PLS – In brief
A look at current financial reporting issues

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Does your contract manufacturing arrangement contain an embedded lease?

At a glance

IFRS 16, 'Leases', will impact the accounting and financial reporting for companies in the pharmaceutical and life sciences (PLS) industry in many areas. This In brief highlights key considerations regarding the evaluation of contract manufacturing arrangements for potential embedded leases. The new leases standard requires lessees to record an asset and a liability on the balance sheet for nearly all leases. This requirement also applies to any leases embedded in other arrangements. To identify embedded leases, companies will need to consider arrangements not typically thought of as leases, including supply contracts, data centre agreements, outsourcing contracts and contract manufacturing arrangements. This publication focuses on the latter as an example of an arrangement that might contain an embedded lease. Determining whether an arrangement contains an embedded lease often requires a detailed analysis that involves significant judgement.

What is the issue?

Contract manufacturing agreements can take many different forms. Generally, these agreements are structured such that a pharmaceutical company (Pharma) outsources the manufacturing of product to a contract manufacturing organisation (CMO).

The general rule under the new leases standard is that an arrangement contains a lease if (1) there is an explicitly or implicitly identified asset in the contract, and (2) the customer controls the identified asset over the period of use.

1. Identified asset

Contract manufacturing agreements could contain tangible assets that are explicitly specified in the contract. Examples might include machinery, production lines, and/or dedicated space in a facility. Even where no asset is explicitly specified in the contract, a tangible asset might be implicitly specified at the time when the asset (such as a machine or production line) is made available for use, provided that no alternative assets exist for the supplier to fulfil its obligations under the contract.

If an asset is explicitly or implicitly identified, the existence of substitution rights by the supplier will need to be evaluated. Where such rights are substantive, despite the existence of a specified asset, the customer would not have the right to use an identified asset, and thus a lease would not exist. A supplier's right to substitute an asset is considered substantive only if both of the following conditions exist: (1) the supplier has the practical ability to substitute alternative assets throughout the period of use; and (2) the supplier would benefit economically from the exercise of its right

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to substitute the asset. This assessment is completed at inception of the arrangement based on facts and circumstances that exist as of that date.

The following factors are examples that might indicate that an arrangement does not contain a substantive substitution right and therefore includes the use of an identified asset:

- The contractual arrangement prevents the CMO from substituting the identified asset.

- The contractual arrangement allows the CMO to substitute the identified asset; however, Pharma designed aspects of the production line, which is highly specialised for Pharma's product.

- Alternative machines or production lines are not readily available to the supplier, or cannot be sourced by another entity in a reasonable period of time and without incurring costs that exceed the related benefits from substitution.

- The costs to relocate the manufacturing process to a different production line or machine exceed the related benefits. This might particularly be the case, for example, where the manufacturing process is highly specialised, complicated, or temperature controlled. Pharma should carefully assess each contract manufacturing agreement for these and similar terms. A supplier's ability to use alternative assets temporarily, while they repair or upgrade a production line, does not represent a substantive substitution right.

Where Pharma is unable to readily determine if there is a substantive substitution right, it is presumed that no substitution right exists.

2. Right to control the use of an identified asset over the period of use

If Pharma concludes that the arrangement implicitly or explicitly identifies an asset, it must then evaluate whether it controls the use of that asset throughout the period of use. Pharma should assess whether, throughout the period of use, it has (1) the right to obtain substantially all of the economic benefits from use of the identified assets, and (2) the right to direct the use of the identified asset. Both criteria must be met for the arrangement to contain a lease. The following are among the factors that should be considered to determine whether Pharma controls the asset:

- The frequency and timing of purchase orders generated. Where this substantially determines whether and when the related machine or production line produces output, this might indicate that the customer (that is, Pharma) effectively has the right to direct the use of the related identified assets.

- Pharma's role in the operating decisions. If Pharma can dictate specific operating instructions or must approve operating decisions, that might be an indicator that the customer has the right to direct the use of the asset.

- Whether the CMO has the right and ability to sell the product to another customer. If the CMO can sell the product to anyone other than Pharma (for example, to a collaborative partner), that might be an indicator that the CMO (and not Pharma) has the right to direct the use of the asset.

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Example #1:

Facts: Customer A enters into an arrangement with a CMO to produce medical equipment and disposables ('the Products') that customer A then sells to outside customers. The CMO has multiple production lines that it uses to fulfil orders for multiple customers. The arrangement allows the CMO to choose the production line used to fulfil customer A's orders. Even after the production of the Products commences on a product line, CMO can easily change to a different production line, with minimal transfer costs, because other production lines are available. Customer A submits legally binding purchase orders quarterly to the CMO, and it is contractually required to provide an annual non-binding production forecast. The Products are generic, and can easily be stored, and the CMO has full discretion over the operating process, including the selection of materials to use in production.

Question: Does this arrangement contain a lease?

Discussion: This arrangement is not likely to contain a lease under IFRS 16. While the use of an asset (that is, the production line) is implicit in the contract, there is likely no identified asset, because substantive substitution rights exist (assuming that the CMO can benefit from substitution). Even if there was no substantive substitution, there is likely not a lease, because the CMO has the right to change the operating process and decide when the output is produced.

Example #2:

Facts: Assume the same facts as in Example#1, except that there is a dedicated production line for the Products, the CMO is contractually unable to use any other production line, the Products are highly specialised, and purchase orders are very frequent and effectively determine whether, when and how much output is produced. In addition, key operating decisions are standardised, and any changes in operating procedures are subject to approval by customer A.

Question: Does this arrangement contain a lease?

Discussion: This arrangement is likely to contain a lease under IFRS 16. An identified asset is explicit in the contract (that is, the production line), and there are no substitution rights. There is a dedicated production line, and customer A appears to effectively control the decision-making rights over the use of the production line, because customer A's purchase orders effectively determine whether, when and how much output is produced by the dedicated production line. The CMO does not have the right to change the operating instructions, including types of materials/components, overall production process, and other decisions related to the output, without prior authorisation by customer A. Customer A also has substantially all of the economic benefits from use of the production line.

Lease arrangements that contain variable payments

Once a lease has been identified (including embedded leases), the accounting is impacted by whether the payments are fixed or variable. Fixed payments required under the lease can come in many forms, such as fixed annual payments or fixed monthly payments to guarantee capacity (often described as 'capacity fees' in lease arrangements). Companies will need to carefully review their lease agreements to ensure that all fixed payments have been identified. Variable lease payments are payments made by a lessee to a lessor for the right to use an underlying asset that vary because of changes in facts or circumstances occurring after the commencement

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date, other than the passage of time. Any payments that vary based on an index or a rate should initially be measured using the index or rate at the commencement date. Other variable lease payments will not impact the initial accounting for a lease (unless those payments are in-substance fixed lease payments), meaning that they are not included in the value of the initial lease liability and right-of-use (ROU) asset recorded at inception of a lease.

Provision	Type of payment	Impact
Per unit price defined but no contract minimums	Variable payments	Excluded from the initial measurement of lease liability and ROU asset, but disclosed.
Per unit price defined with contract minimums	Minimum payments are fixed	The minimum payment allocated to the lease component is included in the initial measurement of lease liability and ROU asset. Anything above the minimum payment allocated to the lease component is disclosed.

Example #3

Facts: Pharma enters into a two-year contract manufacturing agreement with Supplier, a CMO, to manufacture drug product. Pharma has concluded that it has an embedded lease for the production line. Pharma pays Supplier a fee for each batch of drug product produced. The contract specifies the minimum monthly volume of the drug product that is contractually required to be purchased by Pharma. The specified volume cannot be changed by Pharma during the term of the arrangement.

Question: How should Pharma account for this embedded lease under IFRS 16?

Discussion: Pharma is required to purchase minimum volumes throughout the two-year period of use. As a result, although the total consideration is variable, the minimum volumes establish a fixed minimum consideration. First (assuming that Pharma has not elected to account for non-lease components as part of the lease component), Pharma should allocate the fixed consideration between the leased production line (lease component) and drug product (non-lease component), based on their relative stand-alone price at lease commencement. Then, Pharma would record an ROU asset and a lease liability on its balance sheet at the present value of the amount allocated to the lease.

Example #4

Facts: Assume the same facts as in Example #3, except that the contract contains no minimum monthly volume.

Question: How should Pharma account for this embedded lease under IFRS 16?

Discussion: While this contract manufacturing agreement contains an embedded

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lease, the consideration is 100% variable. Because variable consideration is excluded from the value of the initial ROU asset and lease liability, there would be no initial lease liability for this agreement. Instead, Pharma would record variable lease expense for the embedded lease component over the two-year period. Under the new leases standard, Pharma can elect not to separate lease components from non-lease components and, instead, to treat the entire drug product cost as lease expense as the drug is produced / delivered.

Where do I get more details?

PwC clients that have questions about this In brief should contact their engagement partners. Engagement teams that have questions should contact: Peter Kartscher (peter.kartscher@il.pwc.com), Ruth Preedy (ruth.e.preedy@pwc.com) or Karsten Ganssauge (karsten.ganssauge@pwc.com) or Richard Brown (richard.brown@pwc.com).

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