In-depth
A look at current financial reporting issues

Pharmaceutical and Life Sciences industry supplement for IFRS 16 ‘Leases’

At a glance

The new lease accounting standard, IFRS 16, ‘Leases’, will fundamentally change the accounting for lease transactions for lessees and is likely to have significant business implications. The International Accounting Standards Board (IASB) issued the standard in January 2016.

Almost all leases will be recognised on the balance sheet for a lessee, with a right-of-use asset and a lease liability that recognise more expenses in profit or loss during the earlier life of a lease. This will have an associated impact on key accounting metrics, and clear communication will be required to explain the impact of changes to stakeholders.

‘A study on the impact of lease capitalisation’, issued in February 2016, identified that the pharmaceutical industry would see a median increase in debt of over 8%. 48% of entities would have an increase in debt of over 25%. This supplement highlights some of the areas that could create the most significant challenges for lessees in the pharmaceutical and life sciences sector as they transition to the new standard. These include:

- the heightened importance of determining whether an arrangement is, or contains, a lease; and
- identification of triggering events that might require reassessment of the lease.

Areas of focus for medical device lessors include arrangements with lease and non-lease components, significant variable payments and initial direct costs.

Lessor entities might consider combining the adoption of the new leasing standard with the new revenue recognition standard (effective 1 January 2018), considering the interdependencies between the two standards.
Overview

IFRS 16 requires lessees to capitalise all leases except for short term leases and leases of low valued assets. This is a significant change from IAS 17 where operating leases were off balance sheet.

The accounting model for lessors is substantially the same as under existing IFRS. Lessors will classify leases as operating or financing. A lease that transfers substantially all risks and rewards incidental to ownership is classified as a finance lease. All other leases are classified as operating leases.

Effective date and transition

The new standard is effective for annual reporting periods beginning on or after 1 January 2019 (for entities within the EU this is subject to EU endorsement).

Earlier application is permitted, but only in conjunction with adopting IFRS 15, ‘Revenue from contracts with customers’. This means that an entity is not allowed to apply IFRS 16 before applying IFRS 15. The date of initial application is the beginning of the annual reporting period in which an entity first applies IFRS 16.

The new standard is required to be adopted using either a full retrospective approach under IAS 8, ‘Accounting policies, changes in accounting estimates and errors’ or a simplified approach. Under the simplified approach, lessees do not need to restate comparative information, but should instead recognise the cumulative effect of applying the standard as an adjustment to the opening retained earnings at the date of initial application. Other practical expedients are also provided for lessor accounting and sale and leaseback transactions.

Impact

The accounting changes are the most obvious impact the new standard will have on pharmaceutical and life science companies. Companies will also need to analyse how the new model will affect current business activities, contract negotiations, budgeting, key metrics, systems and data requirements, and business processes and controls.

More information

In depth INT2016-01 is a comprehensive analysis of the new standard.

‘In the Spotlight: An industry focus on the impact of IFRS16: Pharmaceuticals and Life Sciences’ also looks at some of the practical issues lessees and lessors in the industry might face.
Does the contract contain a lease?

Lease accounting guidance applies to any arrangement that conveys control over an identified asset to another party. Pharmaceutical and life sciences companies often enter into arrangements that may contain embedded leases. Arrangements in which a medical device company recovers the cost of the medical device through the purchase of consumables, or in which a pharmaceutical company utilises the supplier’s assets (such as its manufacturing facility) to produce specific drugs, will need to be evaluated to determine if they are, or contain, a lease.

An arrangement is a lease, or contains a lease, if an underlying asset is explicitly or implicitly identified and use of the asset is controlled by the customer.

If an arrangement explicitly identifies the asset to be used, but the supplier has a substantive contractual right to substitute such asset, then the arrangement does not contain an identified asset. A substitution right is substantive if the supplier can (a) practically use another asset to fulfil the arrangement throughout the term of the arrangement and (b) it is economically beneficial for the supplier to do so. The supplier’s right or obligation to substitute an asset for repairs, maintenance, malfunction or technical upgrade, does not preclude the customer from having the right to use an identified asset.

An identified asset must be physically distinct. A physically-distinct asset may be an entire asset or a portion of an asset. For example, a building is generally considered physically distinct, but one floor within the building may also be considered physically distinct if it can be used independent of the other floors (e.g. point of entry or exit, access to lavatories, etc.). A capacity portion of an asset is not an identified asset if (1) the asset is not physically distinct (e.g. the arrangement permits use of a portion of the capacity of a server to store medical records and data) and (2) a customer does not have the right to substantially all of the economic benefits from the use of the asset (e.g. several customers share the cloud-based server storage capacity and no single customer uses substantially all of the capacity).

A customer controls the use of the identified asset by possessing the right to (1) obtain substantially all of the economic benefits from the use of such asset (‘economics’ criterion); and (2) direct the use of the identified asset throughout the period of use (‘power’ criterion). A customer meets the ‘power’ criterion if it holds the right to make decisions that have the most significant impact on the economic benefits derived from the use of the asset. If these decisions are pre-determined in the contract, the customer must have the right to direct the operations of the asset without the supplier having the right to change those operating instructions, or must have designed the asset in a way that predetermines how, and for what purpose, the asset will be used throughout the period of use, for the contract to be a lease.

The new model differs, in certain respects, from today’s risks and rewards model and may result in the identification of fewer embedded leases compared to current guidance. However, under current lessee guidance, embedded leases are often off-balance sheet operating leases and, as such, application of lease accounting may not have had a material impact on the income statement. Determining whether to apply lease accounting to an arrangement under the new guidance is likely to be far more important, since virtually all leases will result in recognition of a right-of-use asset and lease liability.
Example 1 – Substitution rights

Facts: A medical device company (‘Supplier’) enters into an arrangement with a hospital (‘Customer’) to provide a medical imaging scanner and supply medical imaging consumables (cartridges) for five years. Supplier installs a medical imaging scanner at Customer’s premises on executing the arrangement that requires the use of Supplier’s consumables. The scanner has been customised to run Customer’s proprietary software. Supplier provides the scanner free of charge to Customer. However, Supplier expects to recover the scanner cost through the Customer’s purchase of consumables. Legal title to the scanner remains with Supplier. The contract permits Supplier to substitute the scanner. However, due to the potential disruption substitution would have on Customer’s activities, the contract includes a significant penalty in the event of downtime above a specified threshold. Therefore, it is expected that Supplier will substitute the equipment only in the case of malfunction. Supplier also provides maintenance services.

Question: Does the contract contain a lease?

Discussion: Yes. The contract contains a lease.

The contract does not explicitly specify the scanner. However, since the scanner is on site and customised for Customer, it is implicitly identified. While Supplier has the legal right of substitution, this right is not substantive due to the significant disruption and potential downtime penalty if the equipment was to be substituted (substitution for maintenance or malfunction is not considered a substantive right to substitute). Therefore the arrangement contains an identified asset, i.e. the scanner.

Customer has the right to control the use of the equipment throughout the period of use because:

a. Customer has the right to obtain substantially all the economic benefits from the use of the identified equipment, based on its exclusive access and use of the equipment during the five-year term; and

b. Customer makes the relevant decisions about how and when the equipment is operated by the hospital staff in their practice of medicine, throughout the period of use.

Example 2 – Exclusive supply agreement

Facts: Pharma Corp (‘Customer’) enters into a two-year collaboration agreement with an experienced drug manufacturer, Supplier Corp (‘Supplier’), to exclusively manufacture two well-established drug compounds for a specified geographic region. Customer has arrangements with other manufacturers in other geographic regions to fulfil the demand in those regions. Supplier receives a license to be the exclusive manufacturer of the drug compounds for that geographic region, in exchange for a fee. Customer and Supplier also form a joint steering committee where Customer, in
an advisory capacity, can provide feedback to Supplier and address any queries raised by Supplier. The contract explicitly specifies the manufacturing facility and Supplier does not have the right to substitute the specified facility. The contract specifies the monthly volumes of the two drug compounds that need to be delivered by Supplier. Supplier only has one production line to fulfill the contractual requirements. The specified volume cannot be changed by Customer during the term of the arrangement. Supplier operates the manufacturing facility and makes all manufacturing decisions including how and when the drug compounds are to be produced to meet the specified volume requirements.

**Question:** Does the contract contain a lease?

**Discussion:** No. Although the asset is identified, Customer lacks control of the asset during the period of use and so the contract does not contain a lease.

The asset is identified because the manufacturing facility is explicitly specified in the contract and Supplier has only one manufacturing production line available to fulfil the contract and no substitution rights.

Customer does not have the right to control the use of the manufacturing facility throughout the two-year period of use despite its right to substantially all of the economic benefits from the use of the manufacturing facility. This is because the output from the facility has been predetermined and Customer has no right to change the delivery schedule during the term of the arrangement. Supplier is entitled to make all operating decisions such as determining how and when the facility is operated during the period of use, the production schedule for the two drug compounds, the batch size, etc. Therefore, Supplier has the right to control the use of the identified asset during the period of use.

### Components, contract consideration and allocation

An arrangement may contain lease and non-lease components that are subject to different accounting models. Components are those items or activities that transfer a good or service to the lessee. Arrangements might also contain multiple lease components. The right to use an underlying asset is a separate lease (from other leases within the contract), where the lessee can benefit from using the underlying asset on its own, or together with resources readily available to the lessee and the underlying asset is not highly dependent, on or highly interrelated with, other underlying assets in the contract.

Once the lease and non-lease components are identified, contract consideration is allocated to each component. A lessee should allocate the contract consideration to the separate lease and non-lease components, based on their relative stand-alone prices. As a practical expedient, a lessee may, as an accounting policy election by class of underlying asset, choose to not separate non-lease components from the associated lease component and instead account for them as a single lease component.

A lessor should allocate contract consideration to the separate lease and non-lease components in accordance with the transaction price allocation guidance in IFRS 15. The practical expedient available to a lessee for lease and non-lease components is not available to a lessor.

The guidance specifies that amounts payable by the lessee for activities and costs that do not transfer a good or service to the lessee (for example charges for administrative tasks), are not separate components of the contract but are considered as part of the total consideration allocated to the separately-identified components of the contract.
**PwC observation**

A lessee may elect a practical expedient to account for a lease and the associated non-lease component as a single lease component. If the practical expedient is elected, the cash flows associated with the non-lease component will increase the liability and right-of-use asset recognised on the balance sheet. This is an election by asset class. Companies are likely to consider the significance of the increase to the right-of-use asset and liability relative to the effort and complexity required to obtain reliable information to separately account for the lease and non-lease components. Pharmaceutical and life sciences lessees with material leases will need additional processes, controls and documentation to ensure appropriate and consistent application of the guidance. For example, the guidance requires an appropriate allocation based on relative stand-alone prices that maximise the use of observable prices (the use of the residual method is only permitted in limited circumstances).

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**Example 3 – Identifying components within an arrangement: lab facility**

**Facts:** A biotech company leases a biotech lab facility. The land on which the building is situated and the related laboratory equipment functions as an integrated unit. The lessor does not lease or sell the equipment separately, but other suppliers do. The laboratory equipment can be used in other facilities. The monthly payment to the lessor includes (a) fixed rent for the building, land and laboratory equipment; (b) a fixed amount for property taxes and insurance; (c) a fixed amount for maintenance related to the laboratory equipment; and (d) a fixed amount related to the maintenance of building and land.

**Question:** What are the components in this arrangement?

**Discussion:** The lease components in the arrangement are the building (including land) and laboratory equipment. The non-lease components are the maintenance services for the building (and land) and maintenance services for the laboratory equipment.

The laboratory equipment is considered a separate lease component as it is neither dependent on, nor highly interrelated with, the building or land since it could be sourced from other providers and be used in other lab facilities. Accordingly, the right to use the laboratory equipment is a separate lease component.

Maintenance services for the building (including land) and equipment involve the provision of separate services to the biotech company and are considered as separate non-lease components. The biotech company can either:

1) Separate the lease from the non-lease components and allocate consideration to each component; or
2) Apply the practical expedient for maintenance and account for both the lease and the associated non-lease component as a single, combined lease component

Due to the significance of the maintenance services, the biotech company elects to not apply the practical expedient to combine the non-lease component with the associated lease components.

The fixed payments related to real estate taxes and insurance do not transfer a good or service to the lessee, but are considered as part of the total consideration allocated to the separately-identified components of the contract.
**Initial direct costs**

Initial direct costs are incremental costs of a lease that would not have been incurred had the lease not been executed. Any costs that would have been incurred even if the lease were not executed are not incremental costs and should be excluded from initial direct costs. For example, external legal fees are excluded from initial direct costs assuming the lessee would be required to pay its attorneys for preliminary work performed before a potential lessee was found. However, when a lessee and lessor execute a legally-binding lease commitment prior to drafting the lease agreement, legal fees for drafting might be incremental costs that can be accounted for as initial direct costs.

Pharmaceutical and life sciences companies often enter into multi-year arrangements and might incur significant initial direct costs in the form of commissions paid to obtain the contract. The accounting for such costs depends on both the lease classification and whether control is transferred, as summarised in the following table.

| **Lessee** | All leases | • Include initial direct costs in initial measurement of right-of-use asset.  
• Amortise over the lease term. |
|------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Lessor** | Finance leases (except for manufacturer or dealer lessors) | • Initial direct costs are included in the initial measurement of the net investment in the lease and reduce the amount of income recognised over the lease term.  
• The interest rate implicit in the lease is defined such that the initial direct costs are included automatically in the net investment in the lease and there is no need to add them separately. |
|            | Finance leases (manufacturer or dealer lessors) | • Initial direct costs are excluded from the net investment in the lease and are expensed. |
|            | Operating leases | • Add initial direct costs to the carrying amount of the underlying asset and recognise as an expense over the lease term on the same basis as lease income (typically straight-line). |
Lease classification

Lessees will recognise a right-of-use asset and lease liability for virtually all of their leases (other than exemption elected by a lessee for short-term leases or leases of low-valued assets). There will be no distinction between finance and operating leases for lessee accounting as is the case under IAS 17. However, lessors will continue to classify leases as operating or finance leases.

Example 4 – Lease classification and initial and subsequent measurement

Facts: Medical Device Corp (‘Lessor’) leases specialised medical imaging equipment to a hospital (‘Lessee’) designed and customised to work with Lessee’s proprietary software. Given the age and customisation of the equipment for the Lessee, Lessor would incur significant costs to modify the equipment for use with another lessee or to facilitate its sale. The costs exceed the expected benefit resulting from any such sale. Assume that the arrangement is a lease of the equipment with the following additional facts.

<table>
<thead>
<tr>
<th>Lease term</th>
<th>4.5 years with no renewal option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase option</td>
<td>None</td>
</tr>
<tr>
<td>Present value of lease payments</td>
<td>$200,000</td>
</tr>
<tr>
<td>Fair value of the equipment</td>
<td>$200,000</td>
</tr>
<tr>
<td>Remaining economic life of equipment</td>
<td>5 years</td>
</tr>
<tr>
<td>Title to the asset remains with Lessor upon lease expiration</td>
<td></td>
</tr>
</tbody>
</table>

Question: How should Lessor classify the lease?

Discussion: Lessor would assess the arrangement and classify the lease as a finance lease as follows:

1. The lease does not transfer ownership of the underlying asset to Lessee by the end of the lease term.
2. The lease does not grant Lessee an option to purchase the underlying.
3. Lessee would utilise the equipment for 90% of its remaining economic life (4.5-year lease / 5-year remaining economic life). This is considered a major portion of the remaining economic life.
4. The present value of the sum of the lease payments represents 100% of the fair value of the leased asset ($200,000/$200,000). This amounts to substantially all of the fair value of the leased asset.
5. The underlying asset is of a specialised nature. It is expected to have no alternative use to Lessor at the end of the lease term because the equipment is customised and Lessor would incur significant costs to reprogram the asset for use by another customer.

While the fifth criterion alone would have caused the lease to be classified as a finance lease, the third and fourth criteria also cause the lease to be classified as a finance lease. The leased asset has little use to Lessor upon lease expiration. This results in the lease being priced so that Lessor recovers its investment in the equipment plus a return and Lessee being able to use the equipment for a major portion of its remaining economic life.
**Lease modification and reassessment**

A lease modification is any change to the terms and conditions of a contract that results in a change in the scope of, or the consideration for, use of an underlying asset. A modification is accounted for as a separate lease if: (i) the modification increases the scope of the lease by adding the right to use one or more assets and (ii) the consideration for the lease increases by an amount commensurate with the stand alone price for the increase in scope.

When a modification is a separate lease, the accounting for the original lease is unchanged and the new lease component(s) should be accounted for at commencement, like any other new lease.

*Lessees*

A lessee will allocate the consideration in the modified contract to lease and non-lease components when a lease is modified, but not accounted for as a separate lease. The lessee will also determine the lease term of the modified lease and remeasure the lease liability by discounting the revised lease payments using a revised discount rate.

The lessee should decrease the carrying amount of the right of use asset to reflect the partial or full termination of the lease. A lessee should make an appropriate adjustment to increase or decrease the right-of-use asset for all other lease modifications, depending on the nature of the modification.

There are circumstances when a lessee will also be required to assess and potentially re-measure the right-of-use asset and lease liability subsequent to lease commencement, even without a lease modification. The table below lists out these circumstances and the impact on the lessee’s accounting due to these circumstances.

<table>
<thead>
<tr>
<th>Description</th>
<th>Re-measure lease liability</th>
<th>Update discount rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>An event that gives the lessee a significant economic incentive to exercise/not exercise a renewal or termination option</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>An event occurs that gives the lessee a significant economic incentive to exercise/not exercise a purchase option</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>A contingency on which variable payments are based is met, such that some or all the payments become fixed lease payments</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Amounts due under a residual value guarantee become probable of being owed</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
Lessors

The lessor should account for a modification as a new lease if:

- a modification to a finance lease is not accounted for as a separate lease; and
- the modification would result in the lease being classified as an operating lease had the change been in effect at inception.

Otherwise, the lessor should apply the requirements of IFRS 9 to account for the change in terms.

For lessors in an operating lease, any modifications should be accounted for as new leases effective from the date of the modification.

**PwC observation**

*Reassessment of the likelihood of exercise of extension, termination or purchase options, and consequent reassessment of the lease term, is required when a triggering event occurs which is within the control of the lessee and was not previously included in the determination of the lease term. A change in market-based factors will not, in isolation, trigger a reassessment of options. For example, a reassessment would not be triggered if a lessee is leasing office space and current market conditions for the office space location change, resulting in lease payments that the lessee will be required to make in the extension period now being considered below market. On the other hand, collaboration agreements that might change a company’s strategy for research and development and might impact incentives related to the leased lab space, would require a reassessment to determine whether such an event now results in renewal being considered reasonably certain, or changes the earlier determination that exercise of a renewal option is reasonably certain. It will be important for a company to ensure it has processes and controls in place to identify and monitor triggering events that would require the reassessment of a lease.*
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