



IFRS/IFAS News

April 2019

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Publication - the latest on IFRS 17 implementation - February 2019

At a glance

On 7 February 2019 the IASB continued its discussions on the concerns and implementation challenges arising from IFRS 17 and proposed two further amendments to the Standard to:

- permit an entity to elect to apply IFRS 9 in its entirety rather than IFRS 17 to contracts for which the only insurance risk in the contract is the settlement of some or all of the obligation created by the contract (e.g. death waivers in loan obligations). However, the discussion did not cover insurance risk embedded in credit cards, which is being separately evaluated and will be discussed at a future meeting.
- on transition, under the modified retrospective approach, require an entity to classify a liability that relates to the settlement of claims incurred before an insurance contract was acquired as a liability for incurred claims. This modification would only be permitted to the extent the entity does not have reasonable and supportable information to apply a retrospective approach. For entities applying the fair value approach the Board agreed to propose an amendment that would allow entities to choose classification as a liability for incurred claims.

The Board agreed to retain the transition requirement that prohibits retrospective application of the risk mitigation option under the variable fee approach. It was noted that permitting retrospective application involved the use of hindsight and could give rise to ‘cherry picking’ opportunities. However, the Board acknowledged that the concerns raised by stakeholders are valid, and welcomed a discussion at a future meeting of alternative solutions to this issue that the staff are currently exploring.

For the remaining transition issues the Board agreed to retain the current requirements.

The Staff plans to bring papers on the remaining implementation concerns and challenges to the March 2019 meeting, along with potential sweep issues. The Board will also at a future meeting consider the package of all the proposed amendments to ensure they comply with the criteria the Board agreed in October 2018 and will consider the need for additional disclosures as a consequence of the proposed amendments. An exposure draft is still expected around the end of June 2019.

The views in this publication are based on our observations from the 7 February 2019 meeting, and they might differ in some respects from the official report of the meeting that will be published by the IASB in IASB Update at a later date.

1. In connection with the issuance of IFRS 17, the IASB established a transition resource working group (‘TRG’) to provide a public forum for stakeholders to follow the discussion of questions raised on implementation of the new standard. The purpose of the TRG is to facilitate a public discussion to provide support for stakeholders, and information to the Board, on implementation questions arising from the application of IFRS 17.
2. Since the issuance of the standard, IASB staff have also been engaged in a variety of activities with stakeholders to follow the implementation of IFRS 17. At the IASB meeting on 24 October, the Board agreed to explore potential amendments to IFRS 17 based on a list of implementation issues and concerns compiled by the staff.
The Board noted that the criteria set a high hurdle for change, and any amendments suggested would need to be narrow in scope and deliberated quickly to avoid significant delays in the effective date.
3. The IASB has held several meetings discussing the reported concerns and implementation challenges to date, and we have summarised the proposed amendments to date, including those addressed as annual improvements in June 2018, towards the end of this publication.
4. In its 7 February 2019 meeting the Board evaluated whether six concerns and implementation challenges dealing with scope and transition would meet the criteria for amending the standard. The table below summarises the decisions reached relating to these six issues. For two of the topics, elements of the issues are expected to be discussed further at a future meeting.

Staff paper	Concerns and implementation challenges	IASB Decision
Loans that transfer significant insurance risk (Staff paper 2A)	Scope of IFRS 17 for loans with insurance risk	Amend*
Transition—Optionality and comparative information (Staff paper 2B)	Optionality in transition approaches	Not Amend
	Comparative information on transition	Not Amend
Transition—Risk mitigation option and amounts accumulated in other comprehensive income on transition (Staff paper 2C)	Prohibition of retrospective application of the risk mitigation option under the variable fee approach	Not Amend*
	Cumulative amounts included in other comprehensive income on transition	Not Amend
Transition—Modified retrospective approach (Staff paper 2D)	Requirements in the modified retrospective approach (including where similar issues arise for the fair value approach)	Partly Amend

5. The IASB agreed to propose an amendment to IFRS 17 to introduce an election to apply IFRS 9 in its entirety rather than IFRS 17 to contracts for which the only insurance risk in the contract is the settlement of some or all of the obligation created by the contract. An example is a bank that provides a loan to a customer where repayment of the remaining loan is waived in the event of the debtor's death. The staff had suggested that the entity be required to make the IFRS 9 election on a contract by contract basis. However, after some discussion, Board members suggested instead that the election should be done at the portfolio level, perhaps using the IFRS 17 definition of portfolio. It was clarified that an entity's decision should be described as an election rather than as an accounting policy choice, as the latter would require consistent application at the consolidated group level whereas the former would allow for different elections for different operations within an entity that would not need to be conformed on consolidation.
6. The Board believes that this amendment would satisfy stakeholders' concerns relating to various products, including those issued by banks, where there is embedded insurance cover within a loan or other obligation. Examples include mortgages with death waivers, equity release/reverse mortgages, and student loan contracts whose repayment is income contingent.
7. Although the definition of insurance contracts within the scope of IFRS 17 is mainly unchanged from IFRS 4, the requirements for unbundling of components within an insurance contract are more restrictive under IFRS 17. The Staff noted that this discussion and proposed amendment is not meant to cover contracts beyond those listed in the paper; hence insurance cover embedded in certain credit card contracts is being considered separately by the staff and will be brought to the Board in a future meeting.
8. One Board member proposed that if the IFRS 9 election is made, there should be a requirement that the financial instrument be measured at fair value through profit or loss. However, several Board members noted that if an entity elects to account for such contracts under IFRS 9, the SPPI test (i.e. test to determine if instrument pays solely principal plus interest) is considered to be a robust test for classification of loans and other obligations in this standard and they were reluctant to impose any further requirements. That is, to the extent an instrument is determined to fail the SPPI test, measurement at fair value through profit or loss would be required.
9. Although some Board members suggested that additional disclosures should be required if IFRS 9 is elected, a Board member noted that IFRS 9 disclosures are sufficient and adequately address disclosures for complex financial instruments. In addition, the staff noted that the need for additional disclosures as a consequence of all amendments to IFRS 17 will be addressed by the Board at a later stage.
10. The approach taken by the staff to neither propose an amendment to the definition of insurance contracts nor amend IFRS 17 principles on

separation of investment components was welcomed by the Board. The Board also agreed with this being an election, acknowledging that this would enable entities that mainly write insurance contracts to account for them under IFRS 17, while allowing other entities that mainly issue financial instruments, such as banks, to apply IFRS 9.

Optionality included in the transition requirements

11. The IASB agreed to retain the current requirements in IFRS 17 to allow entities to select either the modified retrospective approach or the fair value approach on transition provided that it is impracticable to apply IFRS 17 retrospectively.
12. One Board member acknowledged the concern raised that a choice of transition method could reduce comparability between entities, and that this lack of comparability could be ongoing for several years subsequent to transition.

The requirement to present comparative information for prior reporting periods

13. All Board members agreed that IFRS 17 should not be amended to allow an option not to restate comparative information at transition, despite this being permitted when IFRS 9 is adopted. The Board noted that the stakeholder suggestion to not require comparatives was raised as a relief to meet the 1 January 2021 effective date requirement, but given the proposed decision to in the Board meeting in November 2018 to defer the effective date by one year, this concern seems to be addressed.
14. Stakeholders also expressed concern that permitting entities to not restate the comparative information on financial assets when IFRS 9 is adopted, whilst requiring restatement for comparative information under IFRS 17 would cause an accounting mismatch. However, during the discussion several Board members emphasised that an entity can avoid this mismatch by choosing to restate IFRS 9 figures as well, assuming they can do so without using hindsight.
15. A few Board members also noted that the starting point in adopting IFRS 17 is significantly different from the starting point for IFRS 9 transition, since IFRS 9 adopters were all previously applying the same requirements (IAS 39). In contrast, IFRS 17 introduces fundamental changes to the accounting for insurance contracts, which are pervasive to insurers' financial statements, and the prior accounting under IFRS 4 was subject to a wide variety of accounting practices. Allowing no restatement of comparatives under IFRS 17 would significantly increase complexity in the financial statements, and thus not meet the criteria for amendment.

Prohibition of retrospective application of the risk mitigation option

16. The Board agreed to retain the transition requirement that prohibits retrospective application of the risk mitigation option under the variable fee approach ('VFA'). It was noted that permitting retrospective application may involve the use of hindsight and could give rise to 'cherry picking' opportunities. However, the Board acknowledged that the concerns addressed by stakeholders on transition are valid, and welcomed a discussion at a future meeting of alternative solutions to this issue that the staff are currently exploring.
17. As background to the above, the staff noted that when entities use derivatives to mitigate financial risks inherent in VFA contracts, the effect of the derivative is included in profit or loss, whilst the effects on the insurance contracts would normally (absent an onerous contract situation) adjust contractual service margin ('CSM'). Entities that apply the risk mitigation option under VFA can choose to not include the effects of changes in financial assumptions in the adjustment of the CSM if certain criteria are met.

18. Stakeholders have raised concerns that at transition, this risk mitigation option is available only on a prospective basis, resulting in potential misstatement of the CSM on transition (as past risk mitigation activity is not reflected) and consequent misstatement of future profit, potentially for many years. Some have suggested that entities should be allowed to apply this election either retrospectively or at least prospectively from the transition date (rather than prospectively from the date of initial application of IFRS 17).
19. Some noted that for any approach, documentation of the previous risk mitigation strategy and objectives would be essential, but acknowledged that the real difficulty would be in deciding which relationships the risk mitigation option would have applied to in previous periods and the extent of the risk mitigation covered by the option. This differs from the IFRS 9 designated fair value option; once the fair value designation in IFRS 9 is selected, there is no choice about how the resulting measurement applies retrospectively.
20. Some Board members expressed sympathy for the suggestion of applying the risk mitigation option prospectively from the transition date, and noted that this would increase the comparability on transition and was interrelated with the previous discussion on comparatives. Others suggested that expanding the option by only one year would not solve the problem, given that the cumulative impact of prior periods' risk mitigation could be substantial. Although the Board voted for prohibiting retrospective application of the risk mitigation option, they left open the possibility of other solutions, to be discussed at a future meeting. Determination of the cumulative amount of insurance finance income or expenses recognised in other comprehensive income ('OCI') on transition.
21. All IASB members agreed to retain the current requirements that permit or require entities that have selected the OCI option to set the cumulative amount recognised in OCI at nil at the transition date to the extent that the entities do not have reasonable and supportable information to apply a retrospective approach (or when entities hold the underlying items under the VFA).
22. Stakeholders have raised concerns that setting the accumulated amount in OCI to nil at transition whilst not similarly setting to nil the amount accumulated in OCI for the related assets, distorts equity on transition and the recognition of future investment margin. They have therefore suggested that entities that do not have reasonable and supportable information to apply this retrospectively should be allowed to deem the cumulative amount in OCI related to corresponding assets as nil at transition to IFRS 17. An alternative suggestion is to permit the accumulated amount in OCI for insurance contracts on transition to be the same amount as the accumulated amount in OCI on the assets. Some Board members noted that this question is interrelated with the retrospective application of the risk mitigation option, and consistent with this decision the Board decided to retain the existing requirements.
23. All Board members agreed to propose adding a specified modification to the modified retrospective approach to require an entity to classify a liability that relates to the settlement of claims incurred before an insurance contract was acquired as a liability for incurred claims. This modification would only be permitted to the extent the entity does not have reasonable and supportable information to apply a retrospective approach. When the fair value approach is applied, the Board agreed to propose to amend the standard to allow a choice to classify such liabilities as incurred claims. The Board decision was in response to stakeholders who noted that in portfolio transfers and some business combinations, the contracts are managed in the same system as those that have been issued by the entity, making it impractical to distinguish claims arising from contracts they have issued from those that they have been acquired.

24. The Board also agreed to the following with regard to the modified retrospective approach:
- retain the existing IFRS 17 requirements on transition related to reasonable and supportable information that an entity:
 - cannot use a specified modification to the extent the entity has reasonable and supportable information to apply the requirement retrospectively;
 - can only use a specified modification when the entity has reasonable and supportable information to apply that modification;
 - not amend IFRS 17 to allow an entity to use/develop its own modifications;
 - not amend the modification related to the use of cash flows that are known to have occurred instead of estimating retrospectively cash flows that were expected to occur, and;
 - not amend IFRS 17 to permit an entity to apply the specified modifications related to groups of insurance under the general model to determine the CSM for groups of contracts under the VFA.
25. Board members noted that the modifications allowed on transition are restricted to meet the objective of developing a transitional approach that is a reasonable approximation of retrospective transition. Allowing further modifications to this model would contradict this objective. However, as some stakeholders have found the requirements challenging, Board members suggested that it could clarify certain requirements. Entities are not prohibited from making necessary estimates in both retrospective application and when applying a specified modification in the modified retrospective approach. For example, if data on actual cash flows has not been collected or has been collected at a different level than required, an entity is required to use reasonable and supportable information to estimate those amounts. A Board member suggested that the staff prepare additional educational material beyond the chart (refer to page 7) appended to the staff papers to clarify the transition requirements.
26. The Board noted that discussions on the remaining implementation challenges and concerns will continue in the March 2019 Board meeting. The Staff propose to bring back a summary of all suggested amendments and assess the total package of amendments against the criteria previously agreed to and consider the need for any amendments in the disclosures as a consequence of the proposed amendments.
27. In its papers for the October 2018 Board meeting the IASB staff presented 25 identified implementation challenges. The majority of these concerns are now addressed and the staff has noted that remaining matters will to be brought back to a future meeting;
- level of aggregation, including effects on transition;
 - further analysis of the risk mitigation exception; and
 - scope for credit cards with an embedded insurance component.
28. The Board will follow due process by issuing an exposure draft that is expected to be issued around the end of the first half of 2019, allowing an appropriate public comment period, and redeliberating responses for any proposed amendments. The expected timeframe for issuance of final amendments proposed to date, considering the due process required, is normally 12 to 18 months.

Area	Meeting	Proposed amendment
Scope	February 2019	Scope of certain loans.
Initial recognition	June 2018	Clarify terminology in paragraph 28 of IFRS 17.
Insurance Acquisition cash flows	June 2018	Clarify paragraph 27 to include those relating to contracts issued and 'expected to be issued'.
	January 2019	Amend requirements for acquisition cash flows related to anticipated future renewals outside the contract boundary (and related amendments).
Risk adjustment for non-financial risk	June 2018	Clarify words related to risk adjustment to avoid the risk of double accounting.
Contractual Service Margin	June 2018	Clarify coverage period for contracts with direct participating features.
	January 2019	Amortisation of the contractual service margin for contracts under the general model that include an investment return service (and related amendments).
Reinsurance Contracts held	January 2019	Recognise a gain on reinsurance held when recognising a loss on onerous underlying insurance contracts that are covered by reinsurance contracts held that cover losses on a proportionate basis (and related amendments).
	January 2019	Risk mitigation exemption expanded to reinsurance held for insurance contracts with direct participation features.
Presentation of Insurance contracts	December 2018	Separate presentation of portfolios of assets and portfolios of liabilities.
Disclosures	June 2018	Clarify wording in the sensitivity analysis disclosure.
Effective date	November 2018	1 year deferral of effective date of IFRS 17 to 1 January 2022.
	November 2018	Temporary exemption to IFRS 9 extended to 1 January 2022.
Business Combinations	June 2018	Consequential amendment to IFRS 3 to be applied prospectively
	June 2018	Exclusion of business combinations under common control in IFRS 17 requirements.
	February 2019	Classification of claims incurred acquired prior to transition under the modified retrospective approach and fair value approach.
Other proposed amendments	June 2018	Revise wording in IFRS 9, IFRS 7 and IAS 32 to achieve intended scope of these standards and IFRS 17.
	June 2018	Update IASB illustrative Example 9 in IFRS 17 with an explanation.

The new definition of a business promises to impact the pharmaceutical industry

At a glance

The IASB's new guidance changes the definition of a business and will likely result in more transactions being recorded as asset acquisitions. The new definition of a business could have a significant impact in the pharmaceutical and life sciences (PLS) industry.

What is the issue?

New guidance

IFRS 3, 'Business Combinations', has been amended to update the definition of a business. The new model introduces an optional concentration test that, if met, eliminates the need for further assessment. To be considered a business, an acquisition would have to include an input and a substantive process that together significantly contribute to the ability to create outputs. The new guidance provides a framework to evaluate when an input and a substantive process are present.

The concentration test

Under the concentration test, companies consider whether substantially all of the fair value of the gross assets acquired is concentrated in a single asset (or a group of similar assets). If so, the assets acquired would not represent a business and no further analysis is required. Gross assets acquired include the consideration transferred (plus the fair value of any non-controlling interest and previously held interest, if any) but exclude cash, deferred tax assets and goodwill resulting from the effects of deferred tax liabilities.

Acquisition of a Biotech entity – one in process research and development (IPR&D) project

Pharma Co purchases from Biotech a legal entity that contains the rights to a Phase 3 compound developed to treat diabetes. Included in the IPR&D is the historical know how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The legal entity also holds an at market value contract research organisation (CRO) contract and an at market contract manufacturing organisation (CMO) contract. No employees, other assets or other activities are transferred.

Is the arrangement the acquisition of a business?

Analysis

No. Pharma Co elects to apply the optional concentration test and would conclude that this is an asset acquisition, because substantially all of the fair value is concentrated in a single identifiable asset. Pharma Co would treat this as an asset acquisition, assuming that it opted to use the concentration test.

The optional concentration test includes the concept of aggregating ‘similar’ assets. In the PLS industry, it is common for acquisitions to include commercial and pre-commercial products in a variety of specialties (such as oncology, diabetes, women’s health) and stages of development (such as pre-clinical, clinical, commercial). Companies should carefully consider the specific facts and circumstances, including product specialty and stage of development, when concluding whether assets purchased in a transaction are similar. A group of intangibles are not similar if they have significantly different risk characteristics. [\[IFRS 3 para B7B\(f\)\(vi\)\]](#).

A transaction is not automatically a business combination if the optional concentration test does not result in an asset classification. An entity would then need to assess the transaction under the full framework in IFRS 3.

Framework in IFRS 3

IFRS 3 requires a business to include, as a minimum, an input and a substantive process that together significantly contribute to the ability to create output. The new guidance provides a framework to evaluate when an input and a substantive process are present, differentiating between transactions with outputs and those with no outputs. Outputs are defined as *“the results of inputs and processes applied to those inputs that provide goods or services to customers, generate investment income (such as dividends or interest) or generate other income from ordinary activities”*. [\[IFRS 3 para B7\]](#).

Without outputs

An acquired process is considered substantive where:

1. the process is critical in converting an acquired input to an output;
2. the inputs include an organised workforce that has the necessary skills, knowledge and experience to perform the process; and
3. the inputs include IP, other economic resources that could be developed to create output, or rights to obtain or create materials/future output; examples include IPR&D.

With outputs

An acquired process is considered substantive where:

1. the process is critical in continuing to produce outputs, and the input includes an organised workforce with the necessary skills, knowledge or experience to perform that process; or
2. the process significantly contributes to the ability to continue to produce outputs and is unique or scarce or cannot be replaced without significant cost.

Contracted workforce

An acquired contract could give access to an organised workforce (for example, outsourced research services). The entity needs to assess whether the organised workforce provides a substantive process that it controls. Factors to consider include: the service is not ancillary or minor; it would be difficult to replace the workforce; and the duration of the contract and renewal terms.

Acquisition of a Biotech entity – two IPR&D projects

Pharma Co purchases from Biotech a legal entity that contains rights to two Phase 3 compounds developed to treat diabetes and Alzheimer's. Included in the IPR&D is the historical know how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The legal entity also holds an at market value CRO contract. The research could be performed by a number of CROs. No employees, other assets or other activities are transferred.

Is the arrangement the acquisition of a business?

Analysis

No. Pharma Co would conclude that this is an asset acquisition.

The concentration test is not passed, since all of the fair value is not concentrated in a single identifiable asset; this is because two dissimilar IPR&D compounds are acquired.

Pharma Co would then analyse the transaction, referring to the framework without outputs. The acquisition includes an input of IPR&D and a CRO contract. The contract gives access to an organised workforce. It is likely that the organised workforce would not be considered to be substantive, given that the services could be replaced at no significant cost with another CRO.

Acquisition of a Biotech entity – several IPR&D projects

Pharma Co purchases from Biotech a legal entity that contains: rights to several dissimilar IPR&D projects (each having significant fair value); senior management and scientists who have the necessary skills, knowledge or experience to perform R&D activities; and tangible assets (including a corporate headquarters, a research lab and lab equipment). Biotech does not yet have a marketable product, and it has not yet generated revenues.

Is the arrangement the acquisition of a business?

Analysis

Yes. Pharma Co would conclude that this is a business combination.

The concentration test is not applied, because the fair value of the assets acquired is not concentrated in a single asset or a group of similar identifiable assets.

Further analysis is required, following the framework without outputs, to assess whether a process is acquired and whether the process is substantive. A business is acquired, because the organised workforce is a substantive process that is critical to the ability to develop and convert the inputs (workforce, IPR&D and tangible assets) into outputs.

What is the impact of more asset acquisitions?

The changes to the definition of a business will likely result in more acquisitions being accounted for as asset acquisitions. There are a number of accounting differences between business combinations and asset acquisitions; these include the recognition of goodwill and the divergent treatment of deferred taxes, contingent consideration and transaction costs, amongst others. Application of the changes will also affect the accounting for disposal transactions, since the requirements of IFRS 10 apply to the recognition of proceeds from the sale of a business, whereas the requirements of IFRS 15 apply to the recognition of proceeds from the sale of an asset. IFRS 10 requires the consideration received to be recognised at fair value; IFRS 15 constrains variable consideration where it is highly probable to reverse and, in licensing transactions, sales and usage-based royalties are recognised when the subsequent sale or usage occurs.

When does it apply?

Entities are required to apply the amendments to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after 1 January 2020. Earlier application is permitted (subject to EU endorsement for EU application).

On 12 February 2019, DSAK IAI has approved the exposure draft amending PSAK 22, Business Combinations, to adopt the above guidance. It is proposed to be effective on 1 January 2021. Early adoption is permitted. This amendment is still on exposure draft (proposal), and DSAK IAI is currently allow public to provide suggestions and/or response to complete the draft until 28 June 2019.

Does your contract manufacturing arrangement contain an embedded lease?

At a glance

IFRS 16/PSAK 73, 'Leases', will impact the accounting and financial reporting for companies in the pharmaceutical and life sciences (PLS) industry in many areas. This publication 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 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.

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/PSAK 73. 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/PSAK 73. 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 date, other than the passage of time.

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/PSAK 73?

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.

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

Question: How should Pharma account for this embedded lease under IFRS 16/PSAK 73?

Discussion: While this contract manufacturing agreement contains an embedded 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.

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