

IFRS news

Emerging issues and practical guidance*

Supplement – IFRS by industry

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Hot topics in pharmaceuticals and life sciences



There is no IFRS specifically for the pharmaceutical industry ('pharma'). However, several recent and forthcoming developments in accounting will have significant accounting implications for the industry. In addition, accounting challenges have been raised by changes in US healthcare legislation. Michael Gaull of PwC's Accounting Consulting Services in the UK and Adrian Bennett, Director in PwC Cambridge's pharma and life sciences practice, outline the issues and the consequences.

The IASB is working through a lengthy agenda with far-reaching consequences for many industries. There is more focus on up-front estimation and on fair valuation. Standards are moving towards accounting for an entire transaction at fair value 'when it happens' – which generally occurs when control of a product or of a business transfers from one party to another – rather than when cash is received.

The pharma industry involves large investments in high-risk projects. The work of the IASB and the current accounting challenges particularly affect the pharma industry because historically its business model has resulted in transactions where risk is shared and cash is only paid once success is assured. It is common to license a product for its entire life for a fixed fee plus a royalty. The seller and buyer thereby share in the potential success (and the potential downside) of the licensed product.

Accounting practice has developed such that amounts are recorded when 'earned' or when reasonably certain. The selling entity in the example above would be likely to record the upfront payment as revenue and would record the royalty income as the related products are sold by the licensee.

Developments in business combinations and revenue recognition standards challenge this established accounting model.

Business combinations – contingent consideration

It is common in pharma for a business to be purchased with some of the consideration being contingent on future outcomes. For example, further cash payments may be made if some or all of the acquiree's in-process research and development (IPR&D) projects successfully achieve regulatory approval (for example, milestone payments). The economics of this arrangement allow the buyer and seller to share the risks (and the rewards) of the future performance of the acquired entity's portfolio.

IFRS 3R applies to all business combinations completing now, as it is effective for annual periods beginning on or after 1 July 2009. One of the main changes introduced by IFRS 3R is that contingent consideration is measured at fair value on the date of the business combination (when the acquirer gains control of the acquired business). The contingent consideration, or earn-out, is classified as a liability or as equity in accordance with the financial instruments standard, IAS 32. An earn-out that is a financial liability is remeasured to fair value through the income statement at each reporting date until the contingency occurs. Adjustments to estimates of contingent consideration that were previously recorded against goodwill are recorded in the income statement under IFRS 3R. This is likely to lead to income statement volatility and challenges in initial and subsequent measurement of consideration.

The revised standard may result in 'day 2' accounting volatility because of tensions between historical cost and fair value. A substantial payment to the previous owners may be required if an IPR&D project meets key approval milestones. The successful IPR&D project may generate substantial profits over 20 years. However, the increased amounts due under the contingent consideration arrangement are likely to be recognised as an expense in the income statement before the project generates any revenue at all.

Accounting for contingent consideration such as earn-outs and milestone payments poses various challenges for pharmaceutical and life sciences entities undertaking business combinations under IFRS 3 (revised). The following questions should be considered before buying a business.

What form should the consideration take?

All contingent consideration is measured at fair value at the acquisition date. Goodwill is not affected by the form of the consideration, whether it is debt, equity or some other asset or liability. However, accounting for contingent consideration after the acquisition date is different depending on how it has been classified at the acquisition date. This may influence how an acquirer structures the payments and should be considered before a transaction is undertaken. An arrangement in which the acquirer issues a fixed number of its own equity shares if a milestone is reached, for example, is likely to be classified as equity under IFRS 3R and would not be remeasured after the date of acquisition (see examples in boxes below). However, although using a fixed number of shares reduces accounting volatility, it means that the eventual value transferred on settlement is dependent on the acquirer's future share price as well as the resolution of the contingency.

How is contingent consideration valued?

Valuation may be a difficult issue. Many forms of contingent consideration are based on entity-specific variables that are not observable in any market, such as the outcome of research

projects. Nevertheless, IFRS 3R requires it to be measured at fair value. There is no exemption for impracticability or inability to measure reliably. All contingent consideration arrangements are recognised without regard to whether eventual payment or settlement is probable.

Are amounts contingent consideration or employee compensation?

IFRS 3R includes guidance on determining whether payments to owners are for the business or for their post-acquisition services. Arrangements are often made with vendors who are also employees of the acquired business. The owners might be, for example, the key scientists who have worked on the entity's research project. An analysis is needed to determine if payment arrangements are payments for the vendors in their capacity as shareholders or in their capacity as employees. Payments that are determined to be employee compensation are included in the post-acquisition income statement.

Example 1 – Entity buys business with milestone payments payable in cash

ABC Pharmaceuticals intends to buy XYZ Limited mainly in order to gain access to a significant in-process development project for a new HIV vaccine patent. XYZ Limited is a business. ABC Pharmaceuticals agrees to pay the owners of XYZ Limited C420 million in cash. A further C40 million is payable if the new HIV vaccine receives FDA (the US Food and Drug Administration) approval within five years.

The transaction is accounted for as a business combination in accordance with IFRS 3R.

How does ABC Pharmaceuticals account for the milestone payment?

ABC Pharmaceuticals has a contractual obligation to deliver cash to the owners of XYZ Limited contingent upon receiving FDA approval. The contingent consideration is therefore classified as a financial liability. It is recognised at its fair value at the acquisition date. As fair value takes account of the probabilities of different outcomes, contingent consideration is recognised whether it is probable that regulatory approval will be achieved or not. The probability of the vaccine receiving FDA approval will form part of the valuation of the contingent consideration liability at the time of acquisition. It will therefore be neither zero nor C40 – one of which is the amount that will ultimately be paid – but somewhere in between.

The contingent consideration should be remeasured to fair value at each balance sheet date, with changes recorded in the income statement. Say that the contingent consideration has a fair value of C5, because the probability of success is low at the acquisition date, then this is the amount that will affect goodwill. Should the project eventually be successful, the remeasurement of C35 will flow through the income statement.

Example 2 – Entity buys business with milestone payment made by a fixed number of equity instruments

ABC Pharmaceuticals acquires XYZ Limited. XYZ Limited is a business. ABC Pharmaceuticals pays C200 million in cash and agrees to issue Brown's owners 500,000 ordinary shares if one of XYZ Limited's development projects successfully goes through its Phase II trials within two years of the acquisition date. The transaction is accounted for as a business combination in accordance with IFRS 3R.

How does ABC Pharmaceuticals account for the milestone payment?

ABC Pharmaceuticals has agreed to issue equity instruments; there is no obligation to deliver cash or another financial asset, and the number of shares that will be delivered is fixed at 500,000. The contingent consideration is therefore classified as equity. It is recognised at its fair value at the acquisition date, and it is not subsequently remeasured. The total consideration for the business combination is C150 million plus the fair value of the potential issue of equity instruments.

Contingent consideration and other issues arising from application of IFRS 3R to pharma are considered in the forthcoming PwC publication *Business combinations: how will new standards affect you?*

Revenue recognition

The IASB has issued an exposure draft proposing a new, comprehensive, model for revenue recognition: ED/2010/06, 'Revenue from contracts with customers' (see *IFRS news*, July August 2010, p1). While any new standard is not likely to be effective until at least 2014, many contracts and arrangements in pharma can last for a number of years. Entities need to be aware of the proposals now, as they will affect existing and future revenue contracts.

The new model is based on the principle that an entity recognises revenue when it has satisfied a performance obligation to its customer. This occurs when control of the relevant good or service is transferred to the customer.

While the proposed revenue recognition standard will change the model under which pharma entities will recognise revenue in the future, it is not expected to lead to a significant change in the amount or timing of revenue from the majority of pharma entities' product sales and related discounts, rebates and returns. This is because control is likely to pass at the same time as risks and rewards are transferred under existing requirements.

Milestone and royalty income

One of the most significant effects will be changes in the recognition and measurement of royalties and milestones receivable under licensing or collaboration arrangements. Like an earn-out in a business combination, entities sell or license products, and both buyer and seller wish to share risk. One of the methods by which this is done is for the agreement to

include contingent payments – milestones and/or royalties. Under the new model, this variable or contingent consideration will not be recognised as the amounts are 'earned', which usually approximated the receipt of cash. These amounts will instead be recognised, on a probability-weighted basis, when the related performance obligation has been satisfied and the amount of consideration can be reliably estimated.

A reliable estimate can be made when an entity:

- has experience with identical or similar types of contracts. Management should refer to the experience of other entities if it has no experience of its own; and
- does not expect circumstances surrounding those types of contracts to change significantly. In assessing whether circumstances may change significantly, management should consider the impact of external factors, time until the uncertainty is expected to be resolved, the extent of experience and the variability in the range of possible outcomes.

The question for pharma entities is whether or not arrangements involving milestones and royalties are considered sufficiently 'similar' to estimate outcomes reliably. Research and development services by their nature have highly uncertain outcomes, and other R&D contracts may not be a guide to the potential outcomes of the contract in question. Entities will first determine when the performance obligation is satisfied. In such a case, no revenue may be recognised until potential outcomes can be estimated. However, this is likely to be before the relevant milestone event is achieved or failed and therefore before the point at which many entities are recognising revenue today under the milestone method of revenue recognition.

However, a sales-based royalty for a currently marketed product may be reliably estimable. Royalty revenue may be recognised when the related performance obligation is satisfied (for example, when a licence is granted) rather than at the point the milestone is achieved. The point at which an entity can reasonably estimate the royalty stream revenue will be a matter of judgement.

Licences

The proposed accounting standard includes guidance on licences of intangible assets. It distinguishes between licences that qualify in substance as an outright sale and those that qualify as a licence (either exclusive or non-exclusive) for a specified period of time. This will affect pharma entities that have entered into, or are contemplating, licensing arrangements or collaborations.

Where a licence is in substance a sale of technology or intellectual property, or where it is a sale of a non-exclusive licence (for example, a Microsoft software licence), revenue is recognised when the licence is delivered to the customer. For exclusive licences, revenue will be recognised over the period of the licence. However, when a licence gives the licensee exclusive control of the intellectual property for substantially all of its economic life (for example, for the period to patent expiry), the entire proceeds (including the fair value of contingent amounts such as royalties, if they can be measured reliably) are

recorded upfront as a sale. Many licences in pharma will be for the entire patent life of a product, and upfront recognition will be appropriate. However, there may be circumstances where determining whether a licence is a sale of technology or an exclusive licence requires further consideration, and a different pattern of revenue recognition may be required.

Example – exclusive licence

A licensor grants rights to develop intellectual property in one territory to Entity A and grants the rights to develop the same intellectual property in a different territory to Entity B. The rights are likely to be substantially different for each customer. Each will therefore represent an exclusive licence. Revenue recognition will then depend on whether the licence is for substantially all the useful economic life of the asset (for example, the term of the patent to the underlying IP). If not, revenue should be recognised over the licence term.

Collaborations

The revenue recognition issues described above – variable consideration (milestones and royalties) and licences – will both be major issues for pharma companies. Many pharma contracts will combine both these issues. Complex collaborations will require particular attention under the proposed standard.

Entities will need to determine:

- What are the distinct performance obligations?
- When are the performance obligations satisfied?
- What is the total amount of consideration, and when can the elements be reliably estimated?
- How is the consideration allocated between different performance obligations?

This is likely to prove challenging in practice. We encourage pharma entities to respond to the IASB on the revenue recognition proposals (comments are due by 22 October). More details of the impact on pharma entities are contained in the publication *Revenue recognition – full speed ahead: Pharmaceuticals and life sciences supplement*.

US healthcare reform

Legislation was enacted in the US in March that will lead to significant change for healthcare users and providers, in addition to suppliers to the healthcare industry. PwC recently issued a publication providing guidance on this (*US healthcare reform: Accounting issues*). The main accounting issues for pharma entities are summarised below. Some are effective immediately.

- *Annual fee on pharmaceutical manufacturers* – a charge will be levied on the manufacturing sector for each calendar year beginning after 2010. The fee ranges from \$2.5 billion to \$4.1 billion and is payable no later than 30 September of the applicable calendar year. This is a non-deductible fee, which will be levied across the industry based on market share.
- *Revenue and channel considerations* – several changes are introduced that will impact the estimates a pharma entity will make about the ultimate amount it expects to receive

for its sales. In particular, there will be some changes to the calculation of Medicaid rebates. This may pose practical difficulties; it is conceptually no different from other rebates.

- *Changes to the Retiree Drug Subsidy* – changes the tax treatment of the Retiree Drug Subsidy (RDS) require the amount of the subsidy received to be offset against the employer's deduction for health care expenses; the subsidy was previously ignored for tax purposes.

Annual fee on pharmaceutical manufacturers

Three key accounting questions arise. Firstly, when to recognise the charge, which is levied in one year (beginning 2011) but calculated based on the prior year's sales to relevant government programmes. Our view is that the charge should be recognised in the year in which it is levied, and so the first year in which an amount is recognised is 2011. Secondly, whether the charge should be recognised at a point or over time. A liability arises as soon as a de minimis level of sales to relevant programmes is made. However, we believe the expense should be charged rateably over the year in question because the fee is intended to be an annual one. In substance, it allows an entity to participate and sell their products to government programmes in the year that the annual fee is paid

The final issue is presentation in the income statement, and it is a difficult one. Our view is that under IFRS, the charge should be presented as a deduction from revenue. However, the EITF, which interprets US GAAP in the US, recently proposed a consensus-for-exposure that it should be classified as an expense. We are monitoring developments in the US.

Changes to the RDS

While employers used to be able ignore the subsidy for tax purposes, it now reduces the employer's deduction for healthcare expenses. This changes the deferred tax benefit (asset) associated with the RDS liability. The key question is how this change should be accounted for. The answer may be complex because under IFRS, the deferred tax rules require the effect of a change in tax laws to be recorded in the income statement except to the extent that it relates to items that were previously recognised outside profit or loss. The RDS liability may have been recognised through both the income statement and the statement of other comprehensive income over a number of years, depending on an entity's policy for recognising actuarial gains and losses.

First an entity will have to determine how the associated deferred tax amounts arose (that is, whether in the income statement or not). The effect of the change in tax law should then be appropriately apportioned between the 2010 income statement and statement of other comprehensive income, as a current period adjustment.

Further information and publications are available from pwc.com/pharma, or contact Simon Friend, Global Pharmaceuticals and Life Sciences Leader (+ 44 20 7213 4875) or your local PwC contact.