for medical technology entities that sell equipment and specialised consumables for use in the equipment.⁹ In the example, the equipment does not require any significant customisation 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 specialised 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 those distinct goods or services 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.

Life sciences entities will need to evaluate whether certain promises meet the criteria to be accounted for as a series.

⁹ IFRS 15. IE58G-IE58K.

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 the distinct goods or services are substantially the same, life sciences entities first need to determine the nature of the promised goods or services. If the nature of the promise 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.

When 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 its 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 recognised as the life sciences entity provides those specific services if certain criteria are met. See section 6.3 in our general publication for further discussion. Consider the following example:

Illustration 2 – 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 enrolment 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 recognised 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 recognised as revenue throughout the R&D services period, including during the development period after the milestone is achieved.

Illustration 2 – Accounting for R&D services that are a single performance obligation versus a single performance obligation under the series requirement (cont'd)

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 recognise the milestone payment as it enrolls patients in the clinical trial if certain criteria are met.¹⁰ Assuming those criteria are met and the 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 recognised 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 recognised 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.

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, 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, that 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 of discounts 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 when 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, that 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

¹⁰ IFRS 15.85.

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 significant judgement. See Questions 4-10 to 4-12 in our general publication for further discussion.

Consider the following example:

Illustration 3 – 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 the customer 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 recognised 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

Life sciences entities commonly enter into arrangements with customers that include many types of variable consideration.

To apply the requirements for variable consideration, life sciences entities will need to evaluate the facts and circumstances of each contract (or type of contract) and likely need to apply more judgement than they do under legacy IFRS.

Forms of variable consideration

Variable consideration is defined broadly and can take many forms (e.g., discounts, rebates, refunds, credits, price concessions, outcomes-based pricing, milestone payment, performance bonuses and penalties). Variable consideration can result from explicit contract terms or can be implied by a life sciences entity's past business practices or intentions under a contract. It is important for life sciences entities to appropriately identify the different instances of variable consideration included in a contract because the second step of estimating variable consideration requires entities to apply a constraint (as discussed below) to all variable consideration.

Life sciences entities that provide rebates and/or discounts on the price of goods or services they provide to customers once the customers meet specific volume thresholds must determine whether to apply the requirements for variable consideration or the application guidance for customer options. As discussed in Question 4-12 of our general publication, if a volume rebate or discount is applied prospectively, we believe the rebate or discount generally would be accounted for as a customer option, rather than as variable consideration. This is because the consideration for the goods or services in the present contract is not contingent upon, or affected by, any future purchases and the volume rebates or discounts affect only the price of future (optional) purchases. If this is the case, life sciences 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 a separate performance obligation, as discussed above.

However, we believe 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 customer's total purchases subject to the rebate programme. That is, the consideration is contingent on the occurrence or non-occurrence of future events. These concepts are illustrated in Example 24 in the standard.¹¹

Life sciences 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 (e.g., if the goods subject to a rebate programme are also sold with a right of return).

¹¹ IFRS 15. IE124-IE128.

Estimating variable consideration and applying the constraint

To include variable consideration in the estimated transaction price, a life sciences entity must conclude that it is 'highly probable' that a significant revenue reversal of the cumulative revenues recognised under the contract will not occur in future periods once the uncertainty related to the variable consideration is resolved. This requirement, known as the variable consideration constraint, is aimed at preventing over-recognition of revenue.

Variable consideration estimation methods

A life sciences entity is required to estimate variable consideration using either the 'expected value' or the 'most likely amount' method depending on which method better predicts the amount of consideration to which it will be entitled.

Under the expected value method, life sciences entities will determine the expected value of variable consideration using the sum of probability-weighted amounts in a range of possible amounts under the contract. To do this, a life sciences entity will need to identify the possible outcomes and the probabilities of those outcomes.

The Board indicated in the Basis for Conclusions that the expected value method may better predict expected consideration when an entity has a large number of contracts with similar characteristics.¹² This method may also better predict consideration when an entity has a single contract with a large number of possible outcomes. The IASB clarified that an entity preparing an expected value calculation is not required to consider all possible outcomes, even if the entity has extensive data and can identify many possible outcomes. Instead, the IASB noted in the Basis for Conclusions that, in many cases, a limited number of discrete outcomes and probabilities can provide a reasonable estimate of the expected value.¹³

Under the most likely amount method, life sciences entities will determine the amount of variable consideration using the single most likely amount in a range of possible consideration amounts. The Board indicated in the Basis for Conclusions that the most likely amount method may be the better predictor when the entity expects to be entitled to one of two possible amounts (e.g., when a life sciences entity is entitled to receive all or none of a milestone payment for successfully completing a stage of clinical development, a prompt pay discount).¹⁴

Life sciences 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 changes to accounting policies, accounting systems and/or internal control over financial reporting. For example, a life sciences entity may need to update its documentation, processes and controls for calculating rebates on product sales to estimate these rebates using an expected value or most likely amount method.

¹² IFRS 15.BC200.

¹³ IFRS 15.BC201.

¹⁴ IFRS 15.BC200.

Illustration 4 – Estimating variable consideration and applying the constraint

Biotech enters into an arrangement with Pharma under which Biotech provides a licence to a product candidate that is starting phase II clinical studies and performs R&D services for a specified period of time. Assume that these two promises are determined to be distinct. Biotech receives an upfront payment upon execution of the arrangement and may receive milestone payments upon: (1) enrolment of a specified number of patients in a phase II clinical study; (2) completion of phase III clinical studies; (3) regulatory approval in the US; and (4) regulatory approval in the European Union.

Analysis:

Under the standard, Biotech will include in the transaction price, the upfront payment and its estimate of the milestone payments it expects to receive. The amount of consideration that Biotech can include in the transaction price is limited to amounts for which it is highly probable that a significant reversal of cumulative revenues recognised under the contract will not occur in future periods.

Because the milestone for patient enrolment only has two possible outcomes (e.g., Biotech enrolls or does not enrol the specified number of patients), Biotech determines that the most likely amount method is the better predictor of the milestone payment. It then determines that it can include the amount associated with the enrolment milestone in the transaction price, because it is highly probable that doing so will not result in a significant revenue reversal. Biotech based this determination on its prior experience with enrolling participants in similar studies, clinical trial results on the product candidate to date and the significance of the milestone payment compared to the cumulative revenues expected to be recognised under the contract at the time of the enrolment milestone.

However, due to the significant uncertainty associated with the other future events that would result in milestone payments, Biotech initially determines that it cannot include these amounts in the transaction price (i.e., the other milestone payments are fully constrained at contract inception). At the end of each reporting period, Biotech will update its assessment of whether the milestone payments are constrained by considering both the likelihood and magnitude of a potential revenue reversal.

How we see it

Life sciences entities may recognise revenue related to some bonuses and milestone payments sooner than they do under the legacy requirements because IFRS 15 requires them to include in the transaction price the consideration to which they expect to be entitled, after applying the variable consideration constraint. This will be a change in practice for life sciences entities that, under legacy IFRS, generally did not recognise revenue that was contingent on a future event (e.g., a milestone payment, a performance bonus) unless it was probable that the economic benefits associated with the transaction would flow to the entity and the amount of revenue could be reliably measured. Some entities, therefore, deferred recognition until the contingency was resolved.

However, we expect life sciences 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 approval (e.g., European Medicines Agency (EMA) approval of a new drug) until the uncertainty associated with these payments is resolved.

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

Life sciences entities often provide customers with a right to return a transferred product for a specified period of time after sale. A right of return creates variability in the transaction price that a life sciences entity needs to estimate.

A life sciences entity will recognise revenue based on the amount to which it expects to be entitled through to the end of the return period. Therefore, it will not recognise the portion of the revenue subject to the constraint until the amount is no longer constrained, which could be at the end of the return period. The life sciences entity will recognise the amount received or receivable that is expected to be returned as a refund liability, representing its obligation to return the customer's consideration. The standard also requires a return asset to be recognised at the time of the initial sale (i.e., when recognition of revenue is deferred due to the anticipated return), if an entity expects to receive the returned product in saleable or repairable condition. This return asset represents an entity's right to recover the goods returned by the customer. Life sciences entities must present the return asset (if recognised) separately from both the refund liability (i.e., on a gross basis) and inventory.

Consider the following example, which is similar to Example 22 in the standard:¹⁵

Illustration 5 – Right of return

Pharma enters into 50 contracts with customers. Each contract includes the sale of a product for CU100 (50 products × CU100 = CU5,000 total consideration). Cash is received when control of a product transfers. Pharma's return policy allows a customer to return products six months before expiration and up to 12 months after expiration.

Pharma decides to use the portfolio approach (described in IFRS 15.4) to estimate the variable consideration. Pharma has significant experience in estimating returns for this product and customer class. Pharma decides to use the expected value method and estimates variable consideration of CU4,700 (CU100 × 47 products not expected to be returned).

Pharma considers the variable consideration constraint and determines that, although the returns are outside its influence, it has significant experience in estimating returns for this product and customer class. Pharma concludes that it is probable that a significant reversal in the cumulative amount of revenue recognised (i.e., CU4,700) will not occur over the return period.

¹⁵ IFRS 15.IE110-IE115.

Illustration 5 – Right of return (cont'd)

Upon transfer of control of the 50 products, Pharma does not recognise revenue for the three products that it expects to be returned. Pharma records revenue of CU4,700 and a refund liability of CU300. No return asset is recorded because the product cannot be resold.

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 IFRS. However, life sciences entities may have to revise their policies and processes for estimating returns, given the need to consider the variable consideration constraint.

Separately presenting the right of return asset and refund liability on the balance sheet will be a change in practice for some medical technology entities. For other entities in the life sciences industry, returns frequently have no value because of product expiration or requirements to destroy returned inventory.

Life sciences entities can no longer wait until a product is sold to an end-consumer to recognise revenue from a distributor or reseller if the only uncertainty is variability in pricing.

Distributor and reseller arrangements

Under the standard, life sciences entities that sell their products through distributors or resellers may recognise revenue sooner than under legacy IFRS. IAS 18.14 required that the amount of revenue be recognised 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 IFRS 15, entities will need to estimate variable consideration (i.e., the end sales price) based on the information available at contract inception, taking into consideration the effect of the variable consideration constraint. That is, life sciences entities are required to estimate the transaction price, taking into consideration the amount of returns and other variable components of pricing (e.g., charge-backs). The amount included in the transaction price will be recognised as revenue at the time that control of the products transfers to the distributor or reseller.

How we see it

Under legacy IFRS, when the sales price charged to distributors or resellers is not finalised, many life sciences entities wait to recognise revenue until cash is received or known with a high degree of certainty, which typically is when the product is sold to the end-consumer (e.g., upon being prescribed to a patient). Under the standard, the practice of waiting until the product is sold to the end consumer to recognise any revenue will no longer be acceptable if the only uncertainty is the variability in the pricing. However, in some cases, the outcomes under the standard and legacy IFRS could be similar if a significant portion of the estimated revenue is constrained.

Significant financing component

To determine whether a significant financing component exists, a life sciences entity will need to consider all relevant facts and circumstances, including: (1) the difference between the cash selling price and the amount of promised consideration for the promised goods or services; and (2) the combined effect

of the expected length of time between the transfer of the goods or services and the receipt of consideration and the prevailing market interest rates.

The standard describes several factors that indicate that there is not a significant financing component. These include situations in which a substantial amount of the consideration promised by the customer is variable and the amount or timing of that consideration varies based on a future event that is not within the control of the customer or the entity (e.g., a sales-based royalty).

It may be reasonable for a life sciences entity to attribute an adjustment for a significant financing component to one or more, but not all, of the performance obligations in the contract. For example, a life sciences entity that receives an upfront payment as part of the consideration transferred in exchange for a licence to use IP (described below) and R&D services will need to evaluate whether the contract contains a significant financing component associated with the R&D services. If certain criteria are met, the life sciences entity may need to apply requirements in the standard under which specific forms of consideration (i.e., variable consideration or discounts) are allocated to one or more, but not all, performance obligations to determine how much of the upfront payment relates to the licence and how much relates to the R&D services. However, this determination of whether a significant financing component exists will require the use of judgement, especially because cash is fungible.

As a practical expedient, a life sciences entity may decide not to adjust the promised amount of consideration for the effects of a significant financing component if it expects, at contract inception, that the period between the transfer of a promised good or service to a customer and the payment for that good or service will be one year or less.

Licences of IP

A licence provides a customer with rights to use, or access, the IP of an entity. Life sciences entities commonly enter into arrangements with customers that include licences of IP, such as licences for product candidates or patented drug formulas. The standard provides application guidance specific to the recognition of revenue related to licences of IP and sales-based or usage-based royalties provided in exchange for licences of IP that differs in some respects from the recognition model for other promised goods and services.

A life sciences entity will have to analyse the facts and circumstances of each contract (or type of contract) in order to determine when and how to apply the application guidance to licences of IP and may need to use more judgement than it did under legacy IFRS. The units of account and timing of revenue recognition may also change.

Determining whether a licence is distinct

The application guidance for licences of IP is only applicable to licences that are distinct. When the licence is the only promised item in the contract, the assessment of whether the contract includes a distinct licence of IP is straightforward and the application guidance is clearly applicable to that licence. However, contracts for licences 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 licence and additional goods and services are distinct and, therefore, separate performance

obligations, by applying the requirements on identifying performance obligations from Step 2 of the standard. Consistent with the requirements of Step 2, a licence of IP that is not distinct is combined with other promised goods and services into a single performance obligation. Consider the following two examples, which are similar to Cases A and B in Example 56 in the standard:¹⁶

Illustration 6 – Identifying performance obligations – licence 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 specialised nature of the process. As a result, the licence cannot be purchased separately from the manufacturing service.

Analysis:

Because the customer cannot benefit from the licence without the manufacturing service, the licence 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. See further discussion in Example A of Illustration 8 below.

Illustration 7 – Identifying performance obligations – licence is distinct

Assume the same facts as in Illustration 6 above, except that the manufacturing process is not specialised 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 licence together with other readily available resources (i.e., because other entities can provide the manufacturing service); and (2) manufacturing services together with the licence 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 customise 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 licence independently of fulfilling its promise to manufacture the drug for the customer).

As a result, Pharma A concludes that the licence and the manufacturing services should be accounted for as separate performance obligations. See further discussion in Example B of Illustration 8 below.

¹⁶ IFRS 15.IE281-IE288.

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

If the licence 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 licence 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 licences contain substantive contractual restrictions on how the customer may employ a licence. The standard explicitly states in IFRS 15.B62 that restrictions of time, geography or use do not affect the licensor's determination of whether the promise to transfer a licence 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 licences) or is an attribute that defines the scope of the licence. If a life sciences entity determines that a licence contains multiple promises, it will need to evaluate whether those promises represent multiple performance obligations. The requirement for contractual restrictions in IFRS 15.B62 does not replace the requirement to appropriately identify the goods or services promised to the customer in accordance with Step 2 of the model in the standard.¹⁷

When analysing 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 fulfil 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 under Step 2 of the model.

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., licences for multiple rights to use product candidates or patented drug formulas) or over the same period of time (e.g., licences 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 1 of the contract and Country B starting in year 2 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 year 2.

¹⁷ IFRS 15.BC414R.

Life sciences entities will need to apply judgement to determine (based on the requirements in Step 2 of the model) 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. As described in Example 11, Case D, in the standard, a contractual restriction that requires a customer to purchase goods or services from the entity (and not from 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.¹⁸

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 licence 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 licence 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 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 for that third party 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 licence of IP and manufacturing services).

Determining the nature of the entity's promise

Life science entities will need to evaluate the nature of a promise to grant a licence of IP in order to determine whether the promise is satisfied (and revenue is recognised) over time or at a point in time. The standard states that an entity provides a customer with either: (1) a right to access the entity's IP throughout the licence period (for which revenue is recognised over the licence period); or (2) a right to use the entity's IP as it exists at the point in time that the licence is granted (for which revenue is recognised at a point in time where the customer can first use and benefit from the licence).

¹⁸ IFRS 15.IE58E-IE58F.

In order to help entities determine whether a licence provides a customer with a right to access or a right to use the IP, the Board provided application guidance that explains that a licence is a promise to provide a right of access if it meets all of the following criteria: (i) the contract requires, or the customer reasonably expects, that the entity will undertake activities to significantly affect the IP; (ii) the rights granted by the licence directly exposes the customer to any positive or negative effects of the entity's activities in (i); and (iii) those activities do not result in the transfer of a good or service to the customer as those activities occur.¹⁹

In providing this application guidance, the Board decided to focus on the characteristics of a licence that provides a right to access IP. If the licensed IP does not have those characteristics, it provides a right to use IP, by default. This analysis is focused on situations in which the underlying IP is subject to change over the licence period. The key determinants of whether the nature of an entity's promise is a right to access the entity's IP are whether: (1) the entity is required to undertake activities that affect the licensed IP (or the customer has a reasonable expectation that the entity will do so); and (2) the customer is exposed to positive or negative effects resulting from those changes.

When making this assessment, a life sciences entity should exclude the effect of any other performance obligations in the contract. While the activities considered in this assessment do not include those that are a performance obligation, they can be part of an entity's ongoing ordinary activities and customary business practices. After identifying these activities, the entity will need to determine if they significantly affect the IP to which the customer has rights. Under IFRS 15, activities that significantly affect the IP are those that (a) significantly change the form (e.g., design or content) or functionality of the IP; or (b) affect the ability of the customer to obtain benefit from the IP. In the absence of those activities, the IP is considered as having significant stand-alone functionality and revenue will be recognised at a point in time.

Illustration 8 - Determining the nature of the entity's promise

Example A

Assume the same facts as Illustration 6 above.

Analysis:

Pharma A determines that its promise to grant the licence is the predominant item in the single performance obligation that includes the manufacturing service. Therefore, it considers the licensing application guidance to determine the nature of its promise in granting that licence. Pharma A concludes that it is licensing a right to use the IP because the licence is for a mature drug that has significant stand-alone functionality (i.e., it can be used to treat a disease or condition). There is also no expectation that Pharma will undertake activities to change the stand-alone functionality of the IP.

If the licence is the only distinct promise in the contract, revenue is recognised at the point in time that control of the licence is transferred to the customer. However, in this example, the licence and the manufacturing service are combined into a single performance obligation and Pharma A applies the requirements in Step 5 of the standard to determine whether the combined

¹⁹ IFRS 15.B58.

Illustration 8 – Determining the nature of the entity’s promise (cont’d)

performance obligation is satisfied at a point in time or over time. Pharma A will likely determine that the combined performance obligation is satisfied over time, up to the end of the fifth year when the manufacturing service is complete.

Example B

Assume the same facts as in Illustration 7 above.

Analysis:

Pharma A assesses the nature of its promise to grant the licence and concludes that this is a right to use the patented drug formula because it is a mature drug that can be used to treat a disease or condition. There is also no expectation that Pharma A will undertake activities to change the stand-alone functionality of the IP. Pharma A will likely determine that the licence is a performance obligation satisfied at the point in time when control of the licence is transferred to the customer.

In assessing the timing of recognition of the revenue from the licence, Pharma A does not consider the manufacturing service because it is a separate performance obligation in the contract.

Licence 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 licence 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 licences of IP and requires that royalties are recognised 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 (in whole or in part). That is, an entity recognises the royalties as revenue when (or as) the customer’s subsequent sales or usage occurs, unless that recognition pattern accelerates 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 IASB explained that this application guidance addresses the *recognition* of sales-based or usage-based royalties received in exchange for a licence of IP rather than measurement of the transaction price.²⁰ 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 licences of IP for which some or all of the consideration is in the form of a sales-based or usage-based royalty. Entities cannot analogise to it for other situations.

²⁰ IFRS 15.BC421I.

The standard requires that the royalty recognition constraint be applied to the overall royalty stream when the sole or predominant item to which the royalty relates is a licence of IP (including when no single licence is the predominant item to which the royalty relates, but the royalty predominantly relates to two or more licences in the contract).²¹

Life sciences entities will need to apply judgement to assess whether a licence of IP is the sole or predominant item to which the royalty relates in a performance obligation that includes a licence 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 licence than to the other goods and services in the contract. For example, consider a contract that provides a licence of IP and R&D services that are combined into a single performance obligation. A life sciences entity could determine whether the licence is the predominant item to which the royalty relates by evaluating whether the customer would consider the licence 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 entirely under the variable consideration constraint. That is, an entity should not split a single royalty and apply the royalty recognition constraint to a portion of it and the variable consideration constraint to the other portion.

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

The IASB discussed, but decided not to expand, the scope of the royalty exception to include sales of IP. The Board also stated that the royalty exception is intended to apply only to limited circumstances (i.e., those circumstances involving licences of IP). Therefore, entities cannot apply it by analogy to other types of transactions.²²

It is also important to note that the royalty recognition constraint applies only to licences of IP for which some or all of the consideration is in the form of a sales-based or usage-based royalty. This would include certain types of variable consideration even if payments are not referred to as 'royalties' in the contract, but are based on a customer's sale or usage and predominantly related to a licence of IP. For example, we generally believe the royalty recognition constraint would apply to fixed amounts of variable consideration that are contingent on the occurrence of a future event (e.g., milestone payments) provided the amounts are determined by reference to sales-based or usage-based thresholds. However, life sciences entities cannot analogise to the royalty recognition constraint for other situations, such as when consideration in a contract is in the form of a sales-based or usage-based royalty, but there is no licence of IP. In such cases, a life sciences entity would follow the requirements in the general model on estimating variable and applying the constraint on variable consideration. Life sciences entities will need to apply judgement to determine whether their contracts for licences of IP contain payments that should be accounted for using the royalty recognition constraint. See Question 8-3 in our general publication for an illustration and further discussion.

²¹ IFRS 15.BC421G.

²² IFRS 15.BC421F.

In some cases, it may not be obvious as to whether the arrangement is an in-substance sale of IP (i.e., a promise that is in the form of a licence, but, in substance, has the characteristics of a sale) or a licence of IP. In such instances, entities would have to exercise judgement to determine whether the control over the underlying IP has been transferred from the entity to the customer and therefore, has been sold.

Life sciences entities will have to estimate the royalties they earned in a reporting period if they lack data on actual sales or usage.

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

Life sciences entities have questioned whether they can recognise revenue for sales-based or usage-based royalties for licences of IP on a lag if actual sales or usage data is not available at the end of a 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 that licensors that lack sales or usage data from the licensee will need to estimate the royalties earned in the current reporting period in accordance with the general model in Step 3. 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 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 likely be required for these estimates. Licensors without this data will need to implement processes and controls to collect data and develop assumptions to make a reasonable estimate.

Recognition of revenue from a licence of IP

IFRS 15 states that revenue from a right-to-use licence cannot be recognised before the beginning of the period during which “the customer is able to use and benefit from the licence”.²³ The IASB explained in the Basis for Conclusions that if the customer cannot use and benefit from the licensed intellectual property then, by definition, it does not control the licence.²⁴ Assuming that all other criteria have been met, a life sciences entity will recognise revenue from a right-to-use licence 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 licence period).

Restrictions on a licensee’s ability to use and benefit from the licence

Renewals of licences of IP

When a life sciences entity and a customer enter into a contract to renew (or extend the period of) an existing licence, the entity needs to evaluate whether the renewal or extension should be treated as a new licence or as a modification of the existing contract. A modification would be accounted for in accordance with the contract modifications requirements in IFRS 15.18-21.²⁵

Distinct rights added through a modification

Life sciences entities frequently modify the terms of arrangements to provide customers with additional rights. The terms of each licence of IP are defined by the contract, which establishes the customer’s rights (e.g., period of time, area of use). We believe that when a contract for a licence of IP is modified,

²³ IFRS 15.B61.

²⁴ IFRS 15.BC414.

²⁵ IFRS 15.BC414T.

the additional and/or modified licence of IP is distinct from the original licence because the new and/or modified rights will always differ from those conveyed by the original licence.

The standard's contract modification requirements specifies that a modification in which the additional promised goods or services are distinct are accounted for on a prospective basis either as: (a) a separate contract; or (b) a termination of the old contract and creation of a new contract. As discussed above, a life sciences entity cannot recognise revenue for the transaction price allocated to the new licence until the customer has the right to use and benefit from it.

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 programmes

To determine the appropriate accounting treatment for 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 exchange for that payment. However, if the payment to the customer 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. See Question 5-22 in our general publication¹ for further discussion.

How we see it

Questions have arisen as to whether a contribution to a not-for-profit or other organisation that funds co-payment assistance programmes is a form of 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 organisations that may fund co-payment assistance programmes 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 when making this determination.

Transition

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

The standard considers a contract to be completed when the entity has transferred all of the good or services identified in accordance with legacy IFRS. Depending on the manner in which life sciences entities elect to transition to IFRS 15, they may not need to apply IFRS 15 to contracts if they have completed performance before the date of initial application, even if they have not yet received the consideration and that consideration is still subject to variability (e.g., royalties, milestones). In the Basis for Conclusions, the IASB noted that “transferred all of the goods or services” does not imply that an entity would apply the ‘transfer of control’ notion in IFRS 15 to goods and services that have been identified in accordance with legacy IFRS. Rather it refers to performance in accordance with the legacy requirements.²⁶ This determination requires life sciences entities to apply judgement in some cases.

Please refer to section 1.3 of our general publication for transition considerations.

Presentation and disclosure

Presentation

When either party to a contract has performed, an entity must present the contract in the statement of financial position as a contract asset or a contract liability, depending on the relationship between the entity’s performance and the customer’s payment. Members of the TRG generally agreed that contract assets and liabilities are determined at the contract level and not at the performance obligation level. That is, an entity would not separately recognise an asset or liability for each performance obligation within a contract, but would aggregate them into a single contract asset or liability.²⁷

Under the standard, entities are not required to use the terms ‘contract asset’ or ‘contract liability’, but must disclose sufficient information so that 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. We believe that a refund liability will not typically meet the definition of a contract liability because a refund liability generally does not represent an obligation to transfer goods or services in the future. However, an entity should determine whether a contract refund liability should be characterised 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

²⁶ IFRS 15.BC441.

²⁷ TRG Agenda paper no. 7, *Presentation of a contract as a contract asset or a contract liability*, dated 31 October 2014.

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 IFRS 15.116-118. See Question 10-4 in our general publication for further discussion.

Disclosure

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

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. For 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 IAS 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). See section 1.3 in our general publication for further discussion.

IAS 34 *Interim Financial Reporting* requires disclosure of disaggregated revenue information, consistent with the requirement included in IFRS 15 for annual financial statements. Although none of the other annual IFRS 15 disclosure requirements apply to interim condensed financial statements, life sciences entities will need to comply with the general requirements in IAS 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.²⁸ This includes disclosure of a life sciences entity's expected transition method once a decision is made.

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

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 information is presented for other purposes, including information presented outside the financial statements (e.g., investor presentations), information reviewed by the chief operating decision maker to evaluate operating segments and information used to evaluate the life sciences entity's financial performance. Categories may

²⁸ IAS 8.30.

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 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, the IASB stated in the Basis for Conclusions that segment revenue disclosures may not always provide users of financial statements with enough information to help them understand the composition of revenue recognised in the period.²⁹ 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 recognised 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).

Disclosure of remaining performance obligations

Entities are required to disclose information about 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 recognise those amounts. The IASB provided 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 IFRS 15.B16.

How we see it

Disclosing the revenue recognised 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.

²⁹ IFRS 15.BC340.

Appendix: The five-step revenue model and contract costs

The standard's core principle is that an entity recognises revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer. That principle is applied using five steps that will require entities to exercise judgement when considering the terms of their contract(s) and all relevant facts and circumstances. Entities have to apply the requirements of the standard consistently to contracts with similar characteristics and in similar circumstances. This table summarises the new revenue model and the requirements for contract costs.

Step 1: Identify the contract(s) with the customer

Definition of a contract

An entity must first identify the contract, or contracts, to provide goods and services to customers. A contract must create enforceable rights and obligations to fall within the scope of the model in the standard. Such contracts may be written, oral or implied by an entity's customary business practices, but must meet the following criteria:

- ▶ The parties to the contract have approved the contract (in writing, orally or based on their customary business practices) and are committed to perform their respective obligations
- ▶ The entity can identify each party's rights regarding the goods or services to be transferred
- ▶ The entity can identify the payment terms for the goods or services to be transferred
- ▶ The contract has commercial substance (i.e., the risk, timing or amount of the entity's future cash flows is expected to change as a result of the contract)
- ▶ It is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer

If these criteria are not met, an entity would not account for the arrangement using the model in the standard and would recognise any non-refundable consideration received as revenue only when certain events have occurred.

Contract combination

The standard requires entities to combine contracts entered into at or near the same time with the same customer (or related parties of the customer) if they meet any of the following criteria:

- ▶ The contracts are negotiated as a package with a single commercial objective
- ▶ The amount of consideration to be paid in one contract depends on the price or performance of another contract
- ▶ The goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation

Contract modifications

A contract modification is a change in the scope and/or price of a contract. A contract modification is accounted for as a new contract, separate from the original contract, if the modification adds distinct goods or services at a price that reflects the stand-alone selling prices of those goods or services. Contract modifications that are not accounted for as separate contracts are considered changes to the original contract and are accounted for, as follows:

- ▶ If the goods and services to be transferred after the contract modification are distinct from the goods or services transferred on or before the contract modification, the entity should account for the modification as if it were the termination of the old contract and the creation of a new contract
- ▶ If the goods and services to be transferred after the contract modification are not distinct from the goods and services already provided and, therefore, form part of a single performance obligation that is partially satisfied at the date of modification, the entity should account for the contract modification as if it were part of the original contract

- ▶ A combination of the two approaches above: a modification of the existing contract for the partially satisfied performance obligations and the creation of a new contract for the distinct goods and services

Step 2: Identify the performance obligation(s) in the contract

An entity must identify the promised goods and services within the contract and determine which of those goods and services (or bundles of goods and services) are separate performance obligations (i.e., the unit of account for purposes of applying the standard).

A promised good or service represents a performance obligation if: (1) the good or service is distinct (by itself or as part of a bundle of goods or services); or (2) the good or service is part of a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer.

A good or service (or bundle of goods or services) is distinct if both of the following criteria are met:

- ▶ The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct)
- ▶ The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract)

In assessing whether an entity's promise to transfer a good or service is separately identifiable from other promises in the contract, entities will need to consider whether the nature of the promise is to transfer each of those goods or services individually or to transfer a combined item or items to which the promised goods or services are inputs. Factors that indicate two or more promises to transfer goods or services are not separately identifiable include, but are not limited to, the following:

- ▶ The entity provides a significant service of integrating the goods or services with other goods or services promised in the contract into a bundle of goods or services that represent the combined output or outputs for which the customer has contracted
- ▶ One or more of the goods or services significantly modifies or customises, or is significantly modified or customised by, one or more of the other goods or services promised in the contract
- ▶ The goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract

If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

Series requirement

Goods or services that are part of a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer must be combined into one performance obligation. To meet the same pattern of transfer criterion, each distinct good or service in the series must represent a performance obligation that would be satisfied over time and would have the same measure of progress toward satisfaction of the performance obligation (both discussed in Step 5), if accounted for separately.

Customer options for additional goods or services

A customer's option to acquire additional goods or services for free or at a discount is accounted for as a separate performance obligation 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 of discounts typically given for those goods or services to that class of customer in that geographical area or market).

Principal versus agent considerations

When more than one party is involved in providing goods or services to a customer, an entity must determine whether it is a principal or an agent in these transactions by evaluating the nature of its promise to the customer. An entity is a principal (and, therefore, records revenue on a gross basis) if it controls a promised good or service before transferring that good or service to the customer. An entity is an agent (and records as revenue the net

amount it retains for its agency services) if its role is to arrange for another entity to provide the goods or services. Because it is not always clear whether an entity controls a specified good or service in some contracts (e.g., those involving intangible goods and/or services), the standard also provides indicators of when an entity may control the specified good or service as follows:

- ▶ The entity is primarily responsible for fulfilling the promise to provide the specified good or service
- ▶ The entity has inventory risk before the specified good or service has been transferred to a customer or after transfer of control to the customer (e.g., if the customer has a right of return)
- ▶ The entity has discretion in establishing the price for the specified good or service

Step 3: Determine the transaction price

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. When determining the transaction price, entities need to consider the effects of all of the following.

Variable consideration

An entity needs to estimate any variable consideration (e.g., amounts that vary due to discounts, rebates, refunds, price concessions, bonuses) using either the expected value method (i.e., a probability-weighted amount method) or the most likely amount method (i.e., a method to choose the single most likely amount in a range of possible amounts). An entity's method selection is not a 'free choice' and must be based on which method better predicts the amount of consideration to which the entity will be entitled. To include variable consideration in the estimated transaction price, the entity has to conclude that it is highly probable that a significant revenue reversal will not occur in future periods. This 'constraint' on variable consideration is based on the probability of a reversal of an amount that is significant relative to cumulative revenue recognised for the contract. The standard provides factors that increase the likelihood or magnitude of a revenue reversal, including the following: the amount of consideration is highly susceptible to factors outside the entity's influence, the entity's experience with similar types of contracts is limited or that experience has limited predictive value, the contract has a large number and broad range of possible outcomes. The standard requires an entity to estimate variable consideration, including the application of the constraint, at contract inception and update that estimate at the end of each reporting period.

Significant financing component

An entity needs to adjust the transaction price for the effects of the time value of money if the timing of payments agreed to by the parties to the contract provides the customer or the entity with a significant financing benefit. As a practical expedient, an entity can elect not to adjust the transaction price for the effects of a significant financing component if the entity expects at contract inception that the period between payment and performance will be one year or less.

Non-cash consideration

When an entity receives, or expects to receive, non-cash consideration (e.g., property, plant or equipment, or a financial instrument), the fair value of the non-cash consideration is included in the transaction price.

Consideration paid or payable to the customer

Consideration payable to the customer includes cash amounts that an entity pays, or expects to pay, to the customer and credits or other items (vouchers or coupons) that can be applied against amounts owed to the entity. An entity should account for consideration paid or payable to the 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. However, if the payment to the customer exceeds the fair value of the distinct good or service received, the entity should account for the excess amount as a reduction of the transaction price.

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

For contracts that have multiple performance obligations, the standard generally requires an entity to allocate the transaction price to the performance obligations in proportion to their stand-alone selling prices (i.e., on a relative stand-alone selling price basis). When allocating on a relative stand-alone selling price basis, any discount within the contract generally is allocated proportionately to all of the performance obligations in the contract. However, there are two exceptions.

One exception requires variable consideration to be allocated entirely to a specific part of a contract, such as one or more (but not all) performance obligations or one or more (but not all) distinct goods or services promised in a series of distinct goods or services that forms part of a single performance obligation, if both of the following criteria are met:

- ▶ The terms of a variable payment relate specifically to the entity's efforts to satisfy the performance obligation or transfer the distinct good or service
- ▶ Allocating the variable consideration entirely to the performance obligation or the distinct good or service is consistent with the objective of allocating consideration in an amount that depicts the consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to the customer

The other exception requires an entity to allocate a contract's entire discount to only those goods or services to which it relates if certain criteria are met.

To allocate the transaction price on a relative stand-alone selling price basis, an entity must first determine the stand-alone selling price of the distinct good or service underlying each performance obligation. The stand-alone selling price is the price at which an entity would sell a good or service on a stand-alone (or separate) basis at contract inception. Under the model, the observable price of a good or service sold separately in similar circumstances to similar customers provides the best evidence of stand-alone selling price. However, in many situations, stand-alone selling prices will not be readily observable. In those cases, the entity must estimate the stand-alone selling price by considering all information that is reasonably available to it, maximising the use of observable inputs and applying estimation methods consistently in similar circumstances. The standard states that suitable estimation methods include, but are not limited to, an adjusted market assessment approach, an expected cost plus a margin approach or a residual approach (if certain conditions are met).

Step 5: Recognise revenue when (or as) the entity satisfies a performance obligation

An entity recognises revenue only when (or as) it satisfies a performance obligation by transferring control of the promised good(s) or service(s) to a customer. The transfer of control can occur over time or at a point in time.

A performance obligation is satisfied at a point in time unless it meets one of the following criteria, in which case it is satisfied over time:

- ▶ The customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs
- ▶ The entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced
- ▶ The entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date

The portion of the transaction price that is allocated to performance obligations satisfied at a point in time is recognised as revenue when control of the goods or services transfers to the customer. If the performance obligation is satisfied over time, the portion of the transaction price allocated to that performance obligation is recognised as revenue as the performance obligation is satisfied. To do this, the standard requires an entity to select a single revenue recognition method (i.e., measure of progress) that faithfully depicts the pattern of the transfer of control over time (i.e., an input method or an output method).

Licences of intellectual property

The standard provides application guidance on the recognition of revenue for licences of intellectual property (IP) that differs from the model for other promised goods and services. The nature of the promise in granting a licence of IP to a customer is either:

- ▶ A right to access the entity's IP throughout the licence period (a right to access)
- ▶ A right to use the entity's IP as it exists at the point in time in which the licence is granted (a right to use)

The nature of an entity's promise in granting a licence is a promise to provide a right to access the entity's IP if all of the following criteria are met:

- (a) the contract requires, or the customer reasonably expects, that the entity will undertake activities that significantly affect the IP to which the customer has rights;
- (b) the rights granted by the licence directly expose the customer to any positive or negative effects of the entity's activities identified; and
- (c) those activities do not result in the transfer of a good or a service to the customer as those activities occur.

If the licensed IP does not have those characteristics, it provides a right to use IP, by default.

An entity's activities significantly affect the IP to which the customer has rights when either:

- (a) those activities are expected to significantly change the form (for example, the design or content) or the functionality (for example, the ability to perform a function or task) of the IP; or
- (b) the ability of the customer to obtain benefit from the IP is substantially derived from, or dependent upon, those activities. For example, the benefit from a brand is often derived from, or dependent upon, the entity's ongoing activities that support or maintain the value of the IP.

A licence that provides an entity with the right to access IP is satisfied over time "because the customer simultaneously receives and consumes the benefit from the entity's performance as the performance occurs", including the related activities undertaken by entity.³⁰ This conclusion is based on the determination that when a licence is subject to change (and the customer is exposed to the positive or negative effects of that change), the customer is not able to fully gain control over the licence of IP at any given point in time, but rather gains control over the licence period. In contrast, when the licence represents a right to use the IP as it exists at a specific point in time, the customer gains control over that IP at the beginning of the period for which it has the right to use the IP. This timing may differ from when the licence is granted.

Revenue cannot be recognised from a right-to-use licence of IP before the beginning of the period during which the customer is able to use and benefit from the licence because it does not control the licence.

The standard specifies that sales-based and usage-based royalties on licences of IP are recognised when the later of the following events occurs: (1) the subsequent sales 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 (or partially satisfied). This application guidance must be applied to the overall royalty stream when the sole or predominant item to which the royalty relates is a licence of IP (i.e., these types of arrangements are either entirely in the scope of this application guidance or entirely in the scope of the general variable consideration constraint requirements).

Contract costs

IFRS 15 specifies the accounting for costs an entity incurs to obtain and fulfil a contract to provide goods and services to customers. The incremental costs of obtaining a contract (i.e., costs that would not have been incurred if the contract had not been obtained) are recognised as an asset if the entity expects to recover them. The standard provides a practical expedient that permits an entity to immediately expense contract acquisition costs when the asset that would have resulted from capitalising these costs would have been amortised in one year or less.

³⁰ IFRS 15.B60.

An entity accounts for costs incurred to fulfil a contract with a customer that are within the scope of other standards (e.g., inventory, property, plant and equipment, internal-use software) in accordance with those standards. If the costs are not in the scope of other standards, an entity recognises an asset from the costs incurred to fulfil a contract only if those costs meet all of the following criteria:

- ▶ The costs relate directly to a contract or to an anticipated contract that the entity can specifically identify
- ▶ The costs generate or enhance resources of the entity that will be used in satisfying (or in continuing to satisfy) performance obligations in the future
- ▶ The costs are expected to be recovered

Any capitalised contract costs are amortised, with the expense recognised as an entity transfers the related goods or services to the customer. Any asset recorded by the entity is subject to an impairment assessment at the end of each reporting period.

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As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 15,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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