Accounting for outcome-based payment arrangements in the life sciences sector

IFRS accounting considerations for outcome-based payment arrangements

by Frederik Schmachtenberg, Alexandra Lienhard and Sharanya Sreedaran

September 2021

EY
Building a better working world

Contents

Introduction

The use of outcome-based payment arrangements in the life sciences sector is growing in many jurisdictions, especially across Europe. Given the continued pricing pressure exerted by parties responsible for paying for drugs (referred to as "payors" in this publication), the trend of employing innovative pricing strategies to gain drug acceptance will likely continue in the future. This publication discusses some of the accounting considerations for such arrangements when they are within the scope of the International Financial Reporting Standards (IFRS) 15 *Revenue from Contracts with Customers*. The accounting for outcome-based payment arrangements can be complex and is highly dependent on the specific facts and circumstances of each arrangement.

Outcome-based payment arrangements

In outcome-based payment arrangements, the consideration to which an entity is entitled depends upon an outcome (e.g., the performance or actual results of the entity's drug). Such arrangements are often referred to as "risk-sharing arrangements" (RSA).

There are numerous ways to structure an outcome-based pricing arrangement. However, these structures generally fall into one of three categories:

- **Clinical efficacy risk-sharing:** This refers to sharing the risk associated with the therapeutic performance of the product. If the drug fails to meet a clinically defined outcome, the payor will typically receive a refund from the manufacturer.
- **Cost-effectiveness risk-sharing:** This includes setting a target for cost effectiveness, whereby, if the threshold is not met, typically the payor will receive a refund from the manufacturer. For example, a life sciences entity may lower the sales price of a drug in order to reflect similar pricing with a competing therapy.
- **Fixed budgets or price and volume agreements:** This refers to setting a budget based on utilisation and/or price, and can include provisions such as price, utilisation or budget caps. For example, a payor may agree to cover a predetermined number of treatments, with the cost of any additional treatments borne by the manufacturer.

In order to avoid any unintended financial reporting consequences, life sciences entities should include members of the finance function early in the process of structuring an arrangement and should proactively consult with their financial accounting advisory contacts and independent auditors regarding the expected accounting treatment.

How we see it

This publication focuses on some of the accounting implications of outcome-based payment arrangements. Prior to the implementation of such arrangements, entities should consider a number of questions in addition to those addressed in this publication, including:

- When is an outcome-based pricing arrangement appropriate for the entity?
- From a business perspective, what considerations are needed in defining the performance measure and performance period?
- Does the entity have the infrastructure, processes and controls required to manage the patient-level data needed to track outcomes?
- What are the tax implications?
- What compliance issues should be considered?

Scope

When assessing how to account for an outcome-based payment arrangement, the first step is to determine whether the arrangement is within the scope of IFRS 15. Collaborative arrangements, for example, are typically outside the scope of IFRS 15.[1] In the rest of this publication, we consider only those arrangements that are within the scope of IFRS 15.

[1] Please refer to *How IFRS 15 affects life sciences entities* for further discussion on this topic. Available on ey.com/IFRS.

Overview of IFRS 15

The core principle of IFRS 15 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 promised goods or services to a customer.

The principles in IFRS 15 are applied using the following five steps:

1. **Identify the contract(s) with a customer**
2. **Identify the performance obligation(s) in the contract**
3. **Determine the transaction price**
4. **Allocate the transaction price to the performance obligation(s) in the contract**
5. **Recognise revenue when (or as) the entity satisfies its performance obligation(s)**[2]

Life sciences entities, when determining the accounting treatment for their contracts with customers, need to go through each of these five steps and consider all the specific requirements of IFRS 15. This publication highlights only some of the key aspects when applying the five-step model to outcome-based payment arrangements.[3]

Identifying the contract with the customer

The model in IFRS 15 applies to each contract with a customer. Contracts may be written, oral or implied by an entity's customary business practices, but must be legally enforceable and meet specific criteria. The criteria are:

- Approval of the contract by all parties
- Identification of each party's rights in respect of goods and services to be transferred
- Identification of the associated payment terms
- The contract has commercial substance
- It is probable that the entity will collect the consideration to which it expects to be entitled in exchange for the goods or services that will be transferred to the customer[4]

When considering the criterion for identified payment terms, it is important to note that the standard does not require that the transaction price be fixed or stated in the contract with the customer. Provided there will be an enforceable right to payment and the contract contains sufficient information to enable the entity to estimate the transaction price, the contract would qualify for accounting under the IFRS 15 model (assuming the remaining criteria have been met). Therefore, the fact that the amount of consideration depends upon an outcome (e.g., the performance or actual results of the company's drug, a cost-effectiveness target, a price, utilisation or budget cap) would not, in itself, preclude the arrangement from being identified as a contract with the customer under IFRS 15.

---

[2] IFRS 15 (2016).IN7.

[3] Please refer to *Applying IFRS: A closer look at IFRS 15, the revenue recognition standard* for comprehensive guidance on applying the standard and *Applying IFRS: How the new revenue standard will affect life sciences entities* for further discussion on the application of IFRS 15 to life sciences entities. Available on ey.com/IFRS.

[4] IFRS 15.9.

Distinguishing between variable consideration and customer options

For outcome-based arrangements within the scope of IFRS 15 and that meet the IFRS 15 contract criteria, an entity must determine whether to apply:

1. the requirements for variable consideration or

2. the application guidance for customer options

If the payment terms of the arrangement imply a rebate, discount or free products applied prospectively after a certain number of doses, we believe the rebate, discount or free products, generally, would be accounted for as a customer option rather than as variable consideration. This is because the consideration for the goods in the present contract is not contingent upon, or affected by, any future purchases and the volume rebates, discounts or free products affect only the price of future (optional) purchases.

Conversely, we believe that, where the terms of the outcome-based payment arrangements are such that the prices for the products are adjusted retrospectively, such arrangements would give rise to variable consideration. This is because the final price of each product sold depends on its actual performance (or other factors). That is, the consideration is contingent on the occurrence or nonoccurrence of future events.

Appropriately distinguishing between variable consideration and customer option may require the use of judgement and is important because it affects the accounting for the contract at inception and throughout the life of the contract, as well as the required disclosures.

Variable consideration (and constraint)

If the consideration promised in a contract includes a variable amount, an entity is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer.[5]

A life sciences entity is required to estimate variable consideration using either of the following methods, depending on which method better predicts the amount of consideration to which it will be entitled:

- **The "expected value" method:** Using this method, a life sciences entity determines 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, the entity needs to identify the possible outcomes and the probabilities of those outcomes. This method may better predict expected consideration when an entity has a large number of contracts with similar characteristics or when an entity has a single contract with a large number of possible outcomes.
- **The "most likely amount" method:** In this method, a life sciences entity determines the amount of variable consideration using the single most likely amount in a range of possible consideration amounts. This method may be the better predictor when the entity expects to be entitled to one of two possible amounts.[6]

Life sciences entities need to consider all information (e.g., historical, current and forecast) that is reasonably available when applying these methods.

The second step in estimating variable consideration requires life sciences entities to apply a constraint to all variable consideration. That is, an entity is required to include in the transaction price some (or all) of an amount of variable consideration, but only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable consideration is subsequently resolved.[7]

When developing a reliable estimate for outcomes or assessing variable consideration constraint, a life sciences entity would need to consider a number of factors, including:

- **Existence of commercial treatment data —** estimating probabilities for a specific outcome (i.e., a performance measure predetermined between an entity and a payor) may be challenging for a new drug, as performance information will generally be limited to clinical trial data. Generally, clinical trial data alone is not considered a sufficient basis for assessing the likelihood of achieving a performance measure. That is because the clinical data is often not representative, as clinical trials are generally conducted with a tightly controlled group. For example, only patients with certain symptoms or characteristics are allowed in the study or there is a tight control over ensuring that patients take the drug the right way, etc. Furthermore, when using clinical data, an entity should assess whether factors, such as demographics and lifestyles of the patients in the clinical trial, are representative.
- **Experience in other markets where the drug is sold —** in cases where the drug is already marketed in other markets, entities may be able to leverage commercial treatment data from those markets in order to assess the likelihood of achieving a performance measure for the market in question. However, this will require entities to monitor the outcome data in those markets (including those where outcomes-based arrangements may not currently exist). Entities should also consider whether the patient populations in those markets are representative of the patient population in the market where the outcome-based arrangement exists.
- **Length of time for which outcome data is available —** in general, the shorter the period of time for which the outcome data is available (whether from clinical trials or commercial experience), the more difficult it will be to assess the likelihood of achieving a performance measure.

[5] IFRS 15.50.
[6] IFRS 15.53.
[7] IFRS 15.56.

Illustration 1: Clinical risk-sharing arrangement

DrugCo has a drug that treats a certain type of cancer. This cancer is generally incurable, but DrugCo's drug has been proven to increase life expectancy more than traditional therapies. The drug is initially administered over a 10-treatment course. Subsequently patients tumour burdens are evaluated to determine whether patients are responsive, whereupon responding patients may need further treatments. DrugCo enters into an agreement with a payor in market A whereby DrugCo agrees to reimburse the payor the full cost of treatment for those patients whose tumour burden does not show certain predetermined results after the initial course of treatment (e.g., primary tumour stops growing and secondary metastatic tumours shrink). The payor agrees to continue paying for any necessary follow-up treatments for responding patients (i.e., those patients whose tumour burden achieved the predetermined results).

DrugCo has clinical trial data indicating that 80% of patients taking the drug have an increased life expectancy. However, in this case, the clinical trial data does not provide information directly related to evaluating success against the performance measure established with the payor, and thus, has limited predictive value for the purpose. Historical commercial treatment data in markets outside of market A has shown a 65% success rate for achieving the performance measure established with the payor.

The cost of treatment (i.e., revenue to DrugCo) for the 10-treatment course is CU100,000.

Accounting considerations

Since the cost of treatment is adjusted retrospectively, requirements for variable consideration apply. DrugCo assesses that expected-value method is the most appropriate due to a large number of patients, and, thus, possible outcomes under the contract. The amount of this estimated variable consideration that DrugCo can include in the transaction price is limited to the amount for which it is highly probable that a significant reversal will not occur.

Similar considerations would have been relevant if, instead of a full reimbursement, DrugCo provided a retrospective rebate for those patients whose tumour burden had not achieved the established performance measure.

- **Whether the performance measure is based on an appropriately large population size** — generally, it may be more difficult to develop an estimate for a performance measure or assess the likelihood of its achievement based on results of an individual patient or small population of patients due to the inherent uncertainty about how an individual patient will respond to a drug.
- **Objectivity of the performance measure** — in general, the less objective the performance measure, the more difficult it will be to develop reliable estimates of outcomes or assess the likelihood of its achievement. For example, an outcome-based measure that is based on how much pain the patient feels on a scale from 1 to 10 is less objective than measuring blood sugar levels.
- **Length of the performance period** — generally, the longer the required performance period, the more difficult it will be to develop reliable estimates of outcomes or assess the likelihood of its achievement.
- **Monitoring of the drug being administered** — the more monitoring there is of the drug being administered (e.g., to make sure the patients administer the drug in the proper frequency and amounts as prescribed by the healthcare personnel), the more reliable the measurement of the outcomes will be (as the measured outcomes might otherwise be significantly distorted).

If DrugCo, in the example above, determined that the available outcome data was sufficient to conclude that it is highly probable that no significant revenue reversal would

occur with respect to the estimated variable consideration of CU65,000 (based upon a 65% success rate achieved in other markets), it would be able to include this amount within the transaction price and would recognise it as revenue when (or as) it satisfies the related performance obligation. The remaining CU35,000 would be included in the transaction price when it becomes highly probable that a significant reversal in this amount will not occur, which may be when the uncertainty associated with this variable consideration is resolved.

When a life sciences entity determines that it cannot meet the highly probable threshold if it includes all of the variable consideration in the transaction price, the amount of variable consideration that must be included in the transaction price is reduced. The amount included in the transaction price is limited to the amount that, if subsequently reversed when the uncertainty associated with the variable consideration is resolved, would not result in a significant reversal of cumulative revenue recognised. Therefore, even when there is significant uncertainty about the ultimate outcome of a contract, a life sciences entity should not automatically default to constraining the estimate of variable consideration to zero.

The assessment of variable consideration constraint may require significant judgement. The above factors are not intended to be all-inclusive and the specific facts and circumstances of each arrangement must be considered.

Customer options for additional goods

In some outcome-based payment arrangements, life sciences entities provide the customer with the right to future purchases of additional drugs or treatments for free or at a reduced price. Under IFRS 15, such an option gives rise to a separate performance if the option provides a material right to the customer that it would not receive without entering into that contract.[8] If an option is a separate performance obligation, a portion of the transaction price is allocated to the option. Recognition of the allocated amount as revenue is deferred until the option is exercised or expires.[9]

A variation of the scenario in Illustration 1 above is shown in Illustration 2 below.

Concluding remarks

As shown in Illustrations 1 and 2, the accounting for outcomes-based arrangements can be judgemental and complex. Careful consideration of the facts and circumstances related to each arrangement will be necessary to determine the appropriate accounting treatment, as even relatively small variations in an arrangement's terms or the related fact pattern may lead to a different conclusion.

[8] IFRS 15.B40.

[9] For more information on accounting of customer options for additional goods and services refer to section 4.6 of *Applying IFRS: A closer look at IFRS 15, the revenue recognition standard*. Available on ey.com/IFRS.

Illustration 2: Fixed budget/price and volume agreements

DrugCo has a drug that treats a certain type of cancer. This cancer is generally incurable, but DrugCo's drug has been proven to increase life expectancy more than traditional therapies. The drug is initially administered over a 10-treatment course. Subsequently patients tumour burdens are evaluated to determine whether patients are responsive, whereupon responding patients may need further treatments. DrugCo enters into an agreement with a payor in market A, whereby the payor agrees to pay DrugCo for the first 10-treatment course, with the expectation that a patient's tumour burden would demonstrate certain predetermined results after this initial course of treatments. DrugCo has agreed to provide, at no cost to the payor, up to six additional necessary follow-up treatments. The option expires two years after the completion of the initial 10-treatment course.

In exchange for the 10-treatment course, DrugCo is entitled to CU100,000, which is similar to that charged by DrugCo to other payors in other markets.

Accounting considerations

Since the terms of the agreement include free treatments to be provided in the future at the discretion of the customer if certain conditions are met, the application guidance for customer options to purchase additional goods applies. If the option for additional free-of-charge treatments represents a material right, it should be accounted for as a separate performance obligation. DrugCo would need to apply IFRS 15 requirements to allocate a portion of the transaction price to the option and defer the recognition of that amount as revenue until the follow-up treatments are provided, or the option expires.

Contacts

Frederik Schmachtenberg, PhD
Partner
Ernst & Young Ltd
+41 58 286 34 90
frederik.schmachtenberg@ch.ey.com

Alexandra (Sasha) Lienhard
Senior Manager
Ernst & Young Ltd
+41 58 286 3161
alexandra.lienhard@ch.ey.com

Sharanya Sreedaran
Manager
Ernst & Young Ltd
+41 58 289 30 42
sharanya.sreedaran@ch.ey.com

EY | Building a better working world

EY exists to build a better working world, helping to create long-term value for clients, people and society and build trust in the capital markets.

Enabled by data and technology, diverse EY teams in over 150 countries provide trust through assurance and help clients grow, transform and operate.

Working across assurance, consulting, law, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today.

About EY's International Financial Reporting Standards Group

A global set of accounting standards provides the global economy with one measure to assess and compare the performance of companies. For companies applying or transitioning to International Financial Reporting Standards (IFRS), authoritative and timely guidance is essential as the standards continue to change. The impact stretches beyond accounting and reporting to the key business decisions you make. We have developed extensive global resources — people and knowledge — to support our clients applying IFRS and to help our client teams. Because we understand that you need a tailored service as much as consistent methodologies, we work to give you the benefit of our deep subject matter knowledge, our broad sector experience and the latest insights from our work worldwide.

EYG no. 007706-21Gbl

BMC Agency
GA 203825390

ED None

ey.com