

US Healthcare Reform Accounting issues under IFRS

*Pharmaceuticals and
Life Sciences*





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Background

On 23 March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA) that was passed by the Senate in December 2009 and by the House of Representatives in March 2010. In addition, the Senate and House of Representatives passed the Health Care and Education Reconciliation Act (HCERA), which includes a number of changes to PPACA, in late March which was signed into law by President Obama on 30 March 2010.

There are a number of provisions in the new health care law that will impact the accounting for many companies. Among those provisions are the following:

- A new annual fee on pharmaceutical manufacturers
- A new excise tax on medical device manufacturers
- Revenue and channel considerations:
 - Changes to the Medicaid rebate rate
 - Expansion of the 340(b) Public Health Service (PHS) programme
 - Changes for Medicare and Medicaid recipients who are over 65 and indigent
 - Medicare coverage gap
- Changes to the Retiree Drug Subsidy (RDS)

As this is significant new legislation, the discussion below is based on our current understanding of the legislation and the views below are subject to change based on new information or interpretation of the legislation.

Analysis of accounting issues

1. Annual fee on pharmaceutical manufacturers

The legislation imposes an annual fee on the pharmaceutical 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 allocated across the industry based on relative market share.

The calculation will be based on a covered entity's branded prescription drug sales for the preceding year as a percentage of the industry's branded prescription drug sales for the preceding year. However, companies should note the basis of calculation is currently under debate. Branded prescription drug sales means sales of any branded prescription drugs to any specified government programme or pursuant to coverage under any government programme (specifically, Medicare Part D, Medicare Part B, Medicaid, Department of Veteran Affairs, Department of Defense and TRICARE). The sales included in the calculation are reduced for covered entities with branded prescription drug sales less than \$400 million on a sliding scale and eliminated entirely for covered entities with branded prescription drug sales less than \$5 million. Additionally, orphan drugs sales are excluded from this calculation.

The annual fee payable in a given calendar year is determined by reference to sales in the preceding calendar year. As mentioned above, companies should note the basis of calculation is currently under debate. The question arises as to whether the annual fee should be accrued and recognised in the period the relevant sales on which the fee is determined are recognised (e.g. record a liability in 2010 for the amount payable in 2011) or whether the annual fee is more akin to a fee assessed for the annual right to participate in the government programmes that should be recognised in the period in which it is

due (e.g. record a liability in 2011 even though the calculation is based on 2010 sales).

When should the annual fee on pharmaceutical manufacturers be recognised?

We believe that the annual fee should be recognised in the calendar year in which the entity becomes obliged to pay the fee (i.e. the payment becomes unavoidable) based on the payment provisions of the law. This is based on the principles articulated in IFRIC 6, 'Liabilities arising from participating in a specific market – waste electrical and electronic equipment'. This interprets IAS 37, 'Provisions, contingent liabilities and contingent assets' in the context of the disposal of electrical equipment in the European Union. The IFRIC concluded that the "obligation...is linked to participation in the market during the measurement period, rather than to production or sale of items... There is no obligation unless and until a market share exists during the measurement period". [IFRIC 6, para 9]. In the context of the annual fee on pharmaceutical manufacturers, the 'measurement period' is the period when sales are generated that results in an entity being a 'covered entity'. A liability first arises only when sales are made in calendar year 2011, and that liability is calculated based on market share during 2010.

We do not believe that it is appropriate to record the fee in the period that the sales are made which then determine the market share (i.e. 2010 in the example above).

Our view is that the charge should be recognised at the point when the entity has exceeded the *de minimis* level of relevant sales in the calendar year when the obligation arises. After this point an unavoidable obligation arises for the entire amount due to the government, based on the prior year's sales.

Although the entire amount becomes due after the *de minimis* level of relevant sales is made, the fee is intended to be an annual one and in substance allows an entity to participate and sell their products to government programmes in the year that the annual fee is paid. If the fee is not paid, an entity loses the right to participate in selling to US government programmes, but is not precluded from making non-US

government sales. The liability recognised therefore gives rise to an asset, which may be characterised as the implicit right to make sales to US government programmes for the year or as a prepaid rebate on governmental sales for the year. An asset is "...a resource controlled by the entity as a result of past events and from which future economic benefits are expected to flow to the entity". [Framework para 49(a)]. Therefore, the fee may be capitalised and amortised over the relevant year.

How should the annual fee on pharmaceutical manufacturers be classified in the income statement?

We believe an entity needs to assess the substance of the annual fee and clearly disclose the resultant presentation. We believe there are two potential classifications and an entity will need to make a judgment on the classification based on the relative weight of the attributes of this particular fee.

One view is that the charge should be classified as a reduction in revenue. The annual fee is calculated based on sales to government programmes. If an entity makes no sales to government programmes in the relevant period or, importantly, makes sales to non-government programmes, the fee is not payable. It is, therefore, directly linked to one particular customer (the US government).

The other view is that the charge is a licence fee or operating tax and should be classified as an operating expense. It could be argued that the fee is in respect of the government raising funds for healthcare reform rather than the government negotiating sales prices on products it purchases or funds. The government is in substance levying a license fee to enable companies to operate and sell to government bodies in the US market. The government is effectively acting in its capacity as a tax raising or licensing body rather than a customer. Supporting this analysis, the fee is calculated on certain defined sales made in a relevant period and the allocation to market participants is based on the amount of sales in the prior year. There is no direct link between sales and the annual fee in the period in which the liability arises and as such the fee is not akin to a rebate on those sales.

2. Excise tax on medical device manufacturers

The new health care law imposes an excise tax of 2.3% on the sale of any taxable medical device by the medical device manufacturer. The excise tax will apply to sales after 31 December 2012. The legislation states that this tax applies to all devices which are intended for humans except for certain items such as contact lenses, eyeglasses and hearing aids. Additionally, the Secretary can exclude any other medical device determined to be of a type which is generally purchased by the public at retail for individual use. Medical device manufacturers would need to begin accounting for this fee for all sales beginning 1 January 2013 by direct analogy with the fee on pharmaceutical manufacturers.

How should the excise tax on medical device manufacturers be classified in the income statement?

There is no specific IFRS dealing with excise taxes. The key is to determine whether the medical device manufacturer is acting as agent for the government (collecting sales taxes on behalf of customers) or is acting as principal (and the tax is a cost charged to the medical devices manufacturer).

Indicators that the medical devices manufacturer is acting as principal (and the tax is an expense) include but are not limited to:

- Risks and rewards of the transaction – the entity holds the inventory and credit risk and the entity will not be refunded even if the inventory is not sold or receivables are not collected.

The medical devices manufacturer only pays if products are sold. However, amounts are payable whether or not a debtor fails to pay. The debtor may be the US government or it may be insurance companies or individuals. This indicates that the medical devices manufacturer is acting as principal.

- Ability to choose the selling price – the entity has no legal or constructive obligation to change prices in order to reflect excise taxes. The entity bears the taxes and makes the decision whether to pass the tax on to the customer.



The medical devices manufacturer does not have an obligation to pass the charge on to the customer. This indicates that it is acting as principal.

- Basis of calculation – the tax is based on the number of units or on the physical quantity (for example number of cigarettes, or alcoholic content) produced by the entity.

The tax is based on the sales value, which indicates that it is a sales tax and should be presented net of revenue (medical devices manufacturer acting as agent).

- Point of payment – the entity must pay tax to the government when the unit is produced or relatively close to that date.

The tax is payable following sales rather than production, indicating that the medical devices manufacturer is acting as agent and the tax should be presented net within revenue.

The above indicators are mixed. However, the stronger indicators are the medical devices manufacturer having to pay the excise tax—even if its customer does not pay—and the manufacturer not being required to pass the charge on to customers. Our preferred view is that the excise tax is presented as an expense.

3. Revenue and channel considerations

The legislation introduces several changes that will impact the estimates a pharmaceutical company will make regarding the ultimate amount it expects to receive for its sales. These changes include:

- Increases to the Medicaid prescription drug rebate effective as of 1 January 2010.
 - Single source and innovator multiple source outpatient prescription drugs (branded) from 15.1% to 23.1%.
 - Clotting factors and other drugs specifically approved by the FDA exclusively for paediatric indications to 17.1%.
 - Multi-source non innovator (generics) drugs from 11% to 13%.
- Expansion of the 340(b) PHS programme to include certain children's hospitals, cancer hospitals, critical access and sole community

hospitals and rural centres. The law states that this change is effective as of 1 January 2010. However, the Health Resources and Services Administration (HRSA), the organisation who administers the 340(b) programme stated that they do not believe manufacturers are required to provide 340(b) discounts prior to their enrolment in the 340(b) programme. As such, the timing of when this expanded access begins is somewhat unclear and subject to further interpretation.

- Extension of Medicaid rebates to drugs supplied to enrollees of Medicaid managed care organisations (MCOs). This change is effective 23 March 2010.
- Changes to the calculation of Medicaid rebates for new formulations of existing drugs. This change is effective 1 January 2010.
- Changes to the Average Manufacturing Price (AMP) definition effective 1 October 2010.
- Pharmaceutical drug manufacturers will be required to fund 50% of the price that Medicare covered patients would otherwise pay while they are in the Medicare coverage gap starting 1 January 2011.

How will the legislative changes impact pharmaceutical companies?

The legislation will impact the ultimate amount that will be received by each company for each sale to the government. Several of the changes noted above have impacted companies in 2010 while others will begin to impact companies in 2011.

- The increased Medicaid prescription drug rebate applies to all products sold to Medicaid recipients starting on 1 January 2010. Companies have been recording the impact that the increased rebate rate has on products that are sold under these programmes during 2010. In addition, for each period end, companies will need to record the impact for any sales that reside in the wholesale or retail channels and will be utilised by Medicaid recipients.
- The increase in the 340(b) PHS programme is also effective as of 1 January 2010. As discussed above,

there is a difference between the PPACA and HRSA's interpretation of the date that the expanded coverage begins, therefore, manufacturers should work with legal counsel to discuss and conclude as to their view of the effective date. Further, this may be subject to further interpretation and guidance.

Prospectively, given that there will often be new entities added into (or removed from) the programme, manufacturers should have a process in place to check the HRSA database to timely identify any newly added entities. For manufacturers with drugs that have an orphan designation, it will be important to consider the operational challenges, such as timely identification of newly eligible entities, with applying the ceiling price exception to the new entity types.

- The change to MCOs relates to states that have a portion of their Medicaid lives covered by MCOs, for which the states would pay a capitated (fixed) rate. Prior to the PPACA, these MCO plans were only entitled to a commercial discount to the extent they had a contract with manufacturers. Under the PPACA, the statutory Medicaid rebate is now applicable under these plans, in addition to any other contractually agreed rates. Companies have been estimating utilisation for enrollees who are covered by MCO plans during 2010. Medicaid rebates, including Consumer Price Index (CPI) penalties, may be higher than existing contractual rebates to which managed Medicaid plans had been previously entitled. The statute as written was unclear as to the start date for this change. On 1 April 2010, in an email to "The Pink Sheet" DAILY, Centers for Medicare & Medicaid Services (CMS) stated that the effective date of the MCO rebate change is 23 March 2010. Additionally, at each period end, companies will need to estimate the impact resulting from the above described MCO change on their wholesale and retail pipeline assumptions in their accrual models.
- The change related to the new formulation (oral dosage) of existing drugs, deals with the Consumer Price Index for all Urban Consumers (CPI-U) penalty ("additional" Medicaid rebate) for line extensions



(for example, extended release versions of existing products). There is a lack of clear guidance from CMS on how to determine whether something qualifies as a line extension. As such, companies will need to use judgement in determining what qualifies as a line extension and may want to seek external advice to supplement their conclusions. The change is effective retroactive to 1 January 2010.

- As described in the PPACA, the definition of AMP was changed to include only the prices received from (a) wholesalers distributing to Retail Community Pharmacies (RCPs) and (b) RCPs purchasing directly from a manufacturer. An RCP is defined as an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. This would not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

Additionally, the revised definition of “wholesaler” now includes re-packers, own-label distributors, and private-label distributors which is a shift from previous guidance provided by CMS. H.R. 1586 was passed on 10 August 2010, which contains a “fix” to the revised definition of AMP for certain products that are not generally dispensed through RCPs.

Payments received from, and price concessions provided to, any entity that does not conduct business as a wholesaler or an RCP are to be included in the calculation of AMP for all inhalation, infusion, instilled, implanted or injectable drugs that are not generally dispensed through a retail community pharmacy. This amended definition was effective in the fourth quarter of 2010 (October 2010 AMP).

CMS and manufacturers will need to determine several items including what constitutes an eligible “inhalation, infusion, instilled, implanted or injectable drug that is not generally dispensed through a retail community pharmacy” and how

the alternate AMP will be calculated. For example, will it revert to the pre-PPACA AMP or be a modified version of the PPACA description?

- Effective 1 January 2011, pharmaceutical manufacturers will be required to fund 50% of the price that a Medicare recipient would otherwise pay (“Negotiated Price”) of products purchased by Medicare beneficiaries receiving covered Part D drugs while they are in the coverage gap. Pharmaceutical companies will need to estimate the amount of the coverage gap rebate and determine the timing for recognition of the related reduction in revenue. We believe there are two potential views for accounting for the Medicare coverage gap rebate.

One view is a ‘spreading’ model. Under this model, the estimated impact of the coverage gap rebate expected to be incurred for the annual period is recognised rateably using an effective rebate percentage for all sales to Medicare patients throughout the year. This can be supported by analogising to the accounting for volume rebates which takes into account estimated rebates in measuring the fair value of the consideration received under a contractual arrangement. Companies will need to estimate the total expected rebate to their distributor for each year, taking into account products in the distribution channel at the end of the period, in order to determine the amount of net revenue to recognise.

The other view is a ‘point of sale’ model which recognises a reduction in revenue at the time individual sales of products are made into the channel that will then be sold to Medicare beneficiaries who are in the coverage gap. It can be argued that in substance there are two different economic transactions, which are the selling of products to Medicare beneficiaries who are in the coverage gap and the selling of products to those who are outside the coverage gap. In this case, the transactions are not linked and should be accounted for on a case by case basis. However, this view has an additional complication in that companies will need to aggregate data to estimate when the specific sales to Medicare beneficiaries who are in the coverage gap will occur.

Under either view, pharmaceutical companies will need to ensure they have a robust process in place to collect the necessary data to estimate the amount of the coverage gap rebate. As this is an accounting policy choice, companies should apply the accounting consistently and provide sufficient disclosure where the effect is material.

4. Changes to the Retiree Drug Subsidy

The legislation contains a provision that changes the tax treatment of the Retiree Drug Subsidy (RDS). The change requires that the amount of the subsidy received be offset against the employer’s deduction for health care expenses, whereas, previously, the subsidy was ignored for tax purposes. The change does not affect the taxation of the subsidy itself but reduces the employer’s deduction for the costs of healthcare for retirees by the amount of the subsidy received. This change is effective beginning on 1 January 2013.

How should the change in tax treatment of the RDS be accounted for?

Post-employment healthcare plans are accounted for in the same way as defined benefit pension plans under IAS 19, ‘Employee benefits’. A charge is recorded in the income statement for the current service cost, interest cost, past service cost and the effect of any curtailments or settlements. Depending on an entity’s accounting policy, actuarial gains and losses may either have been:

- Recognised immediately in the income statement.
- Recognised immediately in other comprehensive income.
- Partially recognised in other comprehensive income under the ‘corridor’ method.

The temporary difference on which deferred tax is recognised is the difference between the medical cost liability and its tax base (being the carrying amount less amounts deductible in the future).

The deferred tax rules in IFRS require the effect of a change in tax laws be recorded in the income statement except to the extent that it relates to items that were previously recognised outside

profit or loss. [IAS 12, para 60]. This means that an entity will have to determine how the amounts included in the temporary difference arose. 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.

The backwards-tracing for the change in the tax law should be consistent with the approach used for allocating tax deductions. The deferred tax asset, which is impacted by the tax law change, represents the tax on amounts against which tax deductions have not yet been allocated. To the extent that amounts in the performance statements are covered by deductions received on contributions, no deferred tax arises. The deferred tax arises on any excess amounts in the performance statements (that is, in the income statement and statement of other comprehensive income, where presented separately) and the backwards-tracing should be carried out on that basis.

The fact that a medical costs liability recognised on transition to IFRS was charged to equity does not necessarily mean that subsequent changes in the related deferred tax asset will also be recognised in equity. Instead, it is necessary to determine where the items on which the original deferred tax arose would have been recognised if IFRS had been applied in the prior periods.

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