

In depth

A look at current financial reporting issues



Revenue from contracts with customers

The standard is final – A comprehensive look at the new revenue model

Pharmaceutical and life sciences industry supplement

No. 2014-01 (supplement)
June 11, 2014

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At a glance

On May 28, the FASB and IASB issued their long-awaited converged standard on revenue recognition. Almost all entities will be affected to some extent by the significant increase in required disclosures. But the changes extend beyond disclosures, and the effect on entities will vary depending on industry and current accounting practices.

In depth 2014-01 is a comprehensive analysis of the new standard. This supplement discusses some of the more significant impacts to entities within the pharmaceutical and life sciences industry.

Overview

The pharmaceutical and life sciences industry includes a number of sub-sectors, the largest being pharmaceuticals, biotechnology, contract research organizations, and medical devices. The common feature is that each sub-sector develops, produces, and markets a diverse array of products, technologies, and services that relate to human health. Revenue recognition issues arise not only from the sale of drugs and medical devices, but increasingly from arrangements between entities in the industry to develop and bring products to market. Entities in the pharmaceutical and life sciences industry often enter into arrangements to develop drugs, either as a supplier of services, a consumer of those services, or through execution of license arrangements. These complex transactions are impacted by the new revenue standard.

This supplement focuses on how the standard will impact entities in the pharmaceutical and life sciences industry and it contrasts the new revenue standard with current practice under U.S. GAAP and IFRS. The examples and related discussions are intended to provide areas of focus to assist entities in evaluating the implications of the new standard.

Scope

While specific contracts with customers are scoped out of the new standard (e.g., lease contracts, insurance contracts, financial instruments, guarantees excluding warranties, and certain non-monetary exchanges), the standard applies to just about all contracts with customers. A customer is defined as a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. The standard does not apply to contracts where the parties participate in an activity or process (such as developing an asset in a collaboration agreement) and both parties share in the risks and benefits that result from the activity or process.

One challenge for entities in the pharmaceutical and life sciences industry will be evaluating their collaboration arrangements to determine if those arrangements represent contracts with customers. A contract that might be outside the scope of the standard is one with a collaborator or partner with shared risks and benefits in developing a product, because it is not for the sale of goods or services that are an output of the entity's ordinary activities. For example, an agreement between a biotechnology entity and pharmaceutical entity to share equally in the risks and benefits associated with development of a specific drug is likely not in the scope of the standard if the parties have a collaborative relationship rather than a vendor-customer relationship. If, however, the substance of the arrangement is that the biotechnology entity is licensing its IP or selling its compound to the pharmaceutical entity and/or providing research and development ("R&D") services, it will likely be in scope if such activities result in a good or service that is an output of the biotechnology entity's ordinary activities.

Determining whether an arrangement is in the scope of the revenue standard is complex. Arrangements may contain elements of a customer relationship and elements of a collaborator relationship. When analyzing arrangements, entities should identify the activities of the parties, understand the risks and benefits resulting from the activities, and determine if the parties are sharing in those risks and benefits. It will also be important to determine which party receives goods or services and whether those goods or services represent an output of the ordinary activities of the delivering party.

For those contracts, such as collaboration arrangements, that include some components that are in the scope of the revenue standard and other components that are in the scope of other standards, an entity will first apply the separation and/or measurement guidance in the other standard, if any. The transaction price will be reduced by the portion initially measured by the other standard(s) and the revenue standard will apply to the remaining transaction price. For example, an entity might lease a medical device to its customer and also provide related training services and consumables. In this arrangement, the lease is subject to lease accounting while the other components (training services and consumables) are subject to the revenue standard.

Licenses and rights to use

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

Accounting for licenses could be challenging under the new revenue standard. Determining whether a license is distinct from other goods and services in an arrangement is a key part of applying the model. Licenses coupled with other services, such as R&D, must first be assessed to determine if the license is distinct. If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is recognized as the licensor satisfies the combined performance obligation. Distinct licenses fall into one of two categories: (1) rights to use IP or (2) access rights. The accounting for each category of license is described in the chart below.

New standard	Current U.S. GAAP	Current IFRS
<p>There are two types of licenses described in the new standard.</p> <p>The first is a license that provides a customer the right to use an entity's IP as it exists at the point in time the license is granted. For these licenses, revenue is recognized at a point in time when control transfers to the licensee and the license period begins. These licenses provide the customer with a right to IP and the IP does not change after the license transfers to the customer.</p> <p>The second type is a license that provides access to an entity's IP as it exists throughout the license period. Licenses that provide access are performance obligations satisfied over time and, therefore, revenue is recognized over time.</p> <p>A license provides access to an entity's IP if three criteria are met:</p> <ul style="list-style-type: none"> • The licensor will undertake (either contractually or based on customary business practice) activities that significantly affect the IP to which the customer has rights. • The licensor's activities do not otherwise transfer a good or service to the customer as they occur. • The rights granted by the license directly expose the customer to any effects (both positive and negative) of those activities on the IP and the customer entered into the contract with the intent of being exposed to those effects. <p>If a licensing arrangement includes multiple goods or services (such as a license of IP and R&D services), an entity needs to consider whether the license is distinct. If not, it should be combined with other goods or services into a single performance obligation.¹</p>	<p>Consideration is allocated to the license and revenue is recognized when earned, typically when the license is transferred if the license has standalone value.</p> <p>If the license does not have standalone value, the license is combined with other deliverables, typically R&D or manufacturing services into a single unit of account. Revenue for the single unit of account is recognized when earned, typically as the R&D or manufacturing services are performed.</p>	<p>Fees and royalties received for the use of an entity's assets (such as trademarks, patents, record masters and motion picture films) are normally recognized in accordance with the substance of the agreement. As a practical matter, this may be on a straight-line basis over the life of the agreement, for example, when a licensee has the right to use certain IP or technology for a specified period of time.</p> <p>An assignment of rights for a fixed fee that permits the licensee to exploit those rights freely is, in substance, a sale if the licensor has no remaining obligations. Determining whether a license is a sale requires the use of judgment.</p> <p>When a license is sold with services or other deliverables, the vendor is required to exercise judgment to determine whether the different components of the arrangement should be accounted for separately.</p>

¹ The revenue standard includes an example specific to the pharmaceutical and life sciences industry to assist entities in evaluating whether a license is distinct.

New standard	Current U.S. GAAP	Current IFRS
<p>Revenue is recognized as the entity satisfies the combined performed obligation.</p> <p>In order for the license to be considered distinct, the customer must be able to benefit from the IP on its own or together with other resources that are readily available to the customer, and the entity’s promise to transfer the IP must be separately identifiable from other promises in the contract. The new revenue standard provides indicators that assist in determining whether the IP is separately identifiable from other promises in the contract.</p> <p>Revenue cannot be recognized before the beginning of the period during which the customer can use and benefit from the licensed IP, notwithstanding when the license is transferred.</p>		

Impact:

In general, we believe the revenue standard will not have a significant impact on revenue recognition for those licensing arrangements involving a license to IP for the life of the underlying asset in exchange for only an up-front cash payment. However, the terms of the contract, the rights granted to the licensee, and the activities the licensor undertakes that significantly impact the IP will impact whether revenue should be recognized at a point in time or over time. A shared economic interest, such as a sales-based royalty, between a licensor and the licensee, might indicate that the licensor will undertake activities that benefit the licensee over the license period.

Revenue might not be recognized immediately upon transfer of the right for more complex licensing arrangements that include other deliverables such as R&D services, manufacturing services, or arrangements in which the licensor undertakes activities that significantly impact the underlying IP. Guarantees that the patent to the IP is valid and actions to defend that patent from unauthorized use are not considered “activities” that significantly impact the underlying IP.

When licenses are sold with R&D services, the stage of the research on the licensed technology could affect the assessment of whether the license is distinct. For example, certain biotechnology entities do not sell licenses without R&D services for early-stage products. During the discovery stage, an entity may have specialized know-how and technology such that it is the only entity able to provide the R&D services to the customer for the specific licensed product. In this fact pattern, the license might not be a separate performance obligation because the customer cannot benefit from the license without the R&D services and neither the customer nor other third parties have the necessary skills to perform the R&D services. If the license is not distinct, the license and the R&D services should be combined and accounted for as a single performance obligation. The total transaction price is recognized as revenue as the performance obligation is satisfied over the period R&D services are performed. In addition, because the license is combined with the R&D services, the entity might no longer qualify for the exception provided to licenses of IP when determining if sales- or usage-based royalties are excluded from variable consideration. Refer to the “Royalties” section of this supplement for more information.

Another scenario is an arrangement that includes a license of IP and R&D services that involve clinical development activity or clinical trials. In the pharmaceutical and life sciences industry, it is often possible for others to perform clinical development activity or clinical trials. The license and the R&D services might be distinct in this fact pattern if

the entity's promise to transfer the IP is separately identifiable from the R&D services. This is because the licensee could benefit from the license on its own, and could choose to either perform or outsource the clinical trials. In this case, the transaction price is allocated to the two performance obligations on a relative standalone selling price basis, and revenue is recognized as each performance obligation is satisfied. The license of IP would need to be evaluated to determine (1) if it provides the customer with the right to use the IP (with revenue recognized upon commencement of the license) or provides access to the IP (with revenue recognized over time) and (2) whether consideration includes sales- or usage-based royalties for which the exception for variable consideration would be applicable.

Complex licensing arrangements will require careful consideration to determine whether the performance obligations should be accounted for separately. Entities will need to use judgment in evaluating the criteria and indicators in the standard to ensure that combining or separating goods and services results in accounting that reflects the underlying economics of the transaction.

Variable consideration and the constraint on revenue recognition

Variable consideration includes payments in the form of milestone payments, royalties, rebates, price protection, and other discounts and incentives. Common examples of arrangements with variable consideration in the pharmaceutical and life sciences industry include licensing arrangements with milestone payments and sales-based royalties, and distributor arrangements with rebates, price protection, or other incentives.

Under the new revenue standard, the transaction price is the amount of consideration an entity expects to be entitled to in exchange for transferring promised goods or services to a customer. The transaction price, at the inception of the arrangement, might include an element of consideration that is variable or contingent upon the outcome of future events.

If the promised amount of consideration in a contract is variable, an entity should estimate the total transaction price. This estimate can be based on either the expected value (probability-weighted estimate) or the most likely amount of cash flows expected from the transaction, whichever is more predictive. The estimated transaction price should be updated at each reporting date to reflect the current facts and circumstances.

The estimate of variable consideration is subject to a constraint. The objective of the constraint is that an entity should recognize revenue as performance obligations are satisfied to the extent there will not be a significant reversal in the future when the uncertainty is subsequently resolved. An entity will meet this objective if it is probable (U.S. GAAP) or highly probable (IFRS) that there will not be a significant revenue reversal in future periods. Such a reversal would occur if there is a significant downward adjustment of the cumulative amount of revenue recognized for a specific performance obligation.

Entities will need to apply judgment to determine if variable consideration is subject to a significant reversal. The following indicators might suggest that variable consideration could result in a significant reversal of cumulative revenue recognized in the future:

- The amount of consideration is highly susceptible to factors outside the influence of the entity.
- Resolution of the uncertainty about the amount of consideration is not expected for a long period of time.
- The entity has limited experience with similar types of contracts.
- The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions in similar circumstances for similar contracts.
- The contract has a large number and broad range of possible consideration amounts.

Entities will need to determine if there is a portion of the variable consideration (i.e., a minimum amount) that will not result in a significant revenue reversal. That amount will be included in the estimated transaction price. The estimate will be reassessed each reporting period, including any estimated minimum amounts.

Milestone payments

New standard	Current U.S. GAAP	Current IFRS
<p>Milestone payments generally represent a form of variable consideration as the payments are likely to be contingent on future events. Milestone payments are estimated and included in the transaction price based on either the expected value (probability-weighted estimate) or most likely amount approach. The most likely amount is likely to be most predictive for milestone payments with a binary outcome (i.e., the entity receives all or none of the milestone payment).</p> <p>Allocating milestone payments</p> <p>The transaction price is allocated to separate performance obligations based on relative standalone selling prices. If the transaction price includes consideration that is contingent upon a future event or circumstance (e.g., the completion of a phase III clinical trial), the entity should allocate that contingent amount (and subsequent changes to the amount) entirely to one performance obligation if both of the following criteria are met:</p> <ul style="list-style-type: none"> • The contingent payment terms for the milestone relate specifically to the entity’s efforts to satisfy that performance obligation or to a specific outcome from satisfying that separate performance obligation. • Allocating the contingent amount entirely to the separate performance obligation reflects the amount of consideration to which the entity expects to be entitled in exchange for satisfying the performance obligation when considering all of the performance obligations and payment terms in the contract. 	<p>A substantive milestone is defined in ASC 605-28, <i>Revenue Recognition – Milestone Method</i>, and can include milestone payments received upon achievement of certain events such as the submission of a new drug application to the regulator or approval of a drug by the regulator.</p> <p>An entity that uses the milestone method recognizes revenue from substantive milestone payments in the period the milestone is achieved. Non-substantive milestone payments that are paid based on the passage of time or as a result of the licensee’s performance are allocated to the units of accounting within the arrangement and recognized as revenue when those deliverables are satisfied.</p> <p>An entity that does not use the milestone method may use other revenue recognition models to recognize milestone payments (e.g., the contingency adjusted performance model).</p>	<p>Milestone payments received for a license with no further performance obligations on the part of the licensor are recognized as income when they are receivable under the terms of the contract and their receipt is probable.</p> <p>The “milestone method” is often an appropriate method of accounting if it approximates the percentage of completion of the services under the arrangement. The milestone events must have substance, and they must represent achievement of specific defined goals.</p> <p>Management should consider the following factors to determine when milestone payments are recognized as revenue:</p> <ul style="list-style-type: none"> • The reasonableness of the milestone payments compared to the effort, time and cost to achieve the milestones. • Whether a component of the milestone payments relates to other agreements or deliverables. • The existence of cancellation clauses requiring the repayment of milestone amounts received under the contract. • The risks associated with achievement of the milestones. • Obligations under the contract that must be completed to receive payment or penalty clauses for failure to deliver.

New standard	Current U.S. GAAP	Current IFRS
<p>Recognizing milestone income</p> <p>Variable consideration is only recognized as revenue when the related performance obligation is satisfied and the entity determines that it is probable (U.S. GAAP) or highly probable (IFRS) that there will not be a significant reversal of cumulative revenue recognized in future periods. Entities will need to apply judgment to assess whether the amount of revenue recognized is subject to a significant reversal in the future.</p>		

Impact:

Current practice under IFRS and U.S. GAAP is to recognize revenue upon meeting a probability threshold or achieving a certain outcome. Under the new standard, revenue will be recognized on contingent milestones when the performance obligation is satisfied and the entity determines that it is probable (U.S. GAAP) or highly probable (IFRS) that there will not be a significant reversal of revenue in future periods.

Entities will need to evaluate each milestone in a contract to determine whether including an estimate of variable consideration in the transaction price could result in a significant reversal of revenue in the future. For example, an entity might recognize the variable amount prior to achieving a milestone when the milestone relates to the completion of a specific service, and the entity has an established history of providing the service in similar contracts without a significant revenue reversal. This might be the case for a contract research organization performing clinical trial related functions, such as enrolling and testing patients. On the other hand, milestones based on a specific clinical outcome are highly susceptible to factors outside the control of the entity, such as clinical trial results and regulatory approval. Entities may conclude that amounts related to these types of milestones are subject to significant revenue reversal in the future.

Royalties

New standard	Current U.S. GAAP	Current IFRS
<p>Royalty revenue is a form of variable consideration and therefore will be estimated using either the expected value (probability-weighted estimate) or most likely amount approach.</p> <p>Estimated royalties are included in the transaction price if it is probable (U.S. GAAP) or highly probable (IFRS) that a significant reversal of cumulative revenue recognized will not occur in future periods. Entities will need to determine if there is a portion of the variable consideration (i.e., a minimum amount) that will not result in a significant cumulative revenue</p>	<p>Royalties are recognized as they are earned and when collection is reasonably assured. Royalty revenue is generally recorded in the same period as the sales that generate the royalty payment.</p>	<p>Revenue from royalties accrues in accordance with the terms of the relevant agreement and is usually recognized on that basis unless it is more appropriate to recognize revenue on some other systematic basis.</p>

New standard	Current U.S. GAAP	Current IFRS
<p>reversal, and should be included in the transaction price.</p> <p>There is a specific exception for licenses of IP with consideration that varies entirely based on the customer's subsequent sales or usage of the IP (e.g., a sales- or usage-based royalty). For these licenses, the consideration is not included in the transaction price until it is no longer variable (that is, when the customer's subsequent sales or usages occur). This exception is limited to licenses of IP with sales- or usage-based royalties and does not apply to other royalty arrangements.</p>		

Impact:

The new standard contains a limited exception for variable consideration related to sales- or usage-based royalties from licenses of IP. These royalties are not included in the transaction price until the customer's subsequent sales or usage occurs regardless of whether the entity has predictive experience with similar arrangements. This is similar to current practice under U.S. GAAP and IFRS as royalty revenue is generally recognized as the underlying sales are made. The exception is limited to licenses of IP and does not apply to other arrangements.

Despite a number of examples in the implementation guidance, the terms “intellectual property” and “royalty” are not defined under U.S. GAAP or IFRS. As such, judgment will be required to determine whether an arrangement qualifies for the exception. Certain fixed payments might be in-substance variable sales- or usage-based royalties. For example, an arrangement might require a licensee to make a fixed payment that is subject to “claw back” if the licensee does not meet certain sales or usage targets. There is no explicit guidance for these types of fixed payments and therefore the accounting is dependent on an analysis of all of the facts and circumstances.

Another complexity for the pharmaceutical and life sciences industry relates to evaluating how the exception applies to a contract with multiple performance obligations. For example, a biotechnology entity licenses IP and agrees to perform R&D services for a pharmaceutical entity in exchange for consideration that includes a sales-based royalty. The biotechnology entity concludes that the license and the R&D services should be combined and accounted for as a single performance obligation. Since the license is not a separate performance obligation, the entity might conclude that it no longer qualifies for the exception for sales-based royalties. Evaluating whether a license to IP is subject to the exception will be challenging and depend on an analysis of all the facts. The boundaries for determining when the sales- and usage-based exception applies might be an area of the new standard that is subject to further clarification.

Distinguishing between a license of IP and a sale of IP will also be important under the new standard. If an entity sells, rather than licenses the IP, then the exception for excluding sales- and usage-based royalties from the transaction price is not applicable. Accordingly, for sales of IP, a minimum amount of royalty revenue will be initially recognized if it is probable (U.S. GAAP) or highly probable (IFRS) that a significant reversal of cumulative revenue will not occur. The initial estimate of royalty revenue is updated over time as the amount that is not at risk of a significant revenue reversal increases.

Rebates, price protection and other discounts and incentives

New standard	Current U.S. GAAP	Current IFRS
<p>Rebates, price protection, concessions, and other discounts and incentives are types of variable consideration. Therefore, the consideration will be estimated and included in the transaction price based on either the expected value (probability-weighted estimate) or most likely amount approach if it is probable (U.S. GAAP) or highly probable (IFRS), that a significant reversal of cumulative revenue will not occur in the future.</p> <p>The transaction price should include any minimum amount of variable consideration not subject to significant reversal, even if the entire amount cannot be included in the transaction price due to the restraint.</p>	<p>The seller's price must be fixed or determinable for revenue to be recognized. Rebates, price protection clauses, and other discounts and incentives must be analyzed to conclude whether all of the revenue from the current transaction is fixed or determinable.</p> <p>Rebates or refunds are recognized on a systematic and rational basis. Measurement of the total rebate or refund obligation is based on the estimated number of purchases that the customer will ultimately make under the arrangement.</p> <p>If the rebate or incentive payment cannot be reasonably estimated, a liability is recognized for the maximum potential refund or rebate.</p>	<p>Revenue is measured at the fair value of the consideration received or receivable. Fair value is the amount an asset could be exchanged for, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.</p> <p>Trade discounts, volume rebates, and other incentives (such as cash settlement discounts or government clawbacks) are taken into account in measuring the fair value of the consideration to be received.</p> <p>Revenue related to variable consideration is recognized when it is probable that the economic benefits will flow to the entity and the amount is reliably measurable, assuming all other revenue recognition criteria are met.</p>

Impact:

Entities in the pharmaceutical and life sciences industry likely already consider the impact of rebates, price protection, and other concessions on revenue recognition. Entities might see some changes to their accounting and processes related to rebates or concessions as estimates are required upfront and revenue could be affected earlier (i.e., reduced revenue in an earlier period due to an expectation that a concession will be granted). Other changes include those situations where entities did not recognize revenue because the price was not fixed or determinable. Under the new revenue standard, these entities might recognize revenue earlier if there is a minimum amount of variable consideration that is not subject to significant reversal in the future.

Example 1 – Estimating rebates to a customer

Facts: A medical device entity enters into an arrangement to sell a product to a customer. At the end of each year, the customer is entitled to a rebate on its annual purchases. The medical device entity has determined based on its experience with similar contracts that it is probable that including an estimate of variable consideration will not result in a significant cumulative revenue reversal in the future. The estimated amount of the rebate is determined based on the number of units purchased during the year as follows:

Units Purchased	Per Unit Rebate	Expected Probability
0 – 100,000	10%	80%
100,000 – 500,000	15%	15%
500,000+	20%	5%

How should the medical device entity account for the potential rebate to the customer?

Discussion: The medical device entity should estimate the amount of the rebate using an expected value (probability-weighted estimate) or most likely outcome approach, whichever is more predictive. A probability-weighted estimate results in a rebate of approximately 11% ((10% x 80%) + (15% x 15%) + (20% x 5%)). The most-likely outcome approach results in an estimated rebate of 10%. If the medical device entity is unsure whether the estimated amount will result in a significant reversal of revenue, the entity should only include in the transaction price an amount that is probable (U.S. GAAP) or highly probable (IFRS) of not resulting in a significant reversal of revenue (i.e., a minimum amount).

Example 2 – Discounts provided to group purchasing organizations

Facts: A medical device entity sells disposable medical products to hospitals through a network of distributors at list price. The medical device entity has agreements in place with various group purchasing organizations (GPOs) to give a discount of 20% to specific hospitals affiliated with these GPOs. When a GPO-affiliated hospital purchases the disposable medical products from a distributor, it purchases them at the discounted amount. The distributor then requests reimbursement by the medical device entity of the discounted amount. The medical device entity has some historical data related to the mix of sales to GPOs and non-GPOs; however, the range varies significantly from period to period.

How should the medical device entity recognize revenue for this arrangement?

Discussion: The medical device entity should recognize revenue at the time of delivery, which is when the distributor obtains control and can direct the use of the medical products.

The medical device entity will estimate variable consideration, including the estimated discount to be paid on sales to GPO-affiliated hospitals. The amount of revenue recognized will be the amount that is probable (U.S. GAAP) or highly probable (IFRS) of not resulting in a significant reversal of cumulative revenue in the future. Although the medical device entity's history varies significantly, that history may indicate there is a minimum amount of revenue that can be recognized upon shipment of the product.

Sales to distributors and consignment stock

Some pharmaceutical and medical technology entities recognize revenue using a “sell-through” approach. Under the sell-through approach, revenue is not recognized until the product is sold to the end customer, either because inventory is on consignment at distributors, hospitals, or others, or because the final selling price is not determinable until the product is sold to the end customer.

Under the new standard, revenue is recognized upon the transfer of control to the customer. Entities that previously accounted for arrangements using a sell-through approach will need to consider at what point control has passed to the customer based on the indicators provided in the standard, which could impact the timing of revenue recognition.

New standard	Current U.S. GAAP	Current IFRS
Revenue is recognized when or as performance obligations are satisfied, which occurs when control of a good or service transfers to the customer. Control refers to the ability to direct the use of and obtain substantially all of the remaining benefits (i.e., potential cash flows) from the asset. Control also includes the ability to prevent others from directing the use of, or obtaining benefits from, the asset. The benefits from an asset include, but are not limited to:	Revenue is recognized once the risks and rewards of ownership have transferred to the customer.	Revenue is recognized once the risks and rewards of ownership have transferred to the customer.

New standard	Current U.S. GAAP	Current IFRS
<ul style="list-style-type: none"> Using the asset to produce goods, provide services, enhance the value of others assets, settle liabilities, or reduce expenses Physical possession Ability to pledge the asset to secure a loan, sell the asset, or exchange the asset 		

Impact:

The new standard requires an entity that has entered into a consignment stock arrangement with its customer to assess when control transfers to that customer. In the pharmaceutical and life sciences industry, the customer could be a distributor, hospital, or another entity. If the customer has control of the product, including the right (but not the obligation) to return the product to the seller at its discretion and the customer does not have a significant economic incentive to exercise the right feature, control transfers when the product is delivered to the customer. The entity would evaluate the return right as variable consideration. This might result in earlier revenue recognition than under current standards, which focus on the transfer of risks and rewards.

Entities in the pharmaceutical and life sciences industry might account for product sales to a distributor utilizing the sell-through model under current guidance if a reliable estimate of product returns cannot be made. Under the new standard, revenue is recognized when control of the product transfers to the customer. This could result in an entity that currently utilizes a sell-through model recognizing revenue upon shipment to the distributor under the new standard. The amount of revenue recognized will be the amount that is probable (U.S. GAAP) or highly probable (IFRS) of not resulting in a significant reversal of cumulative revenue in the future.

Collaborations and licensing arrangements

Pharmaceutical and biotechnology entities frequently enter into strategic collaborations and licensing arrangements. In determining how to account for such collaborations, the following key issues should be considered:

- Identifying whether the agreement falls within the scope of the new standard
- Identifying the separate performance obligations and determining how to account for them

The standard requires entities to assess whether the counterparty to the arrangement is (1) a customer or (2) a collaborator or partner sharing in the risks and benefits of the arrangement. If such arrangements are outside the scope of the revenue standard, the related income might not meet the definition of revenue, but instead be recorded as a reduction of R&D expense or as other income. The following example illustrates the principles of the five-step approach for an arrangement with multiple performance obligations that is in the scope of the standard.

Example 3 – A collaboration arrangement with multiple performance obligations

Facts: A biotech entity (“Biotech”) enters into a collaboration arrangement with a pharmaceutical entity (“Pharma”). Biotech grants an IP license (“License A”) to Pharma and will perform R&D on the IP. Biotech receives an upfront payment of \$40 million, per-hour payments for R&D services performed, and a milestone payment of \$150 million upon regulatory approval.

How should Biotech account for the arrangement?

Discussion: Biotech determines the arrangement is in the scope of the new revenue standard as Biotech and Pharma have a vendor-customer relationship. Biotech is providing a license and R&D services to Pharma and those goods or services are the output of Biotech’s ordinary activities. The license provides Pharma with the right to use Biotech’s IP and Biotech performs other activities related to the licensed IP that might be separate performance obligations. Biotech determines there are two separate performance obligations in the arrangement: (1) transfer of License A and (2) performance of R&D services. This is because the license could be sold separately and could be used by Pharma with its own resources as Pharma could choose to perform the research itself.

Biotech estimates the payments for R&D services will be \$12 million based on its expected effort taking into consideration past experience with similar arrangements. Thus, at contract inception, Biotech estimates a total transaction price of \$52 million, which includes the upfront payment (\$40 million) and the payments for R&D services (\$12 million).

Biotech estimates the consideration for the contingent milestone (\$150 million) to be zero using the most likely amount approach at inception. Given that regulatory approval is highly uncertain and susceptible to external factors, Biotech cannot estimate an amount that is probable (U.S. GAAP) or highly probable (IFRS) of not resulting in a significant reversal in the future.

Biotech determines that the estimated transaction price at inception (\$52 million) should be allocated to both performance obligations based on the relative standalone selling prices. Biotech determines a standalone selling price of \$45 million for License A and \$15 million for R&D services based on its estimate of the amount of hours necessary to perform R&D services plus a profit margin of 25%. The transaction price at inception is allocated 75% to License A and 25% to R&D as follows (\$ million):

Performance obligation	Stand alone price	Relative %	Upfront payment	Payments for research	Total
1. License A	45	75	30	9	39
2. Research services	15	25	10	3	13
	60	100	40	12	52

Transfer of the license

Biotech transfers License A at the inception of the contract. The license provides Pharma with the right to use Biotech’s IP. Upon transfer of control of the license to Pharma, Biotech recognizes \$39 million of revenue.

R&D services

Biotech recognizes \$13 million of revenue allocated to R&D services over the estimated service period based on a pattern that reflects the transfer of the services. The revenue recognized should reflect the level of service each period. In this case, Biotech uses an output model that considers estimates of the percentage of total R&D services that are completed each period compared to the total estimated services.

The transaction price should be re-assessed at each reporting date. Biotech will include \$150 million from the milestone payment in the total estimated transaction price at the point in time it determines it is probable (U.S. GAAP) or highly probable (IFRS) such amount is not subject to significant revenue reversal in the future. At that time, Biotech should determine if it should allocate the milestone payment entirely to a specific performance obligation (that is, License A or the R&D services) or to both performance obligations. The new revenue standard provides guidance to help entities with this judgment. The new standard indicates that a contingent amount should be allocated entirely to a specific performance obligation if: (1) the contingent amount relates specifically to an entity’s efforts to transfer a good or service; and (2) allocating the contingent amount entirely to the specific performance obligation is consistent with the overall allocation principle when considering all of the performance obligations and payment terms in the contract.

In this example, Biotech makes a judgment that the milestone payment applies to both performance obligations (the license and the R&D services). Therefore, Biotech will allocate the milestone payment to both performance obligations

based on their relative standalone selling prices determined at the inception of the arrangement. The determination that the milestone payment does not only relate to efforts to transfer License A is judgmental and will depend on the specific facts and circumstances of each arrangement.

Other considerations

Time value of money

The transaction price should be adjusted for the effect of the time value of money when the contract contains a significant financing component. A practical expedient allows entities to disregard the time value of money if the period between transfer of the goods or services and payment is less than one year, even if the contract itself is for more than one year. The following factors should be considered when evaluating if an arrangement includes a significant financing component:

- Whether the amount of consideration would substantially differ if the customer paid cash when the goods or services were transferred.
- The expected length of time between the transfer of the promised goods or services to the customer and the customer's payment.
- The prevailing interest rates in the relevant market.

In addition, a contract with a customer would not have a significant financing component if any of the following factors exist:

- The customer paid for the goods or services in advance, and the timing of the transfer of those goods or services is at the discretion of the customer.
- A substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer.
- The difference between the promised consideration and the cash selling price of the good or service arises for reasons other than the provision of finance to either the customer or the entity, and the difference between those amounts is proportional to the reason for the difference. For example, the payment terms might provide the entity or the customer with protection from the other party failing to adequately complete some or all of its obligations under the contract.

It might be challenging to determine whether a significant financing component exists in a contract, particularly in long-term arrangements with multiple performance obligations where goods or services are delivered and cash payments are received throughout the arrangement. Management will need to assess the timing of delivery of goods and services in relation to cash payments to determine if there is a difference in excess of one year that could indicate that a significant financing component exists. Under the new revenue standard, an entity would adjust the transaction price for the effect of the time value of money if the timing of payments agreed to by the parties provides the customer or entity with a significant benefit of financing the transfer of goods or services to the customer. The discount rate used for this purpose should equal the rate that would be reflected in a separate financing transaction between the entity and its customer at contract inception. That rate would reflect the credit characteristics of the party receiving financing in the contract.

Collectibility

Collectibility refers to a customer's credit risk. It is the risk that an entity will be unable to collect from the customer the amount of consideration that the entity is entitled to under the contract. The new standard contains a collectibility threshold that must be met prior to applying the revenue model. An entity needs to conclude it is probable under both U.S. GAAP and IFRS, at the inception of the contract, that the entity will collect the consideration to which it will

ultimately be entitled (i.e., the transaction price) in order for a contract to exist. The assessment of collectibility is based on both the customer's ability and intent to pay as amounts become due. An entity will only consider credit risk and no other uncertainties, such as those related to performance or measurement, as these are accounted for separately as part of determining the timing and measurement of revenue.

The collectibility threshold is not expected to significantly change current practice. An entity will assess whether collection of the transaction price is probable under both U.S. GAAP and IFRS, and, if it is, the entity will recognize revenue as the performance obligation(s) are satisfied, similar to today's practice. If, at contract inception, an entity concludes that collectibility of the transaction price is not probable, then a contract does not yet exist.

Initial and subsequent impairment of customer receivables, to the extent material, will be presented separately below gross margin as an expense. This expense will be separately presented on the face of the income statement if it is material.

Example 4 – The impact of price concessions on the transaction price

Facts: A pharmaceutical entity sells prescription drugs to a government entity in a country in Southern Europe for \$5 million. The pharmaceutical entity has historically experienced long delays in payment for sales to this entity due to slow economic growth and high debt levels in the country. The pharmaceutical entity has sold prescription drugs to this entity for the last five years and continues to sell prescription drugs at its normal market price. In the past, the pharmaceutical entity has ultimately been paid, but only after agreeing to significant price concessions.

How should the pharmaceutical entity account for the \$5 million sale to the government entity?

Discussion: The pharmaceutical entity will need to evaluate its contract with the government entity, at the inception of the arrangement, to determine if it is probable that it will collect the amounts to which it is entitled in exchange for the prescription drugs. The new revenue standard indicates that for purposes of determining the transaction price, the entity should consider the variable consideration guidance, including the possibility of price concessions.

Based on its historical experience, the pharmaceutical entity expects to ultimately provide a price concession of \$3 million to collect its receivable. As a result, the transaction price is \$2 million. The pharmaceutical entity would then evaluate whether it is probable it will collect the adjusted transaction price. Assuming the collectibility hurdle is met, the transaction price will be recognized as the pharmaceutical entity satisfies its performance obligation of delivering the drug.

The new revenue standard includes a similar example (Example 2) illustrating a situation where there is an implicit price concession and the transaction price is not the stated price. However, Example 2 does not address the time value of money. Specifically, before concluding that the transaction price is \$2 million, the pharmaceutical entity will need to consider if there is a significant financing element in the arrangement due to the anticipated length of time between the sale of the prescription drug and expected payment from the governmental entity.

Bill-and-hold arrangements

Pharmaceutical, biotechnology, and medical technology entities may have bill-and-hold arrangements with their customers where an entity bills a customer for a product, but does not ship the product until a later date. Entities can currently recognize revenue when product is billed (rather than on delivery) under arrangements that meet certain criteria.

The new revenue standard focuses on when control of the goods transfers to the customer to determine when revenue is recognized. Depending on the terms of the contract, control may be transferred either when the product is delivered to the customer site or when the product is shipped. However, for some contracts, a customer may obtain control of a product even though that product remains in an entity's physical possession. In that case, the customer has the ability to direct the use of, and obtain the remaining benefits from the product, even though it has decided not to take physical possession of the product.

For a customer to have obtained control of a product in a bill-and-hold arrangement, the following criteria must be met: (1) the reason for the arrangement is substantive, (2) the product has been identified separately as belonging to the

customer, (3) the product is ready for delivery in accordance with the terms of the arrangement, and (4) the entity does not have the ability to use the product or sell the product to another customer. Entities will need to consider the facts and circumstances of their arrangements to determine whether control of the product has transferred to the customer prior to delivery. The requirement to have a fixed delivery schedule often precludes revenue recognition for bill-and-hold arrangements under current U.S. GAAP; however, this requirement is not included in the new revenue standard.

Government vaccine stockpile programs

Government vaccine stockpile programs often require an entity to have a certain amount of vaccine inventory on hand for use by a government at a later date. The bill-and-hold criteria in U.S. GAAP for revenue recognition are typically not met even though these arrangements were at the request of the government. Such arrangements generally do not include a fixed schedule for delivery and the vaccine stockpile inventory may not be segregated from the entity's inventory. In many cases, entities rotate the vaccine stockpile to ensure it remains viable (does not expire). The SEC provides an exception for entities that participate in U.S. government vaccine stockpile programs, which permits them to recognize revenue at the time inventory is added to the stockpile, provided all other revenue recognition criteria have been met. For entities following U.S. GAAP, the exception applies only to U.S. government stockpiles and only to certain vaccines. For entities following IFRS, depending on the substance of the arrangement, revenue might be recognized when the inventory is added to the stockpile if the bill-and-hold requirements under IFRS are met.

Entities that participate in government vaccine stockpile programs will need to assess whether control of the product has transferred to the government prior to delivery under the new standard. The standard does not require a fixed delivery schedule to recognize revenue, but the requirement for transfer of control may not be met if the stockpile inventory is not separately identified as belonging to the customer and is subject to rotation. It is not clear whether the SEC will carry forward its exception once the new revenue standard is effective. Entities will also need to consider their performance obligations under the arrangement if control is deemed to transfer prior to delivery. For example, entities need to assess if the storage of stockpile product, the maintenance and rotation of stockpile product and delivery of product are separate performance obligations.

Right of return

Pharmaceutical, biotechnology, and certain medical technology entities may sell products with a right of return. The right of return often permits customers to return product within a few months prior to and following product expiration. Return rights may also take on various other forms, such as trade-in agreements. These rights generally result from the buyer's desire to mitigate the risk related to the products purchased and the seller's desire to promote goodwill with its customers. The sale of goods with a right of return will be accounted for similar to current guidance, which results in revenue recognition for only those products when the entity concludes it is probable (U.S. GAAP) or highly probable (IFRS) that there is not a risk of significant revenue reversal in future periods.

Pharmaceutical entities usually destroy returned inventory, but certain medical technology entities can resell returned product. The impact of product returns on earnings under the new standard will be largely unchanged from current U.S. GAAP and IFRS. However, the balance sheet will be grossed up to include the refund obligation and the asset for the right to the returned goods. The asset is assessed for impairment if indicators of impairment exist.

Product warranties

Many products are sold with implicit or explicit warranties indicating that the product sold to the customer meets an entity's quality standards and that the product is usable and not defective. Some entities also offer extended warranties, which provide for coverage beyond the standard warranty period.

The new standard draws a distinction between product warranties that the customer has the option to purchase separately (e.g., warranties that are negotiated or priced separately) and product warranties that the customer does not have the option to purchase separately. Judgment will need to be exercised when assessing a warranty not sold separately to determine if there is a service component to be accounted for as a separate performance obligation.

New standard	Current U.S. GAAP	Current IFRS
<p>An entity should account for a warranty that the customer has the option to purchase separately as a separate performance obligation.</p> <p>A warranty that the customer does not have the option to purchase separately should be accounted for in accordance with existing guidance on product warranties so long as the warranty only provides assurance that the product complies with agreed-upon specifications.</p> <p>A warranty, or a part of the warranty, which is not sold separately but provides the customer with a service in addition to the assurance that the product complies with agreed-upon specifications, creates a performance obligation for the promised service.</p> <p>An entity that cannot reasonably separate the service component from a standard warranty should account for both together as a separate performance obligation.</p>	<p>Warranties that protect against latent defects are accounted for as a loss contingency and do not generally constitute a deliverable. An entity records a liability for a warranty contingency and related expense when it is probable that a loss covered by the warranty has been incurred and the amount of the loss can be reasonably estimated.</p> <p>In determining whether the loss can be reasonably estimated, an entity normally takes into account its own experience or other available information.</p> <p>Warranties that provide protection for defects that arise after the product is transferred are considered separate deliverables for which revenue is deferred and recognized over the expected life of the contract.</p>	<p>Products are often sold with a “standard warranty,” which protects the customer in the event that an item sold proves to have been defective at the time of sale (usually based on evidence coming to light within a standard period). This is not usually considered separable from the sale of goods.</p> <p>When the warranty is not a separate element, and represents an insignificant part of the sale transaction, the full consideration received is recognized as revenue on the sale and a provision is recognized for the expected future cost to be incurred relating to the warranty.</p> <p>If an entity sells a product with an extended warranty, it is treated as a multiple-element arrangement and the revenue from the sale of the extended warranty is deferred and recognized over the warranty period. A provision is recognized for replacement only as defects arise through the warranty period. This differs from a standard warranty where provision is made at the time the goods are sold.</p>

Impact:

Similar to existing U.S. GAAP and IFRS, extended warranties give rise to a separate performance obligation under the new revenue standard and, therefore, revenue should be recognized over the warranty period. Warranties that are separately priced under U.S. GAAP may be impacted as the arrangement consideration will be allocated on a relative standalone selling price basis rather than at the contractual price. The amount of deferred revenue for extended warranties might differ under the new revenue standard compared to current guidance as a result. Product warranties that are not sold separately and provide for defects that exist when a product is shipped will result in a cost accrual similar to current guidance.

Disclosures

The revenue standard includes a number of extensive disclosure requirements intended to enable users of financial statements to understand the amount, timing, and judgments related to revenue recognition and corresponding cash flows arising from contracts with customers. We highlight below some of the more significant disclosure requirements, but the list is not all-inclusive.

The disclosures include qualitative and quantitative information about:

- contracts with customers;
- the significant judgments, and changes in judgments, made in applying the guidance to those contracts; and
- assets recognized from the costs to obtain or fulfill contracts with customers.

The disclosure requirements are more detailed than currently required under U.S. GAAP or IFRS and focus significantly on the judgments made by management. For example, they include specific disclosures of the estimates used and judgments made in determining the amount and timing of revenue recognition. Pharmaceutical and life sciences entities could face challenges in estimating standalone selling price for certain deliverables (such as licenses), as well as determining the transaction price for variable consideration, and the judgments and methods used to make the estimates will have to be disclosed.

The revenue standard also requires an entity to disclose the amount of its remaining performance obligations and the expected timing of the satisfaction of those performance obligations for contracts with durations of greater than one year, and both quantitative and qualitative explanations of when amounts will be recognized as revenue. This requirement could have a significant impact on the pharmaceutical and life sciences industry, where long-term contracts are a significant portion of an entity's business.

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