Practical guide to IFRS

Revenue recognition re-exposed ED – implications for pharmaceutical and life sciences industry

November 2011

Overview

The pharmaceutical and life sciences industry includes a number of sub-sectors; the largest being mainstream pharmaceuticals, life sciences, bio-technology and medical devices. The common feature is that they develop, produce and market a diverse array of products, technologies and services that relate to human health. The pharmaceutical sub-sector is high risk as most potential drugs never come to market but those that are successful are often highly profitable. Revenue recognition issues arise not only from the sale of drugs and medical devices but increasingly from the arrangements between entities in the industry to develop and bring to market drugs and other products. Medical devices may be easier products to bring to market, although those involved with the development of success-fee medical technologies, including in vitro diagnostics, have a higher risk profile. Entities in the industry engage in collaborative arrangements to develop drugs, either as a supplier of services, a consumer of those services or on either end of a licence arrangement. These transactions are complex and are mostly likely to be impacted by the proposed revenue recognition standard.

Additionally, many medical technology entities provide multiple products to their customers as part of a single arrangement. For example, entities may sell a medical device and replacement parts, and provide installation, training and service. Certain complex medical devices may incorporate software, and consequently may be subject to the software revenue recognition guidance under existing US GAAP. These transactions also may be impacted by the proposed revenue recognition standard.

The latest proposals on revenue recognition are included in an exposure draft 'Revenue from Contracts with Customers' issued on 14 November 2011 (the '2011 ED') by the IASB and FASB (the 'boards'). The 2011 ED incorporates a number of changes that were made in response to feedback received on the original proposals issued in June 2010 (the '2010 ED'). This supplement focuses only on those proposals that may have a significant impact on entities in the industry and it contrasts the 2011 ED with current practice under US GAAP and IFRS. References to the 'proposed model,' the 'proposed guidance,' and the 'proposed standard' throughout this supplement refer to the 2011 ED unless otherwise indicated. The appendix sets out the key differences between the 2010 ED and the 2011 ED.

The examples and related discussions in this document are based on our current understanding of the 2011 ED and are intended to provide areas of focus to assist companies in evaluating its potential implications. Our tentative conclusions and views are subject to change pending further interpretation and assessment based on the final standard. The boards have indicated that the final standard will have an effective date no earlier than 2015. Full retrospective application will be required with the option to apply limited transition relief. For a more comprehensive description of the proposed standard, refer to PwC's 'Practical guide' or visit www.fasb.org or www.ifrs.org.

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Proposed model

Pharmaceutical, life sciences and medical technology entities will need to assess each contract to determine the timing and amount of revenue to recognise under the proposed standard. The proposed model requires a contract-based approach under which the following steps would apply:

- Identify the contract with the customer;
- Identify the separate performance obligations in the contract;
- Determine the total transaction price;
- Allocate the total transaction price to each performance obligation in the contract; and
- Recognise as revenue the amount of the transaction price allocated to each performance obligation as it is satisfied, provided the entity is reasonably assured to be entitled to that amount.

Performance obligations are satisfied by transferring control of a good or service to a customer, which may either be at a point in time or continuously over time depending on the nature of the arrangement.

Licences and rights to use

Generally a licence is granted by an entity (the 'licensor') to a customer (the 'licensee') and provides the licensee with the right to use, but not own, the intellectual property of the licensor. For example, in the pharmaceutical and life sciences industry, an entity that has developed a pre-regulatory approval drug might license that drug and the underlying intellectual property to another company. Often under the terms of such a licence the licensee can further develop the drug, manufacture and sell the resulting commercialised product. The licensor typically receives an upfront fee and a sales-based royalty stream or milestone payments for specific clinical outcomes. Some licensing arrangements also include ongoing involvement of the licensor, who might provide research, development or manufacturing services relating to the licensed technology.

In licensing arrangements with multiple goods and services, entities will need to determine if the goods and services are distinct and should be accounted for separately or whether they are part of a bundle and should be combined into one performance obligation. The concept of bundling goods and services was primarily introduced into the 2011 ED to address issues in the construction industry. Licensing arrangements and construction contracts may have similar characteristics due to the long-term nature of the projects. This is an area that entities may need to seek further clarification on as the timing of revenue recognition is likely to be affected by whether there is one or more separate performance obligations.

Proposed model	Current US GAAP	Current IFRS
A licence or rights to use intellectual property granted to a customer gives rise to a performance obligation that is satisfied when the customer obtains control of the rights. If a licensing arrangement has multiple deliverables (for example, it also includes ongoing R&D services), an entity should consider whether the licence is a separate performance obligation or whether it should be combined with other performance obligations.	Consideration is allocated to the licence; revenue is recognised when earned, typically when the licence is transferred if the licence has stand-alone value. If the licence does not have stand-alone value, the licence is combined with other deliverables, typically the research or manufacturing services. Revenue for the single unit of account is recognised when earned, typically as the research or manufacturing services are performed.	Fees paid for the use of an entity's assets are normally recognised 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 technology for a specified period of time. An assignment of rights for a fixed fee that permits the licensee to exploit those rights freely and the licensor has no remaining obligations to perform is, in substance, a sale. Determining

Proposed model	Current US GAAP	Current IFRS
Where a licence is a separate performance obligation, revenue should be recognised at the point in time the licence is transferred to the customer (that is, the customer can benefit from the licence) and the consideration is reasonably assured. Where a licence is not a separate performance obligation, it should be combined with another performance obligation(s) and revenue should be recognised upon satisfaction of the related performance obligation(s). Where a licensing arrangement includes an element of variable consideration (for example, royalties), revenue is recognised when reasonably assured. See below for guidance on variable consideration. Furthermore, revenue cannot be recognised before the beginning of the period during which the customer can use and benefit from the licensed intellectual property, notwithstanding when the licence is transferred.		whether a licence is in substance a sale requires the use of judgment. When a licence 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.

Impact

For simple licensing arrangements that result only in the transfer of a technology or intellectual property licence for the life of the underlying asset in exchange for up-front cash, we do not expect the proposed standard to have a significant impact on revenue recognition. For more complex licensing arrangements, which include other deliverables such as research and development services, the proposed standard could have a significant impact for pharmaceutical and life sciences entities. The proposed standard could result in earlier revenue recognition than under current practice, or revenue might not be recognised immediately upon transfer of the right if the licence is not separable from other performance obligations in the contract.

The key issue for entities will be to determine whether the granting of the licence should be accounted for separately or combined with other goods and services. An entity should account for the licence as a separate performance obligation if it is distinct. The granting of a licence is distinct if the entity regularly sells the licence separately or the customer can benefit from the licence either on its own or together with other resources that are readily available. However, an entity will also need to consider whether the licence and other goods and services constitute a 'bundle' and thus are not distinct and accounted for as one performance obligation. Goods and services in a bundle are not distinct if they are highly interrelated and require significant integration services and the bundle of goods and services is significantly modified or customised. The proposed standard does not provide detailed guidance on how to assess whether integration services are 'significant' or when an entity is 'significantly' modifying or customising a good or service.

When licences are sold with research and development services, the stage of the research on the licensed technology may affect the assessment of whether the licence is distinct. For example, certain biotech entities may not sell licences without research services for early-stage products. During the discovery stage, an entity may have specialised know-how and technology making it the only entity able to provide the services for the specific licensed product. The licence may not be a separate performance obligation in this case because the customer cannot benefit from the licence on its own and in addition the research may be considered a significant modification or customisation. Therefore, the licence and the research services together are accounted for as a single performance obligation. The consideration is allocated to the single performance obligation, and revenue is recognised as the performance obligation is satisfied over the period research services are performed.

Another scenario may be when a licence has been granted with research services that comprise clinical development activity or clinical trials. In the industry it would normally be possible for others to perform those clinical trials. This might indicate that the licence and the development services are distinct from each other because at this stage the licensee could benefit from the licence on its own and could choose to either perform or outsource the performance of clinical trials. In this case, the consideration is allocated between the two performance obligations on a relative standalone selling price basis, and revenue is recognised as each performance obligation is satisfied.

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

Variable consideration

The transaction price in a contract reflects the amount of consideration that an entity expects to be entitled to in exchange for goods or services. The transaction price may include an element of consideration that is variable or contingent on the outcome of future events, including (but not limited to) discounts, rebates, refunds, incentives, performance bonuses, price concessions and royalties. Common examples of arrangements with variable consideration in the industry include strategic collaborations and licensing arrangements with milestone payments and sales-based royalties. Milestone payments might be contingent upon the achievement of certain development or sales targets. Royalties are typically based on product sales. Variable consideration is recognised under the proposed standard when the related performance obligation is satisfied and the entity is reasonably assured to be entitled to the amount of consideration allocated to that performance obligation.

Milestone payments

Proposed model	Current US GAAP	Current IFRS
If the promised amount of consideration in a contract is variable, the entity should estimate the total amount of the transaction price to which it will be entitled in exchange for transferring promised goods or services. 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 most predictive of the amount of consideration received. The estimated transaction price should be updated at each reporting date to reflect the circumstances at the reporting date and the changes in circumstances during the reporting period. **1. Allocating milestone receipts** The transaction price should be allocated to separate performance obligations in a contract based on relative standalone selling prices. If the transaction price includes an amount of consideration that is contingent on a future event or circumstance (for example, a specific	A substantive milestone is defined in 'Revenue Recognition – Milestone Method'; it includes 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. An entity that uses the milestone method under current guidance recognises revenue on substantive milestone payments in the period in which the milestone is achieved. Non-substantive milestone payments that may be paid to the licensor based on the passage of time or as a result of the licensee's performance would be allocated to the units of accounting within the arrangement and recognised as revenue when those deliverables are satisfied. An entity that does not use the milestone method may use another revenue recognition model for recognising milestone payments (for example, by analogy to the 'Revenue Recognition of Long-term Power Sales	Milestones received for a licence with no further performance obligations on the part of the licensor are recognised as income when they are receivable under the terms of the contract and their receipt is probable. When development services are being provided (with or without an associated licence) then the vendor/licensor accounts for the milestones using the percentage of completion method. The 'milestone payment 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. Management should consider the following factors to determine when milestone payments are recognised as revenue: • The reasonableness of the milestone

Proposed model	Current US GAAP	Current IFRS
outcome of the entity's performance, such as the completion of a phase III trial/regulatory approval), the entity should allocate that contingent amount (and subsequent changes to the amount) entirely to the related performance obligation if both of the following criteria are met: (a) 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; and (b) allocating the contingent amount of consideration 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. **2. Recognising milestone income** Variable consideration is recognised as revenue when the related performance obligation is satisfied and the entity is reasonably assured to be entitled to the consideration. An entity is reasonably assured to be entitled to the consideration when the entity has experience with similar types of contracts and the experience is predictive of the outcome of the contract. An entity should consider the following indicators that may suggest the experience may not be predictive of the outcome of a contract: • The amount of consideration is highly susceptible to factors outside the influence of the entity; • The uncertainty about the amount of consideration is not expected to be resolved for a long period of time; • The entity's experience with similar types of contracts is limited; and • The contract has a large number and high variability of possible consideration amounts. The proposed standard includes an	Contracts' model or the contingency adjusted performance model.)	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, such as a licence and royalty; • The existence of cancellation clauses requiring the repayment of milestone amounts received under the contract; • The risks associated with achievement of the milestones; and • Obligations under the contract that must be completed to receive payment or penalty clauses for failure to deliver.

Proposed model	Current US GAAP	Current IFRS
exception related to licences for intellectual property in exchange for consideration that varies entirely based on the customer's subsequent sales of a good or service. In that case, the entity would not be reasonably assured to be entitled to that variable consideration until the underlying sales are made.		

Impact

The proposed standard requires entities to determine the total transaction price, including an estimate of variable consideration, at the inception of the contract and on an ongoing basis. To determine the transaction price, entities may apply either the 'expected value' or 'most likely amount' approach, whichever is likely to be the most predictive of the amounts to which they will be entitled. The use of a weighted average assessment in arrangements including milestone payments with a binary outcome may not be most predictive of the actual outcome. Therefore the 'most likely amount' may be more indicative of the actual amounts expected to be received, either zero or 100 per cent of the milestone.

As a general principle, consideration should be allocated to separate performance obligations in a contract based on relative standalone selling prices. Under certain circumstances, however, the entity should allocate the entire amount of contingent consideration (for example, a milestone) to the related performance obligation when the milestone satisfies two conditions: (1) it relates specifically to the entity's efforts to satisfy that performance obligation or to a specific outcome from satisfying that separate performance obligation and (2) 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 other performance obligations and payment terms in the contract. For example, where an entity receives a milestone payment upon regulatory approval of a licensed asset that it continues to develop for its customer, it should consider whether the payment relates only to the licence, research and development services, or to both the licence and the research and development services. Entities will need to use judgment in applying the guidance for each specific arrangement.

Revenue is recognised under current US GAAP and IFRS once a certain trigger (that is, meeting a probability threshold or upon the achievement of a certain event) has been met. Under the proposed standard revenue will not be recognised on contingent milestones until the performance obligation is satisfied and the entity is reasonably assured to be entitled to the milestone payment. Entities will need to evaluate whether they have predictive experience with similar contracts in order to recognise revenue before the milestone occurs. For example, an entity may be reasonably assured to be entitled to a variable amount, prior to the completion of a milestone, when the milestone is related to the completion of a specific service and the entity has an established history of providing this service in similar contracts (this might be the case with a contract research organisation performing clinical trial related functions, such as enrolling and testing patients). On the other hand, when an arrangement has substantive milestones based on a specific clinical outcome, an entity might not be reasonably assured to be entitled to the milestone payments until the specified event occurs, as the consideration is highly susceptible to factors outside the control of the entity (for example, clinical trial results or regulatory approval).

Under the proposed standard, an entity transferring a licence would not be reasonably assured to be entitled to the amounts for sales milestones until the underlying sales to which the milestones relate have occurred. This is consistent with current US GAAP and IFRS.

Royalties

Proposed model	Current US GAAP	Current IFRS
Royalty revenue represents a form of variable consideration, and 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. Royalties are recognised as revenue when the related performance obligation is satisfied and the entity is reasonably assured to be entitled to the consideration associated with the royalty. If an entity licences intellectual property to a customer and the customer promises to pay an amount of consideration that varies entirely based on the customer's subsequent sales of a good or service that uses the licensed intellectual property (for example, a sales-based royalty), the entity is not reasonably assured to be entitled to the promised amount of consideration until the uncertainty is resolved (that is, when the customer's subsequent sales occur).	Royalties are recognised 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.	Revenue from royalties accrues in accordance with the terms of the relevant agreement and is usually recognised on that basis unless it is more appropriate to recognise revenue on some other systematic basis.

Impact

The proposed standard introduces an exception to the model for licences that contain sales-based royalties. An entity is not reasonably assured to be entitled to the amount until the underlying sales of the licensee have actually occurred (regardless of whether they have predictive experience with similar arrangements). The proposed standard might result in similar accounting to current US GAAP and IFRS under which royalty revenue is generally recognised as the underlying sales are made. However, if the technology was sold rather than licensed, earlier revenue recognition could occur if the entity has predictive experience with that type of arrangement. This could result in different accounting for economically similar transactions.

Collaborations and licensing arrangements

Pharmaceutical and life science entities frequently enter into complex strategic collaborations and licensing arrangements. In determining how to account for such collaborations the key issues include:

- Identifying whether the agreement falls within the scope of the proposed standard; and
- Determining what the separate performance obligations are and how to account for them.

The proposed standard requires entities to assess whether the counterparty to the arrangement is (a) a customer or (b) a collaborator or a partner sharing in the risk of the arrangement. If such arrangements are outside the scope of the proposed standard, the related income might not meet the definition of revenue but rather might be recorded as a reduction in R&D expenditure or other income.

The following example illustrates the principles of the proposed model for a collaboration agreement in the scope of the proposed standard with multiple performance obligations.

Example – A collaboration agreement with multiple performance obligations

Facts: A biotech entity ('Biotech') enters into a collaboration arrangement with a pharmaceutical entity ('Pharma') in September 2011. Biotech grants an intellectual property licence ('Licence A') to Pharma and will perform research services on the intellectual property. Biotech receives an upfront payment of C40 million, per-hour payments for research services performed, a milestone payment of C150 million upon regulatory approval, and a 10% royalty on sales of a commercial product (estimated value of C300 million).

Research services are to be provided at cost. The normal rate at which Biotech provides its services is cost+25%.

How does Biotech account for the arrangement?

Discussion: Biotech determines the arrangement is in the scope of the proposed standard as it is providing a licence and services to Pharma in the normal course of business. Biotech determines there are two performance obligations in the arrangement: (1) transfer of Licence A and (2) performance of research services. Management should determine whether the licence and research services are distinct performance obligations. In this case, the licence can be sold separately and can be used by Pharma with its own resources as Pharma could choose to perform the research itself. As such, each performance obligation is distinct and accounted for separately.

Management estimates the payments to be received for research services will be C12 million based on their expected effort taking into consideration experience gained while performing research services on other arrangements. Thus, at contract inception, Biotech estimates the total transaction price to be C52 million, which includes the upfront payment (C40m) and the payments for research services (C12m).

Management estimates the consideration for the contingent milestone (C150m) and royalties (C300m) to be zero using the most likely amount approach at inception. Given that regulatory approval is highly uncertain and susceptible to external factors, management cannot predict the amount to be received for milestones and royalties based on historical experience.

Management allocates the estimated transaction price at inception (C52m) based on relative standalone selling prices to the two performance obligations. Management determines the standalone selling price for Licence A to be C45 million and for research services to be C15m based on its estimate of the amount of hours necessary to perform research services plus a profit margin of 25%. The transaction price at inception is allocated 75% to Licence A and 25% to research services based on the proportion of standalone selling prices relating to each performance obligation, as follows:

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

Transfer of the licence – performance obligation

Biotech transfers Licence A at the inception of the contract. Upon transfer of the licence, Biotech recognises as revenue only the amount to which it is reasonably assured to be entitled allocated to the performance obligation, which is C39m.

Research services – performance obligation

Biotech recognises revenue allocated to research services over the estimated research period based on a pattern that reflects the transfer of the services as the performance obligation for these services is satisfied continuously over the research period. In this case, an output model is used that considers estimates of the percentage of total research services that are completed each period. As a result, C13 million is recognised over the research period.

The transaction price should be re-estimated at each reporting date. At the point in time Biotech determines regulatory approval will be achieved, Biotech includes the contingent milestone of C150m and the related royalties valued at C300m (time value of money has been excluded) in the total transaction price. Biotech determines that the milestone and royalties should be allocated to both performance obligations rather than a specific performance obligation since management believes the consideration relates to both the licence and research services in this arrangement. Therefore, C450m will be allocated to the two performance obligations on the same basis the transaction price was allocated at the inception of the contract as follows:

(In C millions) Performance obligation	Stand alone price	Relative %	Milestone	Royalties	Total
1. Licence A	45	75	112.5	225	337.5
2. Research services	15	25	37.5	75	112.5
	60	100	150	300	450

Transfer of the licence – performance obligation

Biotech recognises revenue of C112.5m related to the milestone receipt allocated to Licence A as the performance obligation to transfer the licence has been satisfied. Biotech does not recognise the C225m related to the royalties until the entity is reasonably assured to be entitled to the amount, which is when subsequent customer sales occur.

Research services – performance obligation

Biotech recognises a portion of C37.5m related to the milestone receipt allocated to research services based on the portion of the performance obligation that has been completed to date. Biotech does not recognise the C75m related to the royalties until the entity is reasonably assured to be entitled to the amount, which is when subsequent customer sales occur.

Other considerations

Government vaccine stockpile programmes

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

The proposed standard focuses on when control of the goods transfers to the customer to determine when revenue is recognised. The requirement to have a fixed delivery schedule often precludes revenue recognition under current US GAAP; however, this requirement is not included in the proposed standard. The proposed standard sets out the following criteria that should be met to conclude control has transferred: the reason for the arrangement is substantive, the product has been identified separately as belonging to the customer, the product is ready for delivery in accordance with the terms of the arrangement, and 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.

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. While these arrangements were at the request of the government, the bill-and-hold criteria in US GAAP for revenue recognition were not met. No revenue could be recognised upon transfer of inventory to the stockpile because typically such arrangements did not include a fixed schedule for delivery and the vaccine stockpile inventory may not be segregated from the entity's inventory. The entity rotated the vaccine stockpile in many cases to ensure it remained viable (did not expire). An exception has been provided by the SEC for entities that participate in US government vaccine stockpile programs, which permits them to recognise revenue at the time inventory is added to the stockpile, provided all other revenue recognition criteria have been met. For entities following US GAAP, the exception applies only to US government stockpiles and only to certain vaccines. For entities following IFRS, depending on the substance of the arrangement, revenue might be recognised 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. The proposed standard does not require a fixed delivery schedule, but the requirement for transfer of control of the inventory 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 if the proposed standard is adopted. Entities will also need to consider their performance obligations under the arrangement if control is deemed to transfer prior to delivery. The storage of stockpile product, the maintenance and rotation of stockpile product and delivery of product may be distinct performance obligations under the arrangement.

Sell-through approach and consignment stock

Pharmaceutical, life science and medical technology entities may currently recognise revenue using a sell-through approach. Revenue is not recognised under this approach 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 has been sold through to the end customer.

The proposed standard requires management to determine when

control of the product has transferred to the customer. Entities will need to consider at what point control of consignment stock has passed to the customer based on the indicators provided in the proposed standard, which will impact the timing of revenue recognition.

Proposed model	Current US GAAP	Current IFRS
Revenue is recognised on the satisfaction of performance obligations, which occurs when control of the good or service transfers to the customer. Factors to consider include, but are not limited to, the customer has: • an obligation to pay; • legal title; • physical possession; • the risks and rewards of ownership; and • accepted the asset.	Revenue is recognised once the risks and rewards of ownership have transferred to the end customer.	Revenue is recognised once the risks and rewards of ownership have transferred to the end customer.
Impact The proposed standard requires an entity that has entered into a consignment stock arrangement with a distributor, hospital, or other customer to assess when control transfers to the customer. 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, control transfers when the product is delivered to the customer. This might result in earlier revenue recognition than current standards, which focus on the transfer of risks and rewards. If the entity has the ability to require the customer to return the product (for example, a call right), control has not transferred to the customer. Revenue is therefore only recognised when products are sold through to an end customer, similar to current accounting.		

Right of return

Pharmaceutical, life science, 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 the entity is reasonably assured will not be returned.

Pharmaceutical entities usually destroy returned inventory, but certain medical technology entities can re-sell returned product. The impact of product returns on earnings under the proposed standard will be largely unchanged from current US 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.

Medical devices

Medical technology entities face certain issues in addition to those noted above. Accounting for an arrangement with multiple deliverables has historically been a challenging area. Entities may routinely enter into multiple element arrangements, such as selling a device, selling replacement parts, and providing installation, training and service for the device. Medical equipment may incorporate software, subjecting the entity to the software revenue recognition requirements under the existing literature. In addition, medical technology entities may offer return rights and product warranties and may sell through distributors, all of which can result in additional challenges. The following

provides a summary of some of the areas within the medical technology sector that may be affected by the proposed standard

Elimination of software-specific guidance – US GAAP

Certain medical technology entities sell complex medical equipment where software is a critical component of the product. A device with both software and non-software elements that work together to deliver the product's essential functionality are scoped out of the software revenue recognition guidance; however, any incidental software or subsequent sales of essential software are accounted for under the software guidance for US GAAP. The proposed standard would replace all industry-specific guidance, including specific software revenue recognition guidance, under US GAAP.

Proposed model	Current US GAAP	Current IFRS
Products with software components The proposed standard requires separation of distinct performance obligations when they are satisfied at different points in time. Management should estimate the standalone selling price if it does not separately sell an identified performance obligation on a standalone basis.	Contract consideration is allocated to the separate software and nonsoftware deliverables based on the relative selling prices of all deliverables in the arrangement. Entities must follow a hierarchy for estimating the selling price of a deliverable. This hierarchy requires the selling price to be based on vendor-specific objective evidence ('VSOE') if available, third party evidence ('TPE') if VSOE is not available, or estimated selling price if neither VSOE nor TPE is available.	Revenue is allocated to individual elements of a contract, but specific guidance is not provided for software arrangements or on how the consideration should be allocated. Separating the components of a contract might be necessary to reflect the economic substance of an arrangement. Separation is appropriate when the identifiable components are delivered at different times, have standalone value, and their fair value can be measured reliably. The price regularly charged when an item is sold separately is the best evidence of the item's fair value.
Impact The elimination of the VSOE requirement for software-related transactions might significantly affect the timing of revenue recognition in situations where revenue was previously deferred due to a lack of VSOE of fair value. The proposed standard is similar to current IFRS guidance.		

Product warranties

Many pharmaceutical, life science and medical technology products are sold with implicit or explicit product warranties that the product sold to the customer meets an entity's quality standards and other applicable regulatory requirements 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 proposed standard draws a distinction between product warranties that the customer has the option to purchase separately (for example, warranties that are negotiated or priced separately) and product warranties that the customer does not have the option to purchase separately. Management will need to exercise judgment when assessing a warranty not sold separately to determine if there is a service component to be accounted for as a separate performance obligation.

Proposed model	Current US GAAP	Current IFRS
An entity should account for a warranty that the customer has the option to purchase separately as a separate performance obligation. 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. 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. An entity that cannot reasonably separate the service component from a standard warranty should account for both together as a separate performance obligation.	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. In determining whether the loss can be reasonably estimated, an entity normally takes into account its own experience or other available information. Warranties that provide protection for defects that arise after the product is transferred are considered separate deliverables for which revenue is deferred and recognised over the expected life of the contract.	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. When the warranty is not a separate element and represents an insignificant part of the sale transaction, the full consideration received is recognised as revenue on the sale and a provision is recognised for the expected future cost to be incurred relating to the warranty. 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 recognised over the warranty period. A provision is recognised for rectification and/or 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. Similar to other contracts, extended warranty contracts should be reviewed to ensure they are not onerous.
Impact Similar to existing US GAAP and IFRS, extended warranties give rise to a separate performance obligation under the proposed standard and, therefore, revenue is recognised over the warranty period. Warranties that are separately priced under US 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 proposed 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 proposed standard requires disclosures to enable users of financial statements to understand the amount, timing and uncertainty of revenues and cash flows arising from contracts with customers. Required disclosures include qualitative and quantitative information about:

- Contracts with customers;
- The significant judgments, and changes in judgments, made in applying the proposed guidance to those contracts; and
- Assets recognised from the costs to obtain or fulfill contracts with customers.

The proposed disclosure requirements are more detailed than currently

required under US 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 will face challenges in estimating standalone selling price for certain deliverables (such as licences), 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 proposed 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. This might have a significant impact on the pharmaceutical and life science industry, where long-term collaboration contracts are a significant portion of an entity's business.

Appendix

The table below provides an overview of changes in the areas we reported in the September 2010 pharmaceutical and life sciences industry supplement.

Topic	2010 exposure draft	2011 exposure draft
Identification of separate performance obligations	An entity recognises revenue from performance obligations separately if the goods or services are distinct. A good or service is distinct if an entity sells an identical or similar good or service separately. A good or service that has a distinct function *and* a distinct profit margin from the other goods or services in the contract is also distinct, even if not sold separately.	*Key changes*: The proposed model still focuses on separate performance obligations for distinct goods and services; however, it provides additional guidance to consider that may result in otherwise distinct goods or services being bundled together in some cases. *Proposed guidance:* A separate performance obligation exists if the goods or services are 'distinct.' Goods or services are 'distinct' if: • The entity regularly sells the good or service separately; or • The customer can use the good or service on its own or together with resources readily available to the customer. A good or service in a bundle is not distinct if the following criteria are met: • The goods and services in the bundle are highly interrelated and require the entity to provide a significant service of integrating the goods or services; and • The bundle of goods or services is significantly modified or customised to fulfill the contract.
Variable consideration • Milestone payments • Royalties • Sales discounts, contractual allowances, rebates and pay for performance arrangements	The transaction price is the consideration that the entity expects to receive from the customer. The transaction price includes the probability-weighted estimate of variable consideration when management can make a reasonable estimate of the amount to be received. An estimate is reasonable only if an entity: • has experience with identical or similar types of contracts; and • does not expect circumstances surrounding those types of contracts to change significantly.	*Key changes:* The proposed guidance focuses on when the entity is 'reasonably assured' of being entitled to variable consideration rather than when it can 'reasonably estimate' the amount. The proposed standard provides guidance on when variable consideration would not be reasonably assured, which is when the amount of consideration in a licence arrangement is based on the customer's subsequent sales, such as sales-based royalties or milestones. In addition, the proposed guidance permits the use of 'the most likely amount,' rather than a weighted average assessment when measuring variable consideration, which may simplify the accounting. See further discussion on variable consideration

Topic	2010 exposure draft	2011 exposure draft
		above. *Proposed guidance:* The transaction price is the consideration that the entity is entitled to under the contract, including variable or uncertain consideration. It is based on the probability-weighted estimate or most likely amount of cash flows from the transaction, whichever is most predictive of the amount to which the entity is entitled. Revenue on variable consideration is only recognised when the entity is 'reasonably assured' to be entitled to it. If an entity licenses intellectual property to a customer and the customer promises to pay an amount of consideration that varies entirely based on the customers subsequent sales of a good or service that uses the licensed IP (for example, sales-based royalty), the entity is not reasonably assured to be entitled to the promised amount of consideration until the uncertainty is resolved (that is, when subsequent sales occur).
Licences and rights to use	The contract is a sale of intellectual property if the customer obtains control of the entire licensed intellectual property (for example, the exclusive right to use the licence for its economic life). The performance obligation is satisfied over the term of the licence if the customer licences intellectual property on an exclusive basis but does not obtain control for the entire economic life of the property. A contract that provides a nonexclusive licence for intellectual property (for example, off-the-shelf software) is a single performance obligation. An entity recognises revenue when the customer is able to use the licence and benefit from it.	*Key changes*: The concept of exclusivity has been removed from the proposals based on feedback from the industry. See further discussion on licences above. *Proposed guidance:* The promised rights are a performance obligation that the entity satisfies when the customer obtains control (that is, the use and benefit) of those rights. An entity should consider whether the rights give rise to a separate performance obligation or whether the rights should be combined with other performance obligations in the contract.
Transfer of goods • Sell-through	Revenue is recognised on the satisfaction of performance	*Key changes:* Most of the guidance on transfer of goods has been carried

Topic	2010 exposure draft	2011 exposure draft
approach and consignment stock	obligations, which can occur at a point in time or continuously over time. Indicators that the customer has obtained control of the good or service may include: • The customer has an unconditional obligation to pay; • The customer has legal title; • The customer has physical possession; and • The customer specifies the design or function of the good or service.	forward from the 2010 ED except that the proposed guidance adds a risk and rewards indicator and eliminates the design or function indicator. *Proposed guidance:* An entity recognises revenue for the sale of a good when the customer obtains control of the good. Indicators that the customer has obtained control of the good include: • The customer has an obligation to pay; • The customer has legal title; • The customer has physical possession; • The customer has significant risks and rewards of ownership; and • The customer provided evidence of acceptance.
Rights of return	Revenue is not recognised for product that is expected to be returned. An entity records a liability for expected refunds to customers using a probability weighted approach. The liability is adjusted as an entity's estimate of expected returns changes.	*Key changes:* There have been no significant changes from the 2010 ED. We do not expect a significant impact versus current US GAAP or IFRS in this area. *Proposed guidance:* Revenue is recognised for the consideration to which an entity is reasonably assured to be entitled (considering the products expected to be returned) and a liability is recognised for the refund to be paid to customers. The refund liability is updated for changes in expected refunds at each reporting period. An asset and corresponding adjustment to cost of sales is recognised for the right to recover goods from customers. The asset is initially measured at the original cost of the goods less any expected cost to recover those goods. Impairment is assessed at each reporting date.

Topic	2010 exposure draft	2011 exposure draft
Bill-and-hold arrangements	Revenue is recognised when control of the goods provided in a bill-and-hold arrangement is transferred. The following criteria must be satisfied: • The customer has requested the contract to be on a bill-and-hold basis; • The product is identified separately as the customer's; • The product is ready for delivery at the time and location specified by the customer; and • The entity does not have the ability to sell the product to another customer.	*Key changes:* There have been no significant changes from the 2010 ED. The proposed guidance and list of indicators for bill-and-hold transactions are consistent with the current guidance for IFRS. There may be situations where revenue is recognised earlier as compared to current US GAAP because there would no longer be a requirement for the vendor to have a fixed delivery schedule from the customer in order to recognise revenue. See further discussion on government vaccine stockpile programs above. *Proposed guidance:* Revenue is recognised when control of the goods is transferred to the customer. All of the following requirements must be met to conclude that the customer has obtained control: • The reason for the bill-and-hold arrangement must be substantive; • The product must be identified separately as the customer's; • The product must be ready for delivery at the time and location specified by the customer; and • The entity cannot have the ability to use the product or sell it to another customer.
Warranties	Revenue is deferred for warranties that require replacement or repair of components of an item (that is, standard warranties), but only for the portion of revenue attributable to the components that must be repaired or replaced. Warranties that provide the customer with coverage for faults (that is, extended warranties) that arise after the entity transfers control to the customer give rise to a separate performance obligation.	*Key changes:* The distinction between warranties that protect against latent defects (that is, standard warranties) and warranties that cover normal wear and tear (that is, extended warranties) has been removed. The proposed guidance requires an entity to account for some warranties as a cost accrual, which is more consistent with current US GAAP and IFRS. *Proposed guidance:* Warranties that the customer has the option of purchasing separately are accounted for as a separate performance obligation. Warranties that the customer does not have the option of purchasing are accounted for as a cost accrual so long as

Topic	2010 exposure draft	2011 exposure draft
		the warranty only provides assurance that the product complies with agreed-upon specifications. An entity that promises both a quality assurance and service-based warranty but cannot reasonably separate them, should account for both as a separate performance obligation.

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