Applying IFRS in Life Sciences

The new revenue ¨zx¥|¤~ª~¥¤ standard - {¥¨ life ©x~z¤xz© x¥£¦v¤~z©¨z¦¥¨ª~¤|«¤yz¨^[gh

November 2014

EY
Building a better working world

Contents

What x¥£¦v¤-z© ¨z¦¥¨ª-¤| «¤yz¨ ^[gh need to know

- Application of IFRS 15 will require life sciences entities to use greater judgement.
- The key issues for life sciences entities include determining how the new standard applies to: collaboration arrangements; arrangements with variable consideration; licences of intellectual property; and reseller arrangements.
- Life sciences entities may have to change their processes and information systems to capture information they need to apply IFRS 15 and to make the required disclosures.
- Early preparation will be the key to successful implementation of IFRS 15.
- IFRS 15 is effective for annual periods beginning on or after 1 January 2017, with early adoption permitted.

Overview

Life sciences entities will have to change some aspects of their revenue recognition practices.

Life sciences entities may need to change certain revenue recognition practices as a result of the introduction of the new revenue standard, IFRS 15 *Revenue from Contracts with Customers*, that was jointly issued by the International Accounting Standards Board (the IASB) and the Financial Accounting Standards Board (the FASB) (collectively, the Boards). The new standard will supersede virtually all revenue recognition requirements in IFRS and US GAAP that life sciences entities apply today.

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

Our *Applying IFRS, A closer look at the new revenue recognition standard* (June 2014)[1], provides an in-depth discussion of the requirements of IFRS 15, while this publication summarises the key implications of the new standard for life sciences entities.

To support stakeholders in the implementation of the new standard, the Boards have established a Joint Transition Resource Group for Revenue Recognition (TRG). The TRG was created to help the Boards determine whether more guidance or education is needed on implementation issues and other matters submitted by stakeholders. The TRG will not make formal recommendations to the Boards or issue application guidance. Separately, the American Institute of Certified Public Accountants (AICPA) has established 16 industry task forces to help develop a new accounting guide on revenue recognition and to aid industry stakeholders in implementing the new standard. A working group has not been established for life sciences. Views and guidance produced by the AICPA are non-authoritative.

The views we express in this publication are preliminary. We may identify additional issues as we analyse the new standard and entities begin to interpret it, and our views may evolve during that process.

Key considerations for life sciences entities

Life sciences entities may recognise some portion of milestone payments before achieving the performance metric or milestone.

Life sciences entities may have to change their processes and controls for making estimates in order to comply with IFRS 15's requirement for estimating variable consideration.

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

Collaboration agreements

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

[1] Available on www.ey.com/ifrs

Life sciences entities may find it challenging to determine whether their collaboration agreements are within the scope of IFRS 15. Identifying the customer can be difficult, especially when multiple parties are involved. This evaluation may require significant judgement, but IFRS 15 does not provide additional application guidance to assist entities in making it. A life sciences entity's collaboration agreement may contain a vendor-customer aspect that would be at least partially within the scope of IFRS 15, if that collaborator or partner meets the definition of a customer.

Estimating variable consideration

In life sciences arrangements, a portion of the transaction price can often vary in amount and timing due to rebates, incentives, rights of return, performance bonuses, milestones, other contingencies (e.g., future royalties) or concessions. IFRS 15 requires an entity to estimate variable consideration using the method (i.e., most likely amount or expected value) that best predicts the amount to which the entity will be entitled. An entity includes in the transaction price, amounts for which it is highly probable that a significant revenue reversal will not occur (i.e., a constraint on variable consideration is applied before including it in the transaction price).

Under current IFRS, an entity cannot recognise consideration that is contingent on a future event (e.g., a milestone payment, a performance bonus) unless it is probable that the economic benefits associated with the transaction will flow to the entity and the amount of revenue can be reliably measured. Some entities, therefore, defer recognition until the contingency is resolved. Under IFRS 15, life sciences entities will have to estimate the consideration to which they expect to be entitled from these bonuses and milestone payments and, after considering the constraint, may recognise some portion of these payments before they achieve the performance metric or milestone. As a result, a life sciences entity may recognise revenue related to some of these items sooner than it does today.

The requirement to estimate variable consideration will likely require life sciences entities to make changes to their accounting policies, accounting systems and/or internal controls over financial reporting. For example, life sciences entities may need to adjust their processes and controls for calculating rebates on product sales due to the requirement in IFRS 15 to estimate variable consideration.

Rights of return

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

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

Reseller and distributor arrangements

Under IFRS 15, life sciences entities that sell their products through distributors or resellers (collectively, resellers) may recognise revenue sooner than they currently do. Today, some entities that use resellers wait until the product is sold to the end-customer to recognise revenue, because they do not meet all of the criteria in the risk and rewards model in IAS 18 *Revenue* to recognise revenue on delivery to the reseller. Thereafter, these entities start recognising revenue when they transfer the products to the reseller once they gain enough experience to estimate returns and other variable components of pricing (e.g., chargebacks).

Under IFRS 15, life sciences entities must first evaluate when control of the product transfers to the customer. In this respect, they need to assess whether their contracts with resellers are consignment arrangements. In a consignment arrangement, control generally does not transfer (and, therefore, revenue is not recognised) until the reseller sells the product to an end-customer. The end result is consistent with current practice.

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

Licences of intellectual property

Life sciences entities' arrangements frequently include licences of intellectual property (IP) for other goods and services, such as research and development or manufacturing services. Entities need to determine if contracts involving IP are contracts with customers or are, instead, financing arrangements. For those that are contracts with customers, entities will need to consider whether such contracts include distinct licences of IP in order to apply the new standard appropriately. Example 56 in IFRS 15[2] illustrates the accounting treatment for a life sciences arrangement involving a licence of IP and manufacturing services.

After determining that a licence of IP is distinct, an entity will have to analyse whether the licence is either a right to access the IP or a right to use the IP. Revenue allocated to a licence that conveys a right to access will be recognised over the licence period. Revenue allocated to a licence that conveys a right to use will be recognised when the licence is granted. Determining the nature of the right conveyed by the licence will be based on the relevant facts and circumstances and implementation questions already have arisen.

IFRS 15 provides an exception to the variable consideration requirements for sales and usage-based royalties from licences of IP, which generally will be recognised when the relevant sales or usage occurs. This will likely result in an accounting treatment that is consistent with current practice.

[2] IFRS 15.IE281-IE288

It is unclear whether this exception will apply to royalties that relate to both licensed IP and other goods or services in a contract (e.g., a contract with two performance obligations, a distinct product candidate licence and research and development services that would be provided over time and would affect the amount of royalties earned). The TRG has discussed a number of views, including whether the exception should apply solely to a licence that is a separate performance obligation or whether it should apply even when the licence is not a separate performance obligation (i.e., when the royalty also relates to a non-licence good or service). It is not yet clear whether the Boards will provide additional application guidance. Life sciences entities should monitor developments.

Next steps

- Entities should perform a preliminary assessment of how they will be affected as soon as possible so they can determine how to prepare to implement the new standard. While the effect on entities will vary, some may face significant changes in revenue recognition. All entities will need to evaluate the requirements of the new standard to determine the effects.
- Entities may also wish to monitor the discussions of the Boards, regulators and TRG as they discuss the interpretation and application of the new standard to common transactions.
- Entities also should consider their communication plans with investors and other stakeholders, including their plan for disclosures about the effects of new accounting standards, as required by IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*.

EY | Assurance | Tax | Transactions | Advisory

About EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

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 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. AU2573
ED None

ey.com