International Financial Reporting Standards (IFRS)
Issues and solutions for the pharmaceuticals and life sciences industries

Pharmaceuticals and life sciences
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**Foreword**

The *IFRS Issues and solutions for the pharmaceuticals and life sciences industries* is our collected insight on the application of International Financial Reporting Standards (IFRS) in this industry – reflecting the practices of many practitioners in the pharmaceuticals and life sciences industry.

This edition has been updated in 2017 to reflect changes in IFRS and interpretations as at that date. It includes solutions for IFRS 15, ‘Revenue’, and IFRS 9, ‘Financial Instruments’, which are issued but only effective for periods beginning on or after 1 January 2018. Each solution is based on a specified set of circumstances. Companies must evaluate their own facts and circumstances which might well differ from those in these solutions. Creativity in licensing, manufacturing and research and development arrangements, for example, lead to variations in underlying substance and corporate structures, requiring an individual case-by-case assessment of the accounting implications, which can be complex.

We hope you continue to find this publication useful in understanding the accounting for common transactions that you encounter in your business. By stimulating debate of these topics through this publication, we hope we will encourage consistent practices by the pharmaceuticals and life sciences industries in financial reporting under IFRS. This consistency will be critical to the continued usefulness and transparency of pharmaceuticals and life sciences companies’ financial reporting.

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1. R&D and intangible assets
1.1 **Capitalisation of internal development costs**

**Background**

A pharmaceutical entity is developing a vaccine for HIV that has successfully completed Phases I and II of clinical testing. The drug is now in Phase III of clinical testing. Management still has significant concerns about securing regulatory approval, and it has not started manufacturing or marketing the vaccine.

**Relevant guidance**

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;
b. The intention to complete the asset and use or sell it;
c. The ability to use or sell the asset;
d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;
e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and
f. The ability to measure reliably the expenditure attributable to the intangible asset.

**Should management start capitalising development costs at this point?**

**Solution**

No, management should not capitalise the subsequent development costs, because the project has not met all of the capitalisation criteria.

There is no definitive starting point for the capitalisation of internal development costs. Management must use its judgement, based on the facts and circumstances of each project.

However, a strong indication that an entity has met all of the above criteria arises when it obtains regulatory authority for final approval. It is the clearest point at which the technical feasibility of completing the asset is proven [IAS 38 para 57(a)], and this is the most difficult criterion to demonstrate. Filing for obtaining regulatory approval is also sometimes considered as the point at which all relevant criteria, including technical feasibility, are considered to be met.

The technical feasibility of the project is not yet proven in the above scenario.
1.2 **Capitalisation of internal development costs when regulatory approval has been obtained in a similar market – Scenario 1**

**Background**

A pharmaceutical entity has obtained regulatory approval for a new respiratory drug in Country Agara. It is now progressing through the additional development procedures and clinical trials necessary to gain approval in Country Belan.

Management believes that achieving regulatory approval in this secondary market is a formality. Mutual recognition treaties and past experience show that Belan’s authorities rarely refuse approval for a new drug that has been approved in Agara.

**Relevant guidance**

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;

b. The intention to complete the asset and use or sell it;

c. The ability to use or sell the asset;

d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;

e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and

f. The ability to measure reliably the expenditure attributable to the intangible asset.

**Can the development costs be capitalised?**

**Solution**

The company can capitalise any additional development costs if it judges that the development criteria have been met. The company has judged that registration is highly probable, and there are likely to be low barriers to obtaining regulatory approval, so it is likely to be technically feasible.
1.3 **Capitalisation of internal development costs when regulatory approval has been obtained in a similar market – Scenario 2**

### Background

A pharmaceutical entity has obtained regulatory approval for a new AIDS drug in Country Spartek and is progressing through the additional development procedures necessary to gain approval in Country Oceana.

Experience shows that significant additional clinical trials will be necessary to meet the Oceanean regulatory approval requirements. Some drugs accepted in Spartek have not been accepted for sale in Oceana, even after additional clinical trials.

### Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;

b. The intention to complete the asset and use or sell it;

c. The ability to use or sell the asset;

d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;

e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and

f. The ability to measure reliably the expenditure attributable to the intangible asset.

*Can the development costs be capitalised?*

### Solution

The company should not capitalise additional development expenditure. It cannot demonstrate that it has met the criterion of technical feasibility, because registration in another market requires significant further clinical trials. Approval in one market does not necessarily predict approval in the other.
1.4  **Capitalisation of development costs for generics**

**Background**

A pharmaceutical entity is developing a generic version of a painkiller that has been sold in the market by another company for many years. The technical feasibility of the asset has already been established, because it is a generic version of a product that has already been approved, and its chemical equivalence has been demonstrated. The lawyers advising the entity do not anticipate that any significant difficulties will delay the process of obtaining commercial regulatory approval.  
*(The scenario assumes that the other conditions in para 57 of IAS 38 can be satisfied).*

**Relevant guidance**

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;

b. The intention to complete the asset and use or sell it;

c. The ability to use or sell the asset;

d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;

e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and

f. The ability to measure reliably the expenditure attributable to the intangible asset.

*Can management capitalise the development costs at this point?*

**Solution**

*There is no definitive starting point for capitalisation; management should use its judgement, based on the facts and circumstances of each development project. Regulatory approval is deemed probable in this scenario, so management can start capitalising internal development costs. [IAS 38 para 57]. It might still be appropriate to expense the costs if there are uncertainties whether the product will be commercially successful. For example, the solution might be different for a generic biological compound ("bio similar") where uncertainty exists over being able to successfully manufacture the product.*
1.5  Accounting for marketing expenditure once development criteria are met

Background

Pharmaceutical entity MagicCure has obtained regulatory approval for a new respiratory drug. MagicCure determined that the development criteria were met when it received regulatory approval. MagicCure is now incurring expenditure to educate its sales force and perform market research.

Relevant guidance

Development costs are capitalised as an intangible asset if the criteria specified in IAS 38 are met.

Capitalisable costs are all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management. [IAS 38 para 66].

Selling, administration, general overheads, inefficiencies and training cannot be capitalised as part of an intangible asset. [IAS 38 para 67].

Should the management of MagicCure capitalise these costs?

Solution

MagicCure should expense sales and marketing expenditure, such as training a sales force or performing market research. This type of expenditure does not create, produce or prepare the asset for its intended use. Expenditure on training staff, selling and administration should not be capitalised. [IAS 38 para 67].
1.6  Accounting for development expenditure once capitalisation criteria are met

### Background

Pharmaceutical entity DeltaB has determined that it has met the six criteria for capitalisation for a vaccine delivery device. It is continuing expenditure on the device to add new functionality. The development of this device will require new regulatory approval.

### Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;

b. The intention to complete the asset and use or sell it;

c. The ability to use or sell the asset;

d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;

e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and

f. The ability to measure reliably the expenditure attributable to the intangible asset.

Capitalised costs are all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management [IAS 38 para 66].

**Should the management of DeltaB capitalise these costs?**

### Solution

*DeltaB should not capitalise the expenditure that it incurs to add new functionality, because new functionality will require filing for new regulatory approval. This requirement implies that technical feasibility of the modified device has not been achieved.*
1.7 **Examples of development costs that can be capitalised**

**Background**

A laboratory is developing a drug to cure SARS. Management has determined that it meets the criteria of paragraph 57 of IAS 38, and that certain development costs must therefore be capitalised, because regulatory approval has been obtained. Management is unsure what costs to include.

**Relevant guidance**

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;

b. The intention to complete the asset and use or sell it;

c. The ability to use or sell the asset;

d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;

e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and

f. The ability to measure reliably the expenditure attributable to the intangible asset.

Development is the application of research findings or other knowledge to a plan or design for the production of new or substantially improved materials, devices, products, processes, systems or services before the start of commercial production or use. [IAS 38 para 8].

**What kinds of expenditure can be considered development costs in the pharmaceutical industry?**

**Solution**

Management should consider the following development costs, assuming that the criteria for capitalising development costs have been met [IAS 38 para 57]:

- Employee benefits for personnel involved in the investigation and trials, including employee benefits for dedicated internal employees;
- Directly attributable costs, such as fees to transfer a legal right and the amortisation of patents and licences that are used to generate the asset;
- Overheads that are directly attributable to develop the asset and can be allocated on a reasonable and consistent basis;
- Allocation of depreciation of property, plant and equipment (PPE) or rent;
- Legal costs incurred in presentations to authorities;
- Design, construction and testing of pre-production prototypes and models; and
- Design, construction and operation of a pilot plant that is not of an economically feasible scale for commercial production, including directly attributable wages and salaries.
1.8 Development of alternative indications

Background

Arts Pharma markets a drug approved for use as a painkiller. Recent information shows that the drug might also be effective in the treatment of cancer. Arts has commenced additional development procedures necessary to gain approval for this indication.

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38 para 57]:

a. The technical feasibility of completing the asset so that it will be available for use or sale;
b. The intention to complete the asset and use or sell it;
c. The ability to use or sell the asset;
d. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;
e. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and
f. The ability to measure reliably the expenditure attributable to the intangible asset.

When should management start capitalising the development costs relating to alternative indications?

Solution

Arts should begin capitalisation of development costs as soon as the criteria of paragraph 57 of IAS 38 are met. Entities involved in developing new drugs or vaccines usually expense development expenditure before regulatory approval. There is no definitive starting point for capitalising development costs of alternative indications. Management must use its judgement, based on the facts and circumstances of each project.

Arts must determine whether the existing approval indicates that technical feasibility has been achieved, to assess if capitalisation is required earlier than achieving regulatory approval for the alternative indication.

Management should consider, amongst other factors:

• The risks associated with demonstrating effectiveness of the new indication;
• Whether a significantly different dosage might be needed for the other indication (potentially requiring new side effect studies); and
• Whether the new indication will target a different group of patients (for example, children versus adults).

If these considerations indicate that the uncertainties are comparable to a new drug, and that commercialisation is substantially dependent on regulatory approval, the entity should not begin to capitalise development costs prior to achieving regulatory approval.
1.9 Cost incurred for performance comparisons

Background

Van Gogh Ltd has obtained regulatory approval for its new antidepressant drug and has started commercialisation. Van Gogh is now undertaking studies to verify the advantages of its drug over competing drugs already on the market. These studies will support Van Gogh’s sales efforts. These studies are not required as a condition for regulatory approval.

Relevant guidance

Development is the application of research findings or other knowledge to a plan or design for the production of new or substantially improved materials, devices, products, processes, systems or services before the start of commercial production or use. [IAS 38 para 8].

The cost of an internally generated intangible asset comprises all directly attributable costs incurred to create, produce and prepare the asset for its intended use. [IAS 38 para 66]. Expenditure might be incurred to provide future economic benefits to an entity, but no intangible asset or other asset is created that can be recognised. This includes, for example, expenditure on advertising and promotional activities. [IAS 38 para 69].

Should costs incurred to compare various drugs, with the intention of determining relative performance for certain indications, be capitalised as development costs?

Solution

The expenditure incurred for studies to identify performance features, after the start of commercial production or use, should not be capitalised as part of the development cost, because it does not qualify for capitalisation under IAS 38. Development costs after an asset has been brought into use are not directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management. The studies are directed at providing marketing support, and the nature of the amounts spent is that of marketing and sales expense. This expense should be included in the appropriate income statement classification.
1.10 Development costs for drug which will treat a small patient group

Background

Da Vinci Pharma is currently developing a drug that will be used in the treatment of a very specific ailment affecting a small group of patients, and management has decided to pursue this drug for reputational reasons. Da Vinci has introduced an innovative pricing mechanism for this drug, whereby a patient will only pay if the drug is proven to be effective. Da Vinci has received regulatory approval, and it believes that all other capitalisation criteria under paragraph 57 of IAS 38 have been met, except for concerns about its market potential.

Relevant guidance

One criterion to be met, in order to qualify for capitalisation as development cost, is that the asset should generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally. [IAS 38 para 57(d)].

An intangible asset should only be recognised if it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity and the cost of the asset can be measured reliably. [IAS 38 para 21].

Should the development costs for a limited market be capitalised?

Solution

All development criteria must be met, in order to start capitalising development costs. A strong indication that an entity has met all of the above criteria arises when it obtains regulatory authority for final approval. Da Vinci should capitalise development costs for this drug when the criteria in IAS 38 are met, which is likely to be on regulatory approval.

Da Vinci will need to assess the capitalised costs for any indication of impairment at each reporting date [IAS 36 para 9], and to test for impairment annually before it is available for use [IAS 36 para 10]. The concern over the potential market might be a trigger for impairment.
1.11 Exchange of intangible assets

Background

Pharmaceutical entity Egram is developing a hepatitis vaccine. Pharmaceutical entity Fiorel is developing a measles vaccine. Egram and Fiorel enter into an agreement to swap the two products. Egram and Fiorel will not have any continuing involvement in the products that they have disposed of. The fair value of Egram’s compound has been assessed as C3 million. The carrying value of the compound is C0.5 million.

Relevant guidance

An intangible asset might be acquired in exchange for a non-monetary asset or assets, or a combination of monetary and non-monetary assets. The cost of the acquired intangible asset is measured at fair value, unless (a) the exchange transaction has no commercial substance, or (b) the fair value of neither the asset received nor the asset given up is reliably measurable. [IAS 38 para 45].

Whether an exchange transaction has commercial substance is determined by considering the degree to which future cash flows are expected to change. An exchange transaction has commercial substance if [IAS 38 para 46]:

a. The risk, timing and amount of the cash flows of the asset received differ from the risk, timing and amount of the cash flows of the asset transferred; or

b. The entity-specific value of the portion of the entity’s operations affected by the transaction changes as a result of the exchange; and

c. The difference in (a) or (b) is significant, relative to the fair value of the assets exchanged.

The fair value of the asset given up is used to measure cost, unless the fair value of the asset received is more clearly evident. [IAS 38 para 47].

How should Egram’s management account for the swap of vaccine products?

Solution

The exchange of vaccine products for different diseases has commercial substance. Egram is switching from a hepatitis vaccine product to a measles vaccine product. The timing and value of cash flows expected to arise from the development and commercialisation of the products differ. Egram’s management should recognise the compound received at the fair value of the compound given up, which is C3 million. Management should also recognise a gain on the exchange of C2.5 million (C3 million – C0.5 million), because there is no continuing involvement.
1.12 Part disposal of an intangible asset

Background
Entity Giant is developing a hepatitis vaccine. Entity Hercules is developing a measles vaccine. Giant and Hercules enter into an agreement to swap these two products. Under the terms of the agreement, Giant will retain the marketing rights to its drug for all Asian countries. The fair value of Giant’s compound has been assessed as $3 million, including $0.2 million relating to the Asian marketing rights. The carrying value of the compound is $0.5 million.

Relevant guidance
An intangible asset might be acquired in exchange for a non-monetary asset or assets, or a combination of monetary and non-monetary assets. The cost of the acquired intangible asset is measured at fair value, unless (a) the exchange transaction has no commercial substance, or (b) the fair value of neither the asset received nor the asset given up is reliably measurable. [IAS 38 para 45].

Whether an exchange transaction has commercial substance is determined by considering the degree to which future cash flows are expected to change. An exchange transaction has commercial substance if [IAS 38 para 46]:

a. The risk, timing and amount of the cash flows of the asset received differ from the risk, timing and amount of the cash flows of the asset transferred; or

b. The entity-specific value of the portion of the entity’s operations affected by the transaction changes as a result of the exchange; and

c. The difference in (a) or (b) is significant, relative to the fair value of the assets exchanged.

The fair value of the asset given up is used to measure cost, unless the fair value of the asset received is more clearly evident. [IAS 38 para 47].

How should Giant’s management account for the swap of vaccine products, assuming that the transaction has commercial substance?

Solution
Giant’s management should recognise the compound received at the fair value of the compound given up, which is $2.8 million ($3.0 million – $0.2 million). The fair value of $0.2 million relating to the Asian marketing rights is excluded from the calculation, because the rights have not been sold. Management should also recognise a gain on the exchange of $2.3 million [$2.8 – (0.5 – ((0.2/3) × 0.5))].
1.13 Licence of technology

**Background**

Pharmaceutical entities Regal and Simba enter into an agreement in which Regal will license Simba’s know-how and technology (which has a fair value of LC3 million) to manufacture a compound for AIDS. It cannot use the know-how and technology for any other project. Regal will use Simba’s technology in its facilities for a period of ten years. The agreement stipulates that Regal will make a non-refundable payment of LC3 million to Simba for access to the technology. Regal’s management has not yet concluded that economic benefits are likely to flow from this compound or that relevant regulatory approval will be achieved.

**Relevant guidance**

An intangible asset should be recognised if [IAS 38 para 21]:

a. It is probable that the future economic benefits from the asset will flow to the entity; and

b. The cost of the asset can be measured reliably.

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

How should Regal account for the three-year licence?

**Solution**

The three-year licence is a separately acquired intangible which is capitalised under paragraph 25 of IAS 38. The probability of economic benefit is assumed to be factored into the price that the buyer is prepared to pay.

The right should be measured at its cost of LC3 million. The intangible asset should be amortised from the date when it is available for use (see Solution 1.19). The technology, in this example, is available for use when the manufacturing of the compound begins. The amortisation should be presented as cost of sales in the income statement (if expenses are presented by function) or as amortisation (if expenses are presented by nature), because it is an expense directly related to the production of the compound.

Regal continues to expense its own internal development expenditure until the criteria for capitalisation are met and economic benefits are expected to flow to the entity from the capitalised asset. See Solution 5.3 for Simba’s accounting under IAS 18, and Solution 6.3 for Simba’s accounting under IFRS 15.
1.14 **In-licence of marketing rights for a drug in development**

**Background**

Sargent and Chagall enter into a collaboration deal in which Sargent in-licenses a new antibiotic from Chagall. Chagall will continue to develop the drug. Sargent will have exclusive marketing rights to the antibiotic if it is approved. The contract terms require the following payments:

a. Upfront payment of LC20 million on signing of the contract;

b. Milestone payment of LC50 million on approval of Phase III clinical trial approval;

c. Milestone payment of LC80 million on securing final regulatory approval; and

Development services are paid at cost plus a reasonable mark-up.

**Relevant guidance**

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

The cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets. [IAS 38 para 26].

**Solution**

Sargent has assessed that the LC20million upfront payment is for the acquisition of an asset rather than prepaid R&D. A separately acquired intangible is capitalised under paragraph 25 of IAS 38. The probability of economic benefit is assumed to be factored into the price that the seller is prepared to accept. The intangible is recognised at cost of LC20 million.

The future milestones must be assessed to determine if they meet the capitalisation criteria. A milestone payment can be outsourced development work or an acquisition of an identifiable asset. The substance of the payment should determine its classification; the label given to a payment is not relevant. This is a judgmental area under the accounting standards, and Sargent should develop an accounting policy that is clearly articulated and understood by the organisation.

A robust method of making this judgement is to assess if the payment is due only on a verifiable outcome or is due for the execution of activities. A verifiable outcome would be the successful completion of Phase III trials. The payment for a verifiable outcome is more likely to indicate the additional value of the intangible asset. The execution of activities might be enrolling 3,000 patients for a clinical trial. The payment for enrolling patients is for normal activities undertaken during the development stage.

The milestones paid by Sargent are for the successful outcome of trials and regulatory approval. They are likely to meet the capitalisation criteria, and so they would be accumulated into the cost of the intangible. Development services are being paid separately at fair value and therefore it is less likely any of the milestone is for prepaid development services.

Industry practice is to follow a cost accumulation approach to variable payments for the acquisition of intangible assets. A liability for payment is recognised for estimated additional payments at the date of recognition of the additional asset.
1.15 Patent acquired in exchange for own shares

Background
Buonarroti entered into a competitive bidding arrangement to acquire a patent. Buonarroti won the bidding, which it agrees to settle in exchange for 5% of its publicly listed shares.

Relevant guidance
For equity-settled, share-based payment transactions, the entity measures the goods received at the fair value of the goods received, unless that fair value cannot be estimated reliably. If the entity cannot estimate reliably the fair value of the goods received, it measures their value by reference to the fair value of the equity instruments granted.

[IFRS 2 para 10].

How should an asset acquired in exchange for listed shares be recognised?

Solution
The acquisition of the patent in exchange for shares is a share-based payment. Buonarroti should recognise the patent at its fair value. If the fair value cannot be measured, the patent would be measured at the fair value of the publicly traded price of the shares on the acquisition date.

The accounting for the seller of the patent under IAS 18 is explained in Solution 5.9. The accounting for the seller of the patent under IFRS 15 is explained in Solution 6.11.
1.16 In-licence of development-phase compound where the licensee continues to do the development work

**Background**

Biotech Co has successfully developed a drug for Syndrome Q through Phase II trials. Biotech and a large pharmaceutical company (Pharma Co) have agreed the following terms:

- Biotech grants a licence to Pharma to manufacture, sell and market the product in the USA for the treatment of Syndrome Q. Biotech retains the patents and underlying intellectual property associated with the product.

- Pharma is to fund and perform all Phase III clinical development work on the drug developed by Biotech.

- There is a development committee that oversees the development of the product. The development committee makes all strategic decisions regarding the product. Biotech is not required to attend the committee, but it has the right to, and expects to, attend.

- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.

- Biotech retains the right to sell the product in the rest of the world.

The consideration payable by Pharma includes:

- An upfront payment of LC10 million on signing the contract.

- Milestone payment of LC20 million on regulatory approval.

- Royalty's payable on sales of 15%.

- Sales milestone of LC20 million in the first year that annual sales exceed LC500 million.

The upfront payments and milestones are non-refundable in the event that the contract is cancelled when the payments have been made.

**Relevant guidance**

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

The cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets. [IAS 38 para 26].

Subsequent expenditure on an intangible can only be capitalised if it enhances the expected future economic benefits of the intangible. [IAS 38 para 20].

*How should Pharma Co account for the in-licence?*
Solution

The upfront purchase of the compound is a separately acquired intangible, which is capitalised under paragraph 25 of IAS 38. Biotech Co has no further performance obligations for development services. The intangible is recognised at cost of LC10 million.

The future milestones must be assessed to determine if they meet the capitalisation criteria. A milestone payment can be outsourced development work or an acquisition of an identifiable asset.

The substance of the payment should determine its classification; the label given to a payment is not relevant. This is a judgmental area under the accounting standards, and Pharma should develop an accounting policy that is clearly articulated and understood by the organisation.

A robust method of making this judgement is to assess if the payment is due only on a verifiable outcome or is due for the execution of activities. A verifiable outcome would be regulatory approval. The payment for a verifiable outcome is more likely to indicate the additional value of the intangible asset that is controlled by the entity. The execution of activities might be enrolling 3,000 patients for a clinical trial. The payment for enrolling patients is for normal activities undertaken during the development stage.

The milestones paid by Pharma are for regulatory approval and a sales target. They are likely to meet the capitalisation criteria, and so they would be accumulated into the cost of the intangible.

Industry practice is to follow a cost accumulation approach to variable payments for the acquisition of intangible assets. A liability for payment is recognised for estimated additional payments at the date of recognition of the additional asset.

Royalties should be accrued for in line with the underlying sales and recognised as a cost of sales.

See Solution 5.6 for the accounting by Biotech under IAS 18 and Solution 6.6 for IFRS 15 guidance.
1.17 **In-licence of development-phase compound where the licensor continues to do the development work**

**Background**

Biotech Co is a well-established company that has the expertise to perform clinical trials. Biotech enters into a contract with Pharma Co with the following terms:

- Biotech grants Pharma a licence to manufacture, sell and market product.
- Biotech is responsible for performing clinical trials and obtaining regulatory approval.
- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.

The consideration payable by Pharma under this agreement comprises:

- An upfront payment of LC10 million.
- Milestone of LC20 million payable for enrolling 1,000 patients for Phase III trials.
- Milestone of LC10 million on regulatory approval.
- Royalties payable on sales of 25%.

**Relevant guidance**

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

The cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets. [IAS 38 para 26].

Subsequent expenditure on an intangible can only be capitalised if it enhances the expected future economic benefits of the intangible. [IAS 38 para 20].

**How should Pharma Co account for the licence?**

**Solution**

Pharma Co needs to assess whether the upfront payment is for the acquisition of an intangible or for prepaid R&D. There is no separate payment for R&D services and therefore it is likely that the upfront is at least in part a prepayment for R&D. Any prepaid recognised is released to the P&L over the development period.

The future milestones must be assessed to determine if they meet the capitalisation criteria. A milestone payment can be outsourced development work or an acquisition of an identifiable asset.

The substance of the payment should determine its classification; the label given to a payment is not relevant. This is a judgmental area under the accounting standards, and Pharma should develop an accounting policy that is clearly articulated and understood by the organisation.

A robust method of making this judgement is to assess if the payment is due only on a verifiable outcome or is due for the execution of activities. A verifiable outcome would be regulatory approval. The payment for a verifiable outcome is more likely to indicate the additional value of the intangible asset that is controlled by the entity. The LC10 million milestone on regulatory approval is likely to meet the capitalised criteria and can be accumulated into the cost of the intangible. The execution of activities is a normal R&D activity and should be expensed.
1.18 Useful economic lives of intangibles

**Background**
A laboratory has capitalised certain costs incurred in the development of a new drug. These costs have met the capitalisation criteria under paragraph 57 of IAS 38, because regulatory approval has been obtained.

**Relevant guidance**
The depreciable amount of an intangible asset should be amortised on a systematic basis over the best estimate of its useful life. [IAS 38 para 97].

Useful life is defined as the period of time over which an asset is expected to be used by the entity. [IAS 38 para 8].

Management should assess the useful life of an intangible asset, both initially and on an annual basis. [IAS 38 paras 88, 104].

*What factors should management consider in its assessment of the useful life of capitalised development costs (including ongoing reassessment of useful lives)?*

**Solution**
Management must consider a number of factors that are relevant to all industries when determining the useful life of an intangible asset. It should also consider industry-specific factors, such as the following:

- Duration of the patent right or licence of the product.
- Anticipated duration of sales of product after patent expiration.
- Competitors in the market place.
1.19 Commencement of amortisation

**Background**

A pharmaceutical entity acquired a compound in Phase III for $5 million on 1 January 20X3. The entity receives regulatory and marketing approval on 1 March 20X4 and starts using the compound in its production process on 1 June 20X4. The entity amortises its intangible assets on a straight-line basis over the estimated useful life of the asset.

**Relevant guidance**

Amortisation of an asset starts when it becomes available for use. The asset should be in the location and condition that is required for it to be operating in the manner intended by management. [IAS 38 para 97].

*When should it begin amortising its intangible assets?*

**Solution**

Amortisation should begin from 1 March 20X4, because this is the date from which the asset is available for use. The intangible asset should be tested for impairment at least annually, prior to 1 March 20X4, irrespective of whether any indication of impairment exists. [IAS 36 para 10(a)].
1.20 Indefinite-lived intangible assets

Background
Management of a pharmaceutical entity has acquired a branded generic drug as part of a business combination. The brand is a well-established leader in the market and has a strong customer loyalty. Management believes that the brand has an indefinite useful life, and it has decided not to amortise it.

Relevant guidance
An intangible asset can be regarded as having an indefinite useful life when there is no foreseeable limit on the period during which it is expected to generate positive cash flows for the entity. [IAS 38 para 88].

Can management regard the brand as having an indefinite life, and how should management account for it?

Solution
Yes, management can regard the brand as having an indefinite life in accordance with IAS 38. Management would need to test the indefinite-lived asset annually for impairment, comparing its recoverable amount with its carrying value. [IAS 36 para 10(a)].

Technological and medical advances will reduce the number of situations where an indefinite life would apply. Only in exceptional cases would the active ingredient of pharmaceutical products have unrestricted economic lives as a result of limited patent lives.
1.21 Indicators of impairment – Intangible assets

Background

A pharmaceutical entity has capitalised a number of products as intangible assets that it is amortising.

Relevant guidance

An entity should assess whether there is any indication that an asset is impaired at each reporting date. [IAS 36 para 9].

Indicators can be external or internal. Examples are included in the standard. [IAS 36 para 12].

What indicators of impairment should management consider?

Solution

Specific indicators relevant to the pharmaceutical entity include:

- Development of a competing drug;
- Changes in the legal framework covering patents, rights or licences;
- Failure of the drug’s efficacy after a mutation in the disease that it is supposed to treat;
- Advances in medicine and/or technology that affect the medical treatments;
- Lower than predicted sales;
- Impact of adverse publicity over brand names;
- Change in the economic lives of similar assets;
- Litigation;
- Relationship with other intangible or tangible assets; and
- Changes or anticipated changes in participation rates or reimbursement policies of insurance companies, Medicare and governments for drugs and other medical products.
**1.22 Indicators of impairment – Property, plant and equipment**

**Background**
GloPharma Ltd announced a withdrawal of a marketed product from the market, due to unfavourable study results. Management informed healthcare authorities that patients should no longer be treated with that product. The property, plant and equipment (PPE) is either dedicated specifically to the production of the terminated product, or it has no foreseeable future alternative use.

**Relevant guidance**
An entity should assess, at the end of each reporting period, whether an asset might be impaired. [IAS 36 para 9].

An entity should consider internal and external sources of information that indicated that there might be an adverse effect in an asset. [IAS 36 para 12].

The carrying amount of an asset should be reduced to its recoverable amount if, and only if, the recoverable amount is less than its carrying amount. That reduction is an impairment loss. [IAS 36 para 59].

*Should an impairment test be carried out for GloPharma Limited?*

**Solution**
Management should carry out an impairment test, because there is a trigger for impairment. The withdrawal of the product from the market will adversely affect the manner in which the property, plant and equipment are used, since there is no alternative use. Management should consider whether this event is an impairment trigger for any other assets held. Any intangible recognised in connection with the marketed product is also likely to be impaired.
1.23 Acquired compound where development is terminated

**Background**

Seurat Pharmaceutical has acquired a new drug compound, which is currently in Phase I clinical development. Seurat has capitalised the costs for acquiring the drug as an intangible asset. Soon after acquisition of the drug, the results of the Phase I clinical trials show that the drug is not likely to be effective for the intended therapy. Management terminates development of the drug.

Seurat’s scientists will use technology directly related to the acquired intangible in developing one of Seurat’s other drugs.

**Relevant guidance**

An intangible asset with a finite useful life should be amortised on a systematic basis over its useful life. Amortisation begins when the asset is available for use in the manner intended by management. [IAS 38 para 97].

The carrying amount of an asset should be reduced to its recoverable amount if, and only if, the recoverable amount is less than its carrying amount. That reduction is an impairment loss. [IAS 36 para 59].

The recoverable amount of an asset is the higher of its fair value less costs of disposal and its value in use. [IAS 36 para 18].

*How should Seurat account for the drug compound?*

**Solution**

*Seurat should not start to amortise the intangible asset when it is acquired, because it is not ready for use.* The poor results of the clinical trials indicate that the intangible asset might be impaired. Management must perform an impairment test on the relevant cash-generating unit, and it might have to write it down to the higher of the compound’s fair value less costs of disposal and the value in use.
1.24 Acquired compound used in combination therapy

**Background**

Picasso Pharma has acquired a new drug compound, which is currently in Phase I clinical development. Picasso has capitalised the costs of acquiring the new drug compound as an intangible asset. Subsequently, Picasso’s scientists detect that the new drug substance is much more effective when used in a combination therapy with another drug. Management stops the current development activities for the new drug.

New Phase I clinical trials are started for the combination therapy.

**Relevant guidance**

An intangible asset with a finite useful life should be amortised on a systematic basis over its useful life. Amortisation begins when the asset is available for use in the manner intended by management. [IAS 38 para 97].

*How should Picasso account for the new drug compound?*

**Solution**

*Picasso should not amortise the intangible asset subsequent to its acquisition, because it is not yet available for use. Picasso should start amortising the intangible asset when the combination therapy obtains regulatory approval and is available for use.*

The intangible asset is not impaired by cessation of development of the initial drug compound as a stand-alone product. The intangible asset continues to be developed by Picasso, which expects to create more value with it by using the new drug compound as part of a combination.
1.25 Impairment of IPR&D prior to approval

Background

Dali Pharmaceuticals has capitalised separately acquired IPR&D as an intangible asset. Dali identified side-effects associated with the compound during development that indicate that its value is severely diminished, and an impairment charge must be recognised.

Relevant guidance

Impairment is shown as a separate line item in an income statement in which expenses are classified by nature. Impairment is included in the function(s) to which it relates if expenses are classified by function. [IAS 1 para 1G5].

Where should Dali classify impairment charges on development intangible assets before such assets are available for use?

Solution

Dali should classify the impairment charge relating to the unapproved drug as a component of R&D expense, if presenting the income statement by function. Dali should classify the charge as an impairment charge, if presenting the income statement by nature of expense.
1.26 Impairment of development costs after regulatory approval

**Background**

Dali Pharmaceuticals has capitalised development costs as an intangible asset relating to a drug that has been approved and is being marketed. Competitive pricing pressure from the early introduction of generic drugs causes Dali to recognise an impairment of the intangible asset.

**Solution**

Dali should classify the impairment consistently with the amortisation expense, which is usually in cost of goods sold if presenting the income statement by function. Dali should classify the charge as an impairment charge, if presenting the income statement by nature of expense.

**Relevant guidance**

Impairment is shown as a separate line item in an income statement in which expenses are classified by nature. Impairment is included in the function(s) to which it relates if expenses are classified by function. [IAS 1 para IG5].

*Where should Dali classify impairment charges on development intangible assets which are currently marketed?*
1.27 Single market impairment accounting

**Background**

Veronese SpA acquired the rights to market a topical fungicide cream in Europe. The acquired rights apply broadly to the entire territory. Patients in Greece prove far more likely to develop blisters from use of the cream, causing Veronese to withdraw the product from that country. Fungicide sales in Greece were not expected to be significant.

**Relevant guidance**

An entity should assess, at each reporting date, whether there is any indication that an asset might be impaired. If any such indication exists, the entity should estimate the recoverable amount of the asset. [IAS 36 para 9].

In assessing whether there is any indication that an asset might be impaired, an entity should consider significant changes with an adverse effect on the entity that have taken place during the period, or are expected to take place in the near future, in the extent to which, or manner in which, an asset is used or is expected to be used. [IAS 36 para 12(f)].

*How should Veronese account for the withdrawal of a drug’s marketing approval in a specific territory?*

**Solution**

The cash-generating unit for the marketing right, in this example, is viewed as sales from Europe. There is an impairment trigger if there is a significant change with an adverse effect on the entity. Veronese should decide if the withdrawal from Greece is considered significant. Veronese’s management should carefully consider whether the blistering in one jurisdiction is indicative of potential problems in other territories. An impairment test should be performed if the issue cannot be isolated.

Any development costs that Veronese has capitalised specifically for achieving regulatory approval in Greece must be written off following the withdrawal of the product from the territory.
Rubens Corp markets a weight-loss drug, for which development costs have been capitalised. A competing drug was launched on the market with much lower pricing. Rubens recognised an impairment of the capitalised development intangible asset, due to a reduction in the amounts that it estimated that it could recover as a result of this rival drug. The competing drug was subsequently removed from the market because of safety concerns. The market share and forecast cash flows generated by Rubens’ drug significantly increased.

**Relevant guidance**

An impairment loss recognised in prior periods for an asset accounted for under the cost model is reversed if there has been a change in the estimates used to determine the asset’s recoverable amount since the last impairment loss was recognised. The carrying amount of the asset is increased to its recoverable amount, but it should not exceed its carrying amount adjusted for amortisation or depreciation if no impairment loss had been recognised for the asset in prior years. That increase is a reversal of an impairment loss. [IAS 36 para 114].

A reversal of an impairment loss reflects an increase in the estimated service potential of an asset, either from use or from sale, since the date when an entity last recognised an impairment loss for that asset. An entity must identify the change in estimate that causes the increase in estimated service potential. [IAS 36 para 115].

**How should Rubens account for reversals of impairment losses for intangible assets accounted for under the cost model?**

**Solution**

The competing drug withdrawal is a reverse indicator. An impairment test should be performed, comparing the carrying amount to the recoverable amount. The revised carrying value of the intangible asset cannot exceed the amount, net of amortisation, which would have been recognised if no impairment charge had been recognised.
Fra Angelico Inc has a major production line that produces its blockbuster antidepressant. The production line has no alternative use. A competitor launches a new antidepressant with better efficacy. Angelico expects sales of its drug to drop quickly and significantly. Management identifies this as an indicator of impairment, although positive margins are forecast to continue. Management might exit the market for this drug earlier than previously contemplated.

### Relevant guidance

An entity should assess, at each reporting date, whether there is any indication that an asset might be impaired. If so, the entity estimates the recoverable amount of the asset. [IAS 36 para 9].

The recoverable amount is defined as the higher of an asset’s fair value less costs to sell and its value in use [IAS 36 para 18]. If either of these amounts exceeds the asset’s carrying amount, no impairment is indicated, and the other amount does not have to be calculated. [IAS 36 para 19].

If there is an indication that an asset might be impaired, this could indicate that the remaining useful life or residual value needs to be reviewed and potentially adjusted, even if no impairment loss is recognised for the asset. [IAS 36 para 17].

**How should Angelico assess the impairment and useful lives of long-lived assets where impairment indicators have been identified?**

### Solution

Angelico must evaluate the carrying value of the antidepressant’s cash-generating unit (including the production line) for impairment relative to its recoverable amount. The recoverable amount is likely to exceed the asset’s carrying value, given the margin achieved on the remaining sales. Angelico could determine that no impairment is required. Angelico should also reduce the remaining useful life to the revised period over which sales are expected.
1.30 Amortisation method of development – Intangible assets

Background

Raphael & Co has begun commercial production and marketing of an approved product. Development costs for this product were capitalised in accordance with the criteria specified in IAS 38. The patent underlying the new product will expire in 10 years, and management does not forecast any significant sales once the patent expires.

Relevant guidance

The depreciable amount of an intangible asset with a finite useful life should be allocated on a systematic basis over its useful life. The amortisation method used should reflect the pattern in which the asset’s future economic benefits are expected to be consumed. [IAS 38 para 97].

Acceptable methods include the straight-line method, the diminishing balance method and the unit of production method. The method used is selected on the basis of the expected pattern of consumption, and it is applied consistently from period to period, unless there is a change in the expected pattern of consumption of benefits. There is rarely, if ever, persuasive evidence to support an amortisation method for intangible assets that results in a lower amount of accumulated amortisation than under the straight-line method. [IAS 38 para 98].

The useful life of an intangible asset that arises from legal rights should not exceed the period of the legal rights, but it might be shorter, depending on the period over which the entity expects to use the asset. [IAS 38 para 94].

What is the appropriate method of amortising the capitalised development costs, once a drug is being used as intended?

Solution

The patent provides exclusivity and premium cash flows over a 10-year period. The economic benefits are consumed rateably over time. The limiting factor of the patent is time. Whether the drug is a blockbuster and exceeds expectations, or it just breaks even, the patent’s economic benefit will still be consumed equally over time. Straight-line amortisation appropriately reflects the consumption of economic benefits.

Raphael should therefore amortise the capitalised development costs on a straight-line basis over the patent’s 10-year life, unless the business plan indicates use of the patent over a shorter period. A systematic and rational amortisation method should be utilised over this shortened remaining useful life. In addition, Raphael should perform impairment testing whenever it identifies an impairment indicator.
1.31 Amortisation life of intangibles

**Background**

Raphael & Co has begun commercial production and marketing of an approved product. The production is done using a licensed technology that will be used in the production of other products for 20 years. The patent underlying the new product will expire in 10 years. An upfront payment for the 20-year licence of the technology and development costs for the new product were capitalised in accordance with the criteria specified in IAS 38.

**Relevant guidance**

The depreciable amount of an intangible asset with a finite useful life should be allocated on a systematic basis over its useful life. The amortisation method used should reflect the pattern in which the asset’s future economic benefits are expected to be consumed. [IAS 38 para 97].

Acceptable methods include the straight-line method, the diminishing balance method and the unit of production method. The method used is selected on the basis of the expected pattern of consumption, and it is applied consistently from period to period, unless there is a change in the expected pattern of consumption of benefits. There is rarely, if ever, persuasive evidence to support an amortisation method for intangible assets that results in a lower amount of accumulated amortisation than under the straight-line method. [IAS 38 para 98].

The useful life of an intangible asset that arises from legal rights should not exceed the period of the legal rights, but it might be shorter, depending on the period over which the entity expects to use the asset. [IAS 38 para 94].

**What is the useful life of the intangibles?**

**Solution**

*Each of these intangibles should be amortised on a straight-line basis. The intangible asset attributable to the patent should be amortised over its 10-year expected useful life. The intangible asset attributable to the technology should be amortised over the full 20-year life. Use of the straight-line method reflects consumption of benefits available from the patent, which is based on the passage of time. If the time over which the technology or patent will generate economic benefits decreases, Raphael should perform impairment testing, and a systematic and rational amortisation method should be utilised over this shortened remaining useful life.*
1.32 Presentation of capitalised development costs

Background

Dali Pharmaceuticals capitalised the development costs relating to a diabetes drug that has been approved and is being marketed. Amortisation of the development costs is being recognised on a straight-line basis over the remaining patent life.

Relevant guidance

Cost of sales consists of those costs previously included in the measurement of inventory that has now been sold and unallocated production overheads and abnormal amounts of production costs of inventories. The circumstances of the entity might also warrant the inclusion of other amounts, such as distribution costs. [IAS 2 para 38].

Under the nature of expenses income statement format, the entity discloses the costs recognised as an expense for raw materials and consumables, labour costs and other costs, together with the amount of the net change in inventories for the period. [IAS 2 para 39]. Under the function of expenses income statement, the costs are recognised as part of costs of goods sold.

The function of expense or ‘cost of sales’ method classifies expenses according to their function as part of cost of sales or, for example, the costs of distribution or administrative activities. At a minimum, an entity discloses its cost of sales under this method separately from other expenses. [IAS 1 para 103].

Where should the amortisation of development costs be classified in Dali’s income statement?

Solution

Dali must use the intellectual property and begin to consume its value, in order to bring the diabetes drug to market. Amortisation of the development intangible should be classified as a cost of sale under the functional income statement format. The amortisation expense should be presented as an amortisation expense under the nature of expenses income statement format. The cost of intellectual property used in production (royalties and intangible asset amortisation) should be classified consistently for products and all periods presented.
### Background

Pharmaceutical entity Astro engages a contract research organisation (CRO) to perform research activities for a period of two years in order to obtain know-how and try to discover a cure for AIDS. The CRO is well known in the industry for having modern facilities and good practitioners dedicated to investigation. The CRO receives a non-refundable, upfront payment of LC3 million in order to carry out the research under the agreement. It will have to present a quarterly report to Astro with the results of its research. Astro has full rights of access to all of the research performed, including control of the research undertaken on the potential cure for AIDS. The CRO has no rights to use the results of the research for its own purposes.

### Relevant guidance

Expenditure on research should be expensed when incurred. [IAS 38 para 54].

**How should Astro account for upfront payments made to third parties to conduct research?**

### Solution

The payment is made for research activity to an external CRO, it does not meet the definition of an intangible asset, and it cannot be capitalised. The upfront payment is recognised as a pre-payment and recognised in the income statement over the period of the research activity.
1.34 Accounting for research which results in a development candidate

**Background**

Sisley Pharma contracts with Wright Pharma to research possible candidates for further development in its anti-hypertension programme. Sisley pays Wright on a cost-plus basis for the research, plus LC100,000 per development candidate which Sisley elects to pursue further. Sisley concludes that the expenditure does not qualify for capitalisation, because regulatory approval for the candidates has not yet been obtained. Sisley will own the rights to any such development candidates. After two years, Wright succeeds in confirming 10 candidates that will be used by Sisley.

**Relevant guidance**

No intangible asset arising from research (or from the research phase of an internal project) should be recognised. Expenditure on research (or on the research phase of an internal project) is recognised as an expense when it is incurred. [IAS 38 para 54].

An intangible asset arising from development (or from the development phase of an internal project) should be recognised if, and only if, an entity can demonstrate meeting all relevant criteria. [IAS 38 para 57].

Expenditure on an intangible item that was initially recognised as an expense should not be recognised as part of the cost of an intangible asset at a later date. [IAS 38 para 71].

**How should Sisley account for the payments to Wright?**

**Solution**

Costs incurred for research should not be capitalised. Sisley’s payments relating to the cost-plus portion of the contract should be expensed. Sisley’s payments relating to the successful identification of candidates should also be expensed. The development candidates were previously identified by Sisley, so no separate intangible has been acquired, and the technological feasibility criterion is not met. The research costs previously expensed cannot be reversed and capitalised with these rights.
1.35 Third-party development of own intellectual property

**Background**

Tiepolo Pharma has appointed Tintoretto Laboratories, a third party, to develop an existing compound owned by Tiepolo on its behalf. Tintoretto will act purely as a service provider, without taking any risks during the development phase, and it will have no further involvement after regulatory approval. Tiepolo will retain full ownership of the compound. Tintoretto will not participate in any marketing and production arrangements. A milestone plan is included in the contract. Tiepolo agrees to make the following non-refundable payments to Tintoretto:

- LC2 million on signing the agreement.
- LC3 million on successful completion of Phase II.

**Relevant guidance**

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

Internally generated intangible assets should only be recognised if, amongst other criteria, the technical feasibility of a development project can be demonstrated. [IAS 38 para 57].

How should Tiepolo account for upfront payments and subsequent milestone payments in a research and development (R&D) arrangement in which a third party develops its intellectual property?

**Solution**

Tiepolo owns the compound. Tintoretto performs development on Tiepolo’s behalf. No risks and rewards of ownership are to be transferred between the parties. By making the initial upfront payment and the subsequent milestone payment to Tintoretto, Tiepolo does not acquire a separate intangible asset, which could be capitalised. The payments represent outsourced R&D services, which needs to be expensed over the development period, provided that the recognition criteria in paragraph 57 of IAS 38 for internally generated intangible assets are not met.
1.36 Joint development of own intellectual property

**Background**

Tiepolo Pharma has appointed Tintoretto Laboratories, a third party, to develop an existing compound owned by Tiepolo on its behalf. The agreement out-licenses Tiepolo’s compound to Tintoretto. Tiepolo and Tintoretto will set up a development steering committee to jointly perform the development, and they will participate in the funding of the development costs according to specific terms. Tiepolo agrees to make the following payments to Tintoretto:

a. LC5 million on signing the agreement, as an advance payment. Tintoretto has to refund the entire payment in the event of failure to successfully complete Phase II.

b. 50% of total development costs on successful completion of Phase II (after deducting the advance payment).

Tiepolo will commercialise the drug. In the case of successful completion of development and commercialisation, Tintoretto will receive milestone payments and royalty streams.

**Relevant guidance**

The price that an entity pays to acquire a separate intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. The effect of probability is reflected in the cost of the asset, and the probability recognition criterion in paragraph 21(a) of IAS 38 is always considered to be satisfied for separately acquired intangible assets. [IAS 38 para 25].

The cost of a separately acquired intangible asset comprises [IAS 38 para 27]:

a. Its purchase price, including import duties and non-refundable purchase taxes, after deducting trade discounts and rebates; and

b. Any directly attributable cost of preparing the asset for its intended use.

Internally generated intangible assets should only be recognised if, amongst other criteria, the technical feasibility of a development project can be demonstrated. [IAS 38 para 57].

**How should Tiepolo account for upfront payments and subsequent milestone payments in an R&D arrangement in which a third party develops its intellectual property?**

**Solution**

Tintoretto becomes party to substantial risks in the development of Tiepolo’s compound, because it is only partly compensated for its development activities if the development succeeds (thereby buying itself into the potential success of the future product). Tiepolo effectively reduces its exposure to ongoing development costs and to potential failure of the development of its compound. However, by paying the refundable advance payment and the subsequent milestone payment (determined to be 50% of total development costs), Tiepolo does not acquire a separate intangible asset, which could be capitalised. The payments represent funding for development of its own intellectual property by a third party. The advance payment and the milestone payment should be expensed as incurred. Tiepolo should record the LC5 million as prepaid expense initially, and it should recognise the pre-paid to R&D expense over the term of the agreement on successful completion of Phase II.
1.37 Cost-plus contract research arrangements

**Background**

Whistler Corp enters into a contract research arrangement with Ruskin Inc to perform research on the geometry of a library of molecules. Ruskin will catalogue the research results in a database.

Whistler will refund all of Ruskin’s direct costs incurred under the contract, and will pay a 25% premium on a quarterly basis as the work is completed.

**Relevant guidance**

Research expenses are recognised as incurred. [IAS 38 para 54]. Examples of research activities include the search for alternatives for materials, devices, products, processes, systems or services. [IAS 38 para 56(c)].

Examples of development activities include the design, construction and testing of a chosen alternative for new or improved materials, devices, products, processes, systems or services. [IAS 38 para 59(d)].

*How should Whistler account for contracted research arrangements?*

**Solution**

*Whistler should expense costs for the contract research as incurred by Ruskin. The activity is within the definition of research. It will not result in the design or testing of a chosen alternative for new or improved materials, devices, products, processes, systems or services that could be capitalised as a development intangible asset. If the payment from Whistler was fixed rather than cost-plus, the accounting treatment would be the same but the research costs would be accrued and spread over the service period.*
2. Manufacturing
2.1 Treatment of trial batches in development

Background

A laboratory is manufacturing a stock of 20,000 doses (trial batches) of a newly developed drug, using various raw materials. The doses can only be used in patient trials during Phase III clinical testing, and they cannot be used for any other purpose. The raw materials can be used in the production of other drugs.

Relevant guidance

Inventories are assets that are [IAS 2 para 6]:

- Held for sale in the ordinary course of business;
- In the process of production for a sale in the ordinary course of business; or
- Materials or supplies that will be used in the production process or rendering of services.

How should management account for the raw materials and trial batches?

Solution

Management should initially recognise the raw materials acquired for the production of trial batches as inventory since the raw materials can be used in the production of other approved drugs. The trial batches do not have any alternative future use, and the technical feasibility of the drug is not proven (the drug is in Phase III). The trial batches (including identified raw materials) should be charged to development expenses in the income statement when they are produced.
2.2 **Treatment of validation batches**

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### Background

A laboratory has just completed the development of a machine to mix components at a specified temperature to create a new formulation of aspirin. The laboratory produces several batches of the aspirin, using the new machinery to obtain validation (approval for the use of the machine) from the relevant regulatory authorities. The validation of the machinery is a separate process from the regulatory approval of the new formulation of aspirin.

### Relevant guidance

The cost of an item of PPE includes the asset’s purchase price and any directly attributable costs of bringing the asset to its working condition, as well as any demolition or restoration costs. [IAS 16 para 16].

Examples of costs that should not be capitalised as PPE are the costs of opening a new facility, the costs of introducing a new product or service, the costs of conducting business with a new class of customer, and administration and other general overhead costs. [IAS 16 para 19].

*Should expenditure to validate machinery be capitalised?*

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### Solution

The laboratory should capitalise the cost of the materials used to obtain the necessary validation for the use of the machinery, together with the cost of the machinery. Validation is required to bring the machinery to its working condition. The cost of the labour involved in the production process should also be capitalised, if it can be directly attributed to the validation process. However, management should exclude abnormal validation costs caused by errors or miscalculations during the validation process (such as wasted material, labour or other resources).
2.3 Indicators of impairment – Inventory

Background
Pharmaceutical company Cerise has decided to suspend temporarily all operations at a certain production site, due to identified quality issues. Cerise initiated a recall of products manufactured on the site. Cerise carries a significant amount of inventory used in the manufacture of the product.

Relevant guidance
Inventories should be measured at the lower of cost and net realisable value. [IAS 2 para 9]. An entity should not carry its inventory at values in excess of amounts expected to be realised from its sale or use. [IAS 2 para 28]. Management should make a new assessment of the net realisable value in each subsequent period. [IAS 2 para 33].

Is the inventory used to manufacture the product impaired?

Solution
Cerise would need to consider all available evidence to determine if there is an impairment. Suspending production and a product recall are indicators that the carrying value of raw material inventory used to manufacture the drug might not be recoverable. Cerise would need to evaluate the reason for the recall, its history with past recalls, the likelihood that the quality issue could be fixed, and if the raw materials have an alternative manufacturing use.

In addition to product recalls, the following events are impairment indicators within the pharmaceutical and life sciences industry:

- Patent expiration;
- Failure to meet regulatory or internal quality requirements;
- Product or material obsolescence;
- Market entrance of competitor products; and
- Changes or anticipated changes in third-party reimbursement policies that will impact the selling price of the inventory.
2.4 Patent protection costs

**Background**
Velazquez Pharma has a registered patent on a currently marketed drug. Uccello Medicines Ltd copies the drug’s active ingredient and sells the drug during the patent protection period. Velazquez goes to trial and is likely to win the case, but it has to pay costs for its attorneys and other legal charges.

**Relevant guidance**
Subsequent expenditure on an intangible can only be capitalised if it enhances the expected future economic benefits of the intangible. [IAS 38 para 20].

*Should legal costs relating to the defence of pharmaceutical patents be capitalised?*

**Solution**
Velazquez should not capitalise patent defence costs, because they maintain rather than increase the expected future economic benefits from an intangible asset. So they should not be recognised in the carrying amount of an asset under paragraph 20 of IAS 38. Patent defence costs have to be expensed as incurred.
2.5 Validation costs of inventory

**Background**

Delacroix SA scrapped the first validation batch produced by its new plant, because it did not meet pre-determined criteria. The subsequent batch met all requirements and was used to successfully validate the plant with the regulatory authorities.

**Relevant guidance**

The cost of an item of property, plant or equipment comprises any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management [IAS 16 para 16]. This includes costs to run normal pre-production tests.

The cost of wasted material, labour or other resources incurred in self-constructing an asset is not included in the cost of the asset. [IAS 16 para 22].

*How should Delacroix account for the first validation batch?*

**Solution**

*Delacroix should expense the first validation batch as validation cost. This cost should be recognised as a component of R&D expense.*
2.6 Recognition of raw materials as inventory

Background

Altdorfer Pharma Corp buys bulk materials used for manufacturing a variety of drugs. The material is used for marketed drugs, samples and drugs in development. The material is warehoused in a common facility, and it is released to production based on orders from the manufacturing and development departments.

Relevant guidance

Inventories are assets that are [IAS 2 para 6]:

a. Held for sale in the ordinary course of business; 
b. In the process of production for such sale; or 
c. In the form of materials or supplies to be consumed in the production process or in the rendering of services.

How should purchased materials be accounted for when their ultimate use is not known?

Solution

Altdorfer should account for raw materials that can be used in the production of marketed drugs as inventory. The material should be accounted for as a marketing expense at the point where it is packaged for use as a sample. The material should be accounted for consistently with the treatment of other R&D expense related to the product, when the material is released to production for use in manufacturing of drugs in development.
2.7 Pre-launch inventory produced before regulatory approval

**Background**
Van Eyck Ltd has an asthma drug in development. Management has determined that the drug has not yet met the criteria in paragraph 57 of IAS 38 to allow capitalisation of development costs. Management believes that there is a 40% likelihood that development will succeed and that final regulatory approval will occur in the short term. Van Eyck takes the risk of building inventories of the finished product in order to facilitate immediate launch after regulatory approval. The inventory has no alternative use.

The inventory building begins with small production runs prior to final regulatory approval, and it continues after the approval.

**Relevant guidance**
Inventories are assets that are [IAS 2 para 6]:
- a. Held for sale in the ordinary course of business;
- b. In the process of production for such sale; or
- c. In the form of materials or supplies to be consumed in the production process or in the rendering of services.

The practice of writing inventories down below cost to net realisable value is consistent with the view that assets should not be carried in excess of amounts expected to be realised from their sale or use. [IAS 2 para 28].

A new assessment is made of net realisable value in each subsequent period. When the circumstances that previously caused inventories to be written down below cost no longer exist, or when there is clear evidence of an increase in net realisable value because of changed economic circumstances, the amount of the write-down is reversed. [IAS 2 para 33].

**What is the carrying amount of pre-launch inventory?**

**Solution**
Van Eyck’s management does not believe that the asthma drug has achieved technological feasibility prior to final regulatory approval.

Inventory manufactured prior to this approval is immediately provided for and written down to zero (that is, the probable amount expected to be realised from its sale at the time of production). The write-down should be recognised in cost of goods sold or as R&D expense, according to its policy.

Van Eyck has demonstrated the probability of the technological feasibility of the drug, by obtaining final regulatory approval. It begins to capitalise the inventory costs. The provision recognised prior to approval should also be reversed, up to no more than the original cost. The reversal should also be recognised through cost of goods sold or as R&D expense, as applicable.
2.8 Treatment of inventory of ‘in-development’ drugs after filing

Background

Laboratory A has produced 15,000 doses of a new drug, following submission of the final filing for regulatory approval, so that it can go to market with the drug as soon as it obtains regulatory approval. The doses cannot be used for any other purpose. Management is considering whether the doses should be recognised as inventory.

Relevant guidance

Inventories are assets that are [IAS 2 para 6]:

a. Held for sale in the ordinary course of business;
b. In the process of production for a sale in the ordinary course of business; or
c. Materials or supplies to be used in the production process.

How should the costs associated with the production of inventory for ‘in-development’ drugs be accounted for?

Solution

Laboratory A should capitalise the doses that it has produced, to the extent that they are recoverable. Final filing for regulatory approval indicates that marketing approval is probable. Therefore, these items of inventory can be treated as fully recoverable.
2.9 Treatment of inventory of ‘in-development’ generic drugs

Background

Tina Pharmaceuticals developed a generic version of an original drug whose patent is due to expire at the end of 20X3. Management believed that the generic version was the chemical equivalent of the original drug, and that economic benefits were probable. Deeming that it had met the recognition criteria of paragraph 57 of IAS 38, it therefore began to capitalise development costs in May 20X3.

Tina produced 15,000 doses of pre-launch inventory of the generic drug in June 20X3. The doses cannot be used for any other purposes. The patent on the original drug expired, and marketing approval for the generic version was received in November 20X3. Management is considering whether the cost of the pre-launch inventory should be capitalised in its financial statements as at 31 October 20X3.

Relevant guidance

Inventories are assets that are [IAS 2 para 6]:

a. Held for sale in the ordinary course of business;

b. In the process of production for a sale in the ordinary course of business; or

c. Materials or supplies to be used in the production process.

How should the costs associated with the production of inventory for generic drugs ‘in development’ be accounted for?

Solution

Pre-launch inventory should be recognised as inventory at the lower of its cost and net realisable value. Management’s conclusion to capitalise development costs is an indication that the generic drug is economically viable, and so it appears reasonable to assume that the pre-launch inventory costs will be realised through future sales.

The marketing approval received after year end is a subsequent event that confirms management’s year end assessment.
2.10 Accounting for vaccine cultures in manufacturing of pharmaceutical products

Background

Caravaggio Corp’s leading product is a vaccine. The vaccine’s antibody is produced using virus cultures. These cultures and the resulting antibody are an important part of Caravaggio’s total inventory costs.

Relevant guidance

IAS 2 applies to all inventories, except biological assets related to agricultural activity and agricultural produce at the point of harvest. [IAS 2 para 2].

A ‘biological asset’ is a living animal or plant. [IAS 41 para 5].

A biological asset should be measured on initial recognition, and at each balance sheet date, at its fair value less estimated point of sale costs. [IAS 41 para 12].

Should vaccine cultures used in the production of pharmaceutical products be measured at cost or at fair value less cost to sell?

Solution

A virus is not a living plant or animal, and so it is outside the scope of IAS 41. Caravaggio should account for its production of vaccine cultures at cost as a component of inventories, following the guidance of IAS 2.
3. Funding for R&D
3.1 Capitalisation of interest on loans received to fund research and development

**Background**

Pharmaceutical entity Pilax has obtained a loan from Qula, another pharmaceutical company, to finance the late-stage development of a drug to treat cancer. Pilax management has determined that the criteria for capitalisation are met after filing for regulatory approval, because they are confident that approval will be received. Pilax capitalises borrowing costs on qualifying assets, as required by IAS 23.

**Relevant guidance**

An entity should capitalise borrowing costs that are directly attributable to the acquisition, construction or production of a qualifying asset as part of the cost of that asset. An entity should recognise other borrowing costs as an expense in the period in which it incurs them. [IAS 23 para 8]. A qualifying asset is an asset that necessarily takes a substantial period of time to prepare for its intended use or sale. [IAS 23 para 5].

The cost of an internally generated intangible asset includes all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management. [IAS 38 para 66]. Allocations of overheads are made on bases similar to those used in allocating overheads to inventories. IAS 23, ‘Borrowing Costs’, specifies criteria for the recognition of interest as an element of the cost of an internally generated intangible asset. [IAS 38 para 66].

**Solution**

Borrowing costs incurred before capitalisation of development costs are expensed. Borrowing costs should be capitalised for qualifying assets once development costs are being capitalised. Capitalisation of borrowing costs should cease once the drug has been fully developed and is available for sale.
3.2 Funding for Phase III trials

Background

Tiepolo Pharma is developing a pharmaceutical compound (compound X), which has successfully passed through Phase II clinical trials.

Randolph Ventures offers to fund, for Tiepolo, the Phase III clinical trial studies and all registration costs. The study results and documentation will be the property of Randolph.

The terms of the agreement are:

- Randolph will keep any trial results, if compound X fails in Phase III, and Tiepolo will transfer the underlying intellectual property (IP).
- Tiepolo has an obligation to acquire the studies and documentation, if compound X achieves regulatory approval. Tiepolo will pay a milestone on regulatory approval equal to 150% of the estimated total development costs. Tiepolo will also pay a 5% royalty on sales for five years.

Randolph subcontracts Tiepolo as a contract research provider to perform the necessary development activities for Phase III clinical trials on its behalf.

Tiepolo will plan and carry out the necessary clinical development project. Tiepolo has a best efforts clause to continue to develop compound X.

Relevant guidance

A financial liability is any liability that is a contractual obligation to deliver cash or another financial asset to another entity. [IAS 32 para 11]. A financial instrument might require the entity to deliver cash or another financial asset, or otherwise to settle it in such a way that it would be a financial liability, in the event of the occurrence or non-occurrence of uncertain future events or on the outcome of uncertain circumstances. The issuer of such an instrument does not have the unconditional right to avoid delivering cash or another financial asset (or otherwise to settle it in such a way that it would be a financial liability). [IAS 32 para 25].

1. Has Tiepolo lost control of compound X?

2. How should Tiepolo account for the funding received?
Solution

1. Has Tiepolo lost control of compound X?

Tiepolo has a contract to conduct development services and the obligation to acquire the outcome of the Phase III studies if the study result is successful. At inception of the contract, the potential future economic benefits for the owner of the Phase III study are limited. There is no alternative use for the study outcome without the patented IP for the underlying compound. Tiepolo directs the Phase III trials. Tiepolo has not lost control of compound X.

2. How should the funding received be accounted for?

Randolph has provided funding for Phase III trials. The contract stipulates that Tiepolo pays back 150% of the cash and a sales-based royalty if the Phase III trials are successful. Tiepolo must transfer the IP of compound X if the trial is unsuccessful. Tiepolo must pay cash contingent on a condition outside its control (that is, successful completion of Phase III). It can avoid paying cash only by the settlement of a non-financial obligation (the IP). This meets the definition of a financial liability.

A financial liability should be measured initially at fair value. Subsequently the liability would be measured at amortised cost. If Tiepolo revises its estimates of payments it shall adjust the carrying about of the liability. This adjustment would be charged to the income statement. Passage of time is dealt with through the unwind of the discount and also charged to the income statement. [IAS 39 para AG8].

Results:

In case of failure – Tiepolo should derecognise the financial liability. Any intangible asset on the balance sheet for compound X should be derecognised, and the balance should go to the P&L.

In case of success – An AG8 adjustment to the liability is required if successful. [IFRS 9 para B5.4.60]. Tiepolo would need to estimate the future royalty payable and recognise a further financial liability. The liability for the development costs would be derecognised on the date when it is paid.

R&D funding arrangements are a complex and judgmental area. Each structure should be evaluated on its specific facts and circumstances.
3.3 Loans and grants to fund research and development from the government/charitable organisations

Background

Warhol Inc is a small start-up company and has obtained financing from the government in country A. The financing, which is in cash, will be used for a research project for the development of a drug. The cash is repayable to the government only if the entity decides to exploit and commercialise the results of the research project. The repayment terms mandate that the entity repays an amount equal to 10% of sales per year, if the entity starts selling the drug.

Warhol should transfer all of the intellectual property to the government, if the project is unsuccessful or if Warhol decides to abandon the project.

Relevant guidance

A financial instrument that does not explicitly establish a contractual obligation to deliver cash or another financial asset might establish an obligation indirectly through its terms and conditions. For example, a financial instrument might contain a non-financial obligation that must be settled if the entity fails to make distributions or to redeem the instrument. If the entity can avoid a transfer of cash or another financial asset only by settling the non-financial obligation, the financial instrument is a financial liability. [IAS 32 para 20(a)].

A benefit of a government loan at below market rate of interest is treated as a government grant. The loan should be recognised and measured in accordance with IFRS 9/IAS 39. The benefit should be measured as the difference between the initial carrying value of the loan and the proceeds received. The benefit is accounted for in accordance with IAS 20, ‘Government grants’.

How should the entity account for the loan obtained from the government?

Solution

The loan meets the definition of a financial liability under IAS 32, and it should be accounted for in accordance with IFRS 9/IAS 39. The entity can avoid delivering cash only by settling the obligation with the intellectual property and research results.

The liability is initially recognised at fair value, and any difference between the cash received and the fair value of the liability is a government grant, which is accounted for under IAS 20, ‘Government grants’.
3.4 Venture Capital Company funds Phase III through a new company

**Background**

Pharma (a large pharmaceutical company) has a number of internally developed compounds which have successfully reached Phase II. Pharma can only continue to develop a selection of these compounds, based on resource constraints. A venture capital company (VC) offers to fund Phase III trials in return for a success payment. VC sets up a new entity, DevCo, and Pharma grants DevCo a licence to carry out the Phase III development and to seek regulatory approval. The licence agreement stipulates that DevCo will make best efforts to continue development. DevCo will outsource the Phase III trials to a contract research organisation (CRO). VC cannot sell DevCo. DevCo cannot sell any compounds to third parties.

Pharma holds a call option to purchase 100% of DevCo. The option can be exercised on successful completion of Phase III at a price based on three times the R&D expenditure. VC holds a put option whereby, on successful completion of Phase III, it can exercise the option to sell DevCo at three times the R&D expenditure back to Pharma (that is, a success payment).

**Relevant guidance**

An investor controls an investee if, and only if, the investor has all of the following:

- Power over the investee;
- Exposure, or rights, to variable returns from its involvement with the investee; and
- The ability to use its power over the investee to affect the amount of the investor's returns.

[IFRS 10 para 7].

An investor with the current ability to direct the relevant activities has power, even if its rights to direct have yet to be exercised. Evidence that the investor has been directing relevant activities can help to determine whether the investor has power; but such evidence is not, in itself, conclusive in determining whether the investor has power over an investee. [IFRS 10 para 12].

An investor is exposed, or has rights, to variable returns from its involvement with the investee when the investor’s returns from its involvement have the potential to vary as a result of the investee’s performance. The investor’s returns can be only positive, only negative, or both positive and negative. [IFRS 10 para 15].

Which party has control of DevCo?
Solution

Pharma controls DevCo, and so it will consolidate. Control requires power over relevant activities, exposure to variable returns, and a link between power and returns under IFRS 10. Control assessments are straightforward for an entity controlled by voting rights. A structured entity exists when control is exercised by other means. The other means can include participating in the determination of purpose and design of the structured entity and asset selection, contractual arrangements, potential voting rights, contingent rights, as well as power over activity that happens outside the structured entity but is relevant to it.

A. Power over relevant activities

A relevant activity is an activity that significantly affects returns. The ultimate return from each product comes from the original compound. The development that DevCo carries out will be successful or unsuccessful, based on the underlying science. Asset selection is therefore the most relevant activity. Although Pharma and VC agree the selection together, Pharma chooses the original set of compounds on offer. Pharma also retains the IP for the compound. When assessing control, the purpose and design of the investee should be considered and, again, this would suggest that asset selection is key; this is because, without it, there would be no purpose to DevCo.

B. Exposure to variable returns

Pharma has a nil or variable positive return on the compound. If the compound is unsuccessful, it has a nil return; and, if the compound is successful, its return will be based on future sales. Paragraph 15 of IFRS 10 states that returns can be wholly positive or negative. Pharma also has the ability to affect the returns through the initial asset selection and its marketing efforts.

C. Rights over those returns

Paragraph B53 of IFRS 10 notes that the rights do not have to be currently exercisable, provided that the investor can exercise its rights when the key decisions over relevant activities need to be made. This is likely to be when the successful drug is returned to Pharma, gains regulatory approval and is brought to market.
4. Business combination
4.1 Acquisition of a single compound

Background
Atom Inc is interested in a single compound, A, of another company, Bark Corp. Bark puts compound A, which is currently in Phase I, into a newly formed shell company (‘NewCo’). The intellectual property of compound A is the only item contributed into NewCo. No scientists or administrative personnel are hired by NewCo, and there are no other assets (such as development equipment) put into NewCo. Atom acquires a 100% interest in NewCo, which gives Atom control over NewCo and compound A. Atom will provide the scientists, equipment and financial support to develop compound A through regulatory approval. Bark will have no further involvement in compound A.

Relevant guidance
A business consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set to qualify as a business. [IFRS 3 paras B7–B12].

Processes are defined as any system, standard, protocol, convention or rule that creates, or has the ability to create, output. [IFRS 3 para B7(b)].

Is the acquisition of the interest in NewCo a business combination?

Solution
The acquisition of the NewCo is likely to be an asset acquisition. An input has been acquired (compound A), but no processes have been acquired. Processes are included in the acquired group when intellectual property is accompanied by blueprints, plans, protocols or employees, such as scientists, researchers or a labour force who will further develop the IP to the next phase or prepare the IP for approval by a regulatory body. The legal form of a transaction does not determine the accounting treatment. It is irrelevant whether or not a legal entity is involved in a transaction and, in certain cases, the acquisition of a legal entity would not be a business combination, due to the facts and circumstances of the transaction. Here, the specific facts indicate that the acquisition of NewCo is an asset acquisition, and it should be accounted for under IAS 38, because NewCo does not meet the definition of a business.
4.2 Acquisition of compound and scientists transfer

**Background**

Company A owns the right to several drug compound candidates that are currently in Phase I. Company A’s activities consist of research and development that is being performed on the early-stage drug compound candidates. Company A employs management and administrative personnel, as well as scientists who are vital to performing the research and development. Company B acquires the rights to the drug compound candidates, along with the scientists formerly employed by company A who are developing the acquired Phase I drug compound candidates.

**Relevant guidance**

Businesses consist of inputs (such as tangible and intangible assets) and processes (such as systems, standards and protocols) applied to those inputs that have the ability to create outputs (such as dividends and lower costs). [IFRS 3 para B7].

An organised workforce, with the necessary skills and experience, might provide the necessary processes that are capable of being applied to inputs to create outputs. [IFRS 3 para B7].

Should company B account for the transaction as a business combination?

**Solution**

*The acquisition of the compound is likely to be a business combination.*

Company B acquired the Phase I drug compounds (inputs), along with the scientists (processes) who are vital to performing the research and development. The scientists have the necessary skills and experience, and provide the necessary processes (through their skills and experience) that are capable of being applied to inputs to create outputs.

Although company B did not acquire a manufacturing facility, testing and development equipment, or a sales force, it determined that the likely market participants are other large pharmaceutical companies that already have these items or could easily replicate them.
4.3 Accounting for acquired IPR&D

Background

Pharmaceutical company A owns the rights to several product (drug compound) candidates. Its only activities consist of research and development performed on the product candidates. Company B, also in the pharmaceutical industry, acquires company A, including the rights to all of company A’s product candidates, testing and development equipment, and it hires all of the scientists formerly employed by company A, who are integral to developing the acquired product candidates. Company B accounts for this transaction as an acquisition of a business.

Relevant guidance

An entity should recognise the identifiable intangible assets acquired [IFRS 3 para B31] at the acquisition date fair value, [IFRS 3 para 18].

An entity should assess whether the useful life of an intangible asset is finite or indefinite. An intangible asset shall be regarded by the entity as having an indefinite useful life when there is no foreseeable limit to the period over which the asset is expected to generate net cash inflows. [IAS 38 para 88].

Assets with indefinite useful life should be tested annually for impairment, or when indications for impairment exist. [IAS 38 para 108]. If there is a change of useful economic life, from indefinite to finite, this is also considered to be an indicator for impairment. [IAS 38 para 110]. Assets with definite useful life should be tested for impairment when indications for impairment exist. [IAS 38 para 111].

Amortisation of an intangible asset should begin when the asset is available for use. [IAS 38 para 97].

How should company B account for the acquired IPR&D?

Solution

Research and development projects acquired as part of a business combination are recognised as an intangible asset, if they can be reliably measured. Company B should measure the acquired IPR&D at its acquisition date fair value. Acquired IPR&D would normally not be amortised, since it is not available for use until an approved product is commercialised.

The acquired IPR&D would be tested for impairment annually or more frequently, whenever an impairment indicator is identified. The impairment test would compare the recoverable amount of the IPR&D asset to its carrying value.

Subsequent expenditure incurred should be accounted for in accordance with IAS 38:

- Research expenditure should be expensed.
- Development expenditure should be expensed, provided that the relevant criteria of IAS 38 are not met (usually until regulatory approval has been achieved).

When the IPR&D becomes available for use, it should be amortised over its useful economic life.
5. Revenue – IAS 18
5.1 Contract for development services

**Background**

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraine over a five-year period. Alpha is engaged only to provide development services, and it will periodically have to update BetaX with the results of its work. BetaX owns the underlying product IP, and it has exclusive rights over the development results. BetaX owns Alpha’s work in progress at all points in the contract.

BetaX will make 20 equal quarterly non-refundable payments of LC250,000 (totalling LC5 million). Payments do not depend on the achievement of a particular outcome, but Alpha is required to demonstrate compliance with the development programme. Alpha’s management estimates that the total cost will be LC4 million.

Alpha has completed many similar contracts, and it has a track record of reliably estimating costs to complete. Alpha incurs costs of LC400,000 in the first quarter of year 1, in line with its original estimate. Alpha is in compliance with the research agreement, including the provision of updates from the results of its work.

**Solution**

Alpha is providing a service to its customer. Alpha should recognise the revenue for the payments using the percentage of completion method. This should be based on an estimate of total costs [IAS 18 para 20] or on a straight-line basis [IAS 18 para 25], whichever provides the best reflection of the stage of completion. A percentage of completion model, based on the estimate of total costs, appears to be the most appropriate for Alpha.

Alpha has met its obligations, the project is developing in line with the estimates, and it is forecasted to be profitable. Alpha should recognise revenue of LC500,000, costs of LC400,000 and profit of LC100,000 for the first quarter. The unbilled LC250,000 of revenue should be recognised as a receivable on Alpha’s balance sheet.

**Relevant guidance**

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants. [IAS 18 para 7].

The stage of completion of a transaction could be determined by a variety of methods. The methods might include the proportion that costs incurred to date bear to the estimated total costs of the transaction. [IAS 18 para 24].

For practical purposes, when services are performed by an indeterminate number of acts over a specified period of time, revenue is recognised on a straight-line basis over the specified period, unless there is evidence that some other method better represents the stage of completion. [IAS 18 para 25].

Revenue is recognised only to the extent of recoverable expenses if the outcome of the transaction involving the rendering of services cannot be estimated reliably. [IAS 18 para 26].

*How should Alpha recognise the payments that it receives from BetaX to conduct development?*
5.2 Development services with upfront and contingent payments

**Background**

CareB has appointed Devox to develop an existing compound on its behalf. Devox will have no further involvement in the compound after regulatory approval. CareB will retain full ownership of the compound (including intellectual rights) at all stages during the development contract and after regulatory approval is obtained. Devox will not participate in any further marketing or production arrangements. A milestone plan is included in the contract. CareB agrees to make the following non-refundable payments to Devox:

a) LC3 million on signing of the agreement;
b) LC1 million on successful completion of Phase III clinical trial; and
c) LC2 million on securing regulatory approval.

Devox expects to incur costs totalling LC3 million up to the point of securing regulatory approval. Management cannot reliably estimate whether the compound will obtain Phase III clinical trial approval or regulatory approval.

**Relevant guidance**

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18 para 7].

The outcome of a transaction can be estimated reliably when all of the following conditions are satisfied: (a) the amount of revenue can be measured reliably; (b) it is probable that the economic benefits associated with the transaction will flow to the entity; (c) the stage of completion of the transaction at the end of the reporting period can be measured reliably; and (d) the costs incurred for the transaction and the costs to complete the transaction can be measured reliably. [IAS 18 para 20].

For practical purposes, when services are performed by an indeterminate number of acts over a specified period of time, revenue is recognised on a straight-line basis over the specified period, unless there is evidence that some other method better represents the stage of completion. [IAS 18 para 25].

*How should Devox recognise revenue for this contract?*
**Solution**

Devox is providing a service to its customer. Devox should recognise the revenue for the payments in accordance with the percentage of completion model. This should be based on an estimate of total costs [IAS 18 para 20] or on a straight-line basis [IAS 18 para 25], whichever provides the best reflection of the stage of completion.

The consideration received includes a fixed amount (the upfront payment) and two contingent amounts (dependent on clinical trial and regulatory approval). Devox does not recognise revenue unless and until there is a probable inflow that can be reliably measured. [IAS 18 para 20].

The upfront payment is initially deferred. The LC3 million has been received, but no services have yet been provided, and so the earnings process is not yet completed. The upfront payment will be recognised as revenue over the expected contract period, on a basis that is consistent with the services being provided (which might be, for example, based on costs incurred as a percentage of total budgeted costs). The future milestone payments are not included in the determination of revenue until Devox can conclude that their receipt is probable, which is unlikely to be possible until the contingencies are resolved.

Devox applies the milestone payment method to recognise revenue arising from the upfront and milestone payments. The ‘milestone payment method’ (each milestone payment is recognised as revenue on successful completion of a milestone) is a common application of the percentage of completion method in the industry.

The upfront payments and milestones in aggregate equate to funding of much of the development work on the compound, based on an overall assessment of the net present value of the project. Devox only receives the milestones if the output of its work is 100% complete and successful. Substantive effort and considerable cost will be incurred in completing the Phase III trial and obtaining regulatory approval. The pattern of milestone payments reflects the work performed.

**Alternatives to the milestone method**

An entity is most likely to use a contingency-adjusted performance model where the milestone method cannot be used. In this model, revenue related to each payment is recognised over the entire contract performance period, starting from contract inception, but not prior to the removal of any contingencies for each individual milestone. Effectively, the percentage of completion is determined by considering, for example, costs incurred as a percentage of total budgeted costs, and that percentage is applied to all payments due under the contract that are no longer contingent. Revenue is true up by re-estimating the percentage of completion and the total non-contingent payments at each reporting date.

The accounting by CareB is explained in Solution 1.35.
5.3 Receipts for out-licensing

Background
Pharmaceutical entities Regal and Simba enter into an agreement in which Regal will license Simba’s know-how and technology to manufacture a compound for AIDS. Regal will use Simba’s technology in its facilities for a period of ten years. Simba receives a non-refundable upfront payment of LC3 million for access to the technology. Simba will also receive a royalty of 20% from sales of the AIDS drug if it is successful.

Relevant guidance
Fees and royalties paid for the use of an entity’s assets are normally recognised in accordance with the substance of the agreement. This is often on a straight-line basis when the licensee has the right to technology for a certain period of time. [IAS 18 para 30].

Revenue is recognised only when it is probable that the fee or royalty will be received. Where a licence fee or royalty is contingent on the occurrence of a future event, this is normally when the event has occurred. [IAS 18 para 20].

How should Simba account for a non-refundable upfront fee received for licensing out its know-how and technology and the royalty to be received on sales?

Solution
Simba’s management recognises the non-refundable upfront fee on a straight-line basis over the ten-year licence term.

Management recognises the royalties as revenue when earned. The royalty should be disclosed as a separate category within revenue, if it is material to Simba’s financial statements.

The accounting by Regal is explained in Solution 1.13.
5.4 **Onerous contracts**

**Background**

Botticelli contracts Cezanne, a pharmaceutical research company, to perform R&D services on a new medical treatment for asthma over a five-year period. Cezanne is engaged only to provide development services, and it will periodically have to update Botticelli on the results of its work. Botticelli has exclusive rights over the development results. Botticelli will make five annual payments of LC1 million (totalling LC5 million). Half of the money is non-refundable, and the other half is refundable if the new drug does not obtain regulatory approval. Cezanne’s management estimates that the total costs will be LC4 million, and that it will incur those costs equally over the development period (that is, LC800,000 per annum). Cezanne must continue to develop for the five years, unless the drug fails.

The project costs have increased after year 3. Cezanne has spent LC3.75 million, and it has received the first three instalments totalling LC3 million from Botticelli. Cezanne expects the costs to continue at LC1.25 million a year.

**Relevant guidance**

An onerous contract is a contract where the unavoidable costs of meeting the obligations under the contract exceed the economic benefits expected to be received under it. [IAS 37 para 68].

An onerous contract is recognised as a provision. [IAS 37 para 66].

*How should Cezanne account for the contract at inception and in year 3?*

**Solution**

**At contract inception**

Cezanne could make a loss of LC1.5 million (costs of LC4 million offset by revenues of LC2.5 million) if regulatory approval is not received. The contract is not onerous when it is signed, even though achievement of regulatory approval cannot be considered highly probable at that point. An onerous contract provision should not be recognised until it is apparent that Cezanne is committed to incur the loss, and results indicate that the development will fail. The risks of success and failure are generally factored into price negotiations such that, at the outset of a contract, the expected revenues (on a weighted average probability basis) exceed the expected costs of fulfilling the contract. The costs should be recognised as an expense as incurred.

**Year 3**

In year 3, costs have increased, and they are likely to total LC6.25 million (LC1.25 million × 5 years). The contract is expected to make a loss of at least LC1.25 million (LC5 million − LC6.25 million), even if the drug is successful. The costs are unavoidable, because Cezanne cannot stop providing the development services. A provision should be recognised. The provision would be measured at the lower of the costs to exit the contract and the net costs to fulfil the contract. [IAS 37 para 68].
5.5 **Outcome-based pay-for-performance arrangements**

**Background**

The Umbrella Insurance Company and Rembrandt Pharmaceuticals put in place a reimbursement scheme in Territory X for treatment of Alzheimer’s with Rembrandt’s newly developed and approved product. Umbrella will only pay, under the scheme, for the drug in Territory X for those patients in whom Rembrandt’s product is shown to effectively slow down the progression of Alzheimer’s. The contract stipulates specific indicators which show that progression has slowed. Umbrella will only pay if all indicators have been evidenced and the required outcome has been demonstrated.

The outcome, at the inception of this arrangement, is unknown. Rembrandt’s product has already been subject to clinical trials during the approval process, but the patient population used in the clinical trials is different from the population in Territory X.

**Relevant guidance**

An entity recognises revenue from the sale of goods where all of the following conditions are satisfied:

a) It has transferred the significant risks and rewards to the buyer;

b) It retains neither continuing managerial involvement, to the degree usually associated with ownership, nor effective control over the goods sold;

c) The amount of revenue can be measured reliably;

d) It is probable that economic benefits will flow to the entity; and

e) The costs incurred or to be incurred can be measured reliably. [IAS 18 para 14].

**How should pharmaceutical entities recognise revenue under pay-for-performance arrangements?**

**Solution**

Rembrandt entered into a contract to sell drugs to be paid for by Umbrella. Umbrella only pays Rembrandt when there is a certain pre-defined outcome. The outcome at the inception of this arrangement is unknown. Rembrandt cannot be sure, on the day that it sells the drug, whether an individual patient will show all indicators of reduced Alzheimer’s. Rembrandt is therefore unlikely to know if it will receive compensation for the drug, and so it should initially defer the revenue.

It is expected that Rembrandt will be able to build a sufficient record of outcomes over time, to judge whether it is probable that it will receive payment. Rembrandt will recognise revenue when it judges that it is probable that it will be compensated and the revenue can be reliably measured.
5.6 Out-licence of development-phase compound where the licensee continues to do the development work

**Background**

Biotech Co has successfully developed a drug for Syndrome Q through Phase II trials. Biotech and a large pharmaceutical company (Pharma Co) have agreed the following terms:

- Biotech grants a licence to Pharma to manufacture, sell and market the product in the USA for the treatment of Syndrome Q. Biotech retains the patents and underlying intellectual property associated with the product.
- Pharma is to fund and perform all Phase III clinical development work on the drug developed by Biotech, to obtain regulatory approval in the USA.
- There is a development committee that oversees the development of the product. The development committee makes all strategic decisions regarding the product. Biotech is not required to attend the committee, but it has the right to, and expects to, attend.
- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.
- Biotech retains the right to sell the product in the rest of the world.

The consideration payable by Pharma includes:

- An upfront payment of LC10 million on signing the contract.
- A milestone payment of LC20 million on approval.
- Royalties payable on sales of 15%.
- A sales milestone of LC20 million in the first year that annual sales exceed LC500 million.

The upfront payments and milestones are non-refundable in the event that the contract is cancelled when the payments have been made.

**Relevant guidance**

An entity recognises revenue from the sale of goods where all of the following conditions are satisfied:

a) It has transferred the significant risks and rewards to the buyer;

b) It retains neither continuing managerial involvement, to the degree usually associated with ownership, nor effective control over the goods sold;

c) The amount of revenue can be measured reliably;

d) It is probable that economic benefits will flow to the entity; and

e) The costs incurred or to be incurred can be measured reliably. [IAS 18 para 14].

Fees and royalties paid for the use of an entity’s assets are normally recognised in accordance with the substance of the agreement. This is often on a straight-line basis when the licensee has the right to technology for a certain period of time. [IAS 18 para 30]. An assignment of rights for a fixed fee or non-refundable guarantee under a non-cancellable contract (which permits the licensee to exploit those rights freely, and the licensor has no remaining obligations to perform) is, in substance, a sale. [IAS 18 para IE20].

The receipt of a licence fee or royalty might be contingent on the occurrence of a future event. Revenue is recognised only when it is probable that the fee or royalty will be received, which is normally when the event has occurred. [IAS 18 para IE20].

**How should Biotech recognise revenue under the out-licensing agreement?**
Solution

Biotech has licensed the rights to its product in the USA.

Biotech’s guarantee to defend the patent from unauthorised use is not considered to be a substantive ongoing obligation, but it is, in substance, akin to a warranty.

Biotech has a seat on a development committee, but it is not required to attend. This is not a substantive ongoing obligation to Pharma. The licence is the only deliverable.

Revenue recognition

Biotech does not have any substantive ongoing obligations that would result in the arrangement being considered a deliverable over time. [IAS 18 para IE20].

Pharma has an exclusive licence to sell the product in the US. There are no substantive restrictions on how it sells or markets the product. Biotech might earn a royalty on those sales, but it has no ability to influence the sales. Revenue is recognised when the risks and rewards of the licence have been transferred to Pharma.

Measuring revenue

The consideration for the licence comprises a fixed element (the upfront payment) and two variable elements (the milestone payments and the royalties).

The upfront payment has been received, and so the economic inflow is probable (in fact, it is certain) and the amount received is reliably measured. The upfront payment can be recognised as revenue when the risks and rewards are transferred.

The milestones relating to regulatory approval are not probable until approval is obtained. The milestone is recognised as revenue when regulatory approval is received. Receipt of the sales milestone is not probable at this stage either.

When the product is commercialised, Biotech will consider whether it is probable that the sales milestone will be received at each reporting date. Biotech should consider the latest available information (for example, sales already made, sales forecasts, and any other relevant factors). The sales milestone is recognised as revenue if it is probable that it will be received. This might not occur until the sales threshold has been met.

Royalties

Any royalty income is recognised as revenue when the underlying sales are made by Pharma, since the probable inflow and reliable measurement recognition criteria are unlikely to be met before the sales are made.

See Solution 1.16 for the accounting of Pharma.
5.7 **Out-licence of development-phase compound where the licensee continues to do the development work**

**Background**

Biotech Co is a well-established company that has the expertise to perform clinical trials. Biotech enters into a contract with Pharma Co with the following terms:

- Biotech is responsible for performing Phase III clinical trials and obtaining regulatory approval.
- Biotech grants Pharma a licence to manufacture, sell and market product.
- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.

The consideration payable by Pharma under this agreement comprises:

- An upfront payment of LC10 million.
- A milestone payment of LC20 million payable on successful completion of a Phase III trial.
- A milestone payment of LC10 million on regulatory approval.
- Royalties payable on sales of 25%.

An internal analysis of Biotech shows that royalties on a similar licence provided without development services, at the same stage of development, would typically be in the range of 23% to 26% of sales.

**Relevant guidance**

Contracts for services should be accounted for using the percentage of completion method. When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction should be recognised by reference to the stage of completion of the transaction at the end of the reporting period. [IAS 18 para 21].

The outcome of a transaction can be estimated reliably when all of the following conditions are satisfied [IAS 18 para 20]:

a) The amount of revenue can be measured reliably;

b) It is probable that the economic benefits associated with the transaction will flow to the entity;

c) The stage of completion of the transaction at the end of the reporting period can be measured reliably; and

d) The costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

**How should Biotech recognise revenue under the out-licensing agreement?**
Solution

Biotech has concluded that it is providing development services on an out-licensed product.

Upfront payment

Because Biotech has concluded it’s providing a service it has assumed that the out-licensed product has no stand-alone value for Pharma without further development. Biotech has not fulfilled any of its obligations under the agreement on initial signing. Therefore, the upfront payment should be deferred and recognised over the development period, using an appropriate measure of progress.

Milestones

The milestone payments are recognised when earned and receivable (that is, when the relevant development work has been completed and when the related revenue has met the recognition criteria in IAS 18). This is likely to be on achievement of each of the milestone events, since, until that point, the related revenue cannot be assessed as being probable.

Royalties

Any royalty income is recognised as revenue when the underlying sales are made by Pharma, since the probable inflow and reliable measurement recognition criteria are unlikely to be met before the sales are made.

See Solution 1.17 for the accounting of Pharma.
5.8 Revenue recognition to customers with a history of long delays in payment

**Background**

Tiepolo Pharma sells prescription drugs to a governmental entity in a country in Southern Europe.

Tiepolo has historically experienced long delays in payment for sales to this entity, due to slow economic growth and high debt levels in the country. The receivables are non-interest bearing.

Tiepolo currently has outstanding receivables from sales to this entity over the last three years, and it continues to sell products at its normal market price.

**Relevant guidance**

A company must conclude that it meets the five revenue recognition criteria in IAS 18, ‘Revenue’, in order to be able to recognise revenue. The two criteria most relevant in this situation are as follows.

a) The amount of revenue can be measured reliably; and

b) It is probable that the economic benefits associated with the transaction will flow to the entity.

[IAS 18 para 14].

*How should Tiepolo’s management account for the outstanding receivables and future sales to the governmental entity in this country of Southern Europe?*
Solution

Tiepolo’s management must first determine that it is probable that it will be paid for the goods that it has delivered. Slow payment does not, on its own, preclude revenue recognition. However, it might well impact the amount of revenue that can be recognised, because the receivable will be discounted at initial recognition.

Price pressure, discounts, price concessions as a result of expected negotiations, caps and clawbacks that might be demanded by governments should be considered, as follows:

- An estimate of discounts and similar allowances that will be granted in the future, based on current market conditions and practice, should be deducted from the amount recognised as revenue.
- Revenue should not be recognised if payment is not expected or the amount of discounts and allowances are expected to be material but cannot be estimated.

Revenue is reduced by any discount recognised at initial recognition expected for slow payment and for expected allowances and discounts. Tiepolo’s management might immediately factor receivables at a discount from face value. A company using this practice should estimate the discount when sales are made, and it should reduce the amount of revenue recognised. The price received from the factor is likely to be a reasonable proxy for expected discounts, allowances and credit risk when receivables are factored immediately.

Any receivables that are not expected to be collected immediately should be considered for discounting.

There is no ‘grace period’ in the standard for receivables that are collected within one year or any other specific period. Accounts receivable should be discounted at initial recognition, with a consequential reduction in revenue, if the effect of discounting is expected to be material.

Consideration should be given to discounting all receivables from new sales at initial recognition. This will involve estimating the date of collection, the actual amounts that will be collected, and determining an appropriate interest rate to use.

Management should use the most recent data available about days’ sales outstanding for the relevant governmental body when estimating the date of collection. Care should be used when relying on payment history, if conditions are seen to be deteriorating. Although payment history might be an indicator, the current environment history might not be a reliable indicator of the future, and all relevant facts will need to be assessed to formulate a judgement of the potential outcome.

Receivables are a form of financing provided to customers, and the appropriate rate to use when discounting is the rate at which the customer could otherwise borrow on similar terms. For a governmental or quasi-governmental body, a reasonable starting point for estimating the appropriate rate would be the most recent rate at which the government or local government (for example, regional bodies) has been able to borrow, which is then adjusted for any specific features in the sales contract.

Tiepolo’s management should determine if additional financial statement disclosure is necessary surrounding concentration of risk. This might include:

a. Volume of business transacted in a particular market or geographic area;

b. Impact on liquidity; and

c. Discussion of counterpart default risk.

Tiepolo’s management should consider qualitative factors in deciding whether its exposure to sovereign government of the country in Southern Europe is material. The public attention on the Eurozone sovereign crisis is a strong indicator that disclosure is material.
5.9 Sale of an intangible asset in exchange for listed shares

Background
Pharmaceutical company Jerome agrees to acquire a patent from pharmaceutical group Kupla in order to develop a more complex drug.

Jerome will pay for the patent by:

a) Issuing shares (which are listed) to Kupla representing 5% of the total issued share capital; and

b) If Jerome is successful in developing a drug and bringing it to the market, Kupla will also receive a 5% royalty on all sales.

The transaction represents an acquisition of an intangible asset by Jerome and a disposal of an intangible asset by Kupla. The transfer of the intangible asset and the transfer of shares occur on the same date.

Kupla’s management expects to classify the shares as:

- Available for sale, under IAS 39; or
- At fair value through other comprehensive income, under IFRS 9.

Kupla’s business model is to develop and sell patents, and so it concludes that this transaction is within the scope of the revenue standard.

Relevant guidance

**IAS 39 guidance**
An entity should initially measure a financial asset that is available for sale at its fair value plus transaction costs directly attributable to the acquisition. [IAS 39 para 43]. The fair value of a financial asset is determined using IFRS 13 and the guidance provided by paragraphs AG66–AG82 of Appendix A to IAS 39.

**IFRS 9 guidance**
An entity should initially measure a financial asset at fair value through other comprehensive income at its fair value plus transaction costs directly attributable to the acquisition. [IFRS 9 para 5.1.1]. The fair value of a financial asset is determined using IFRS 13.

**IAS 18 guidance**
Revenue from royalties should be recognised on an accrual basis in accordance with the substance of the relevant agreement. [IAS 18 para 30]

How should Kupla’s management account for the shares and royalties that it receives?
Solution

Kupla should derecognise the patent and recognise the shares. A gain or loss on disposal will also be recognised. [IAS 38 para 113]. Kupla has concluded that this transaction is a revenue transaction. The fair value of the shares received is part of the consideration received. [IAS 18 para 12]. The royalty revenue is likely to be recognised on an accruals basis as the royalties are earned. [IAS 18 para 30(b)].

Shares

Kupla should initially recognise the shares received at their fair value plus transaction costs that are directly attributable to the acquisition. [IAS 39 para 43; IFRS 9 para 5.1.1]. The fair value would be based on the quoted share price multiplied by the quantity of shares.

The shares should subsequently be measured at fair value at each reporting date, with any gains or losses recognised in other comprehensive income. [IAS 39 para 55; IFRS 9 para 5.7.1]. Impairment losses are recognised in profit or loss when IAS 39 is applied. Impairment requirements do not apply to equity instruments under IFRS 9.
6. **Revenue – IFRS 15**


6.1 Contract for development services

**Background**

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraine over a five-year period. Alpha is engaged only to provide development services, and it will periodically have to update BetaX with the results of its work. BetaX owns the underlying product IP, and it has exclusive rights over the development results. BetaX owns Alpha’s work-in-progress at all points in the contract.

BetaX will make 20 equal quarterly non-refundable payments of LC250,000 (totalling LC5 million). Payments do not depend on the achievement of a particular outcome, but Alpha is required to demonstrate compliance with the development programme. Alpha’s management estimates that the total cost will be LC4 million.

Alpha has completed many similar contracts, and it has a track record of reliably estimating costs to complete. Alpha incurs costs of LC400,000 in the first quarter of year 1, in line with its original estimate. Alpha is in compliance with the research agreement, including the provision of updates from the results of its work.

**Relevant guidance**

Revenue is recognised over time if any of the following criteria is met: 1) the customer simultaneously receives and consumes the benefits provided by the entity’s performance as the entity performs; 2) the entity’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or 3) the entity’s performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date. [IFRS 15 para 35].

Revenue should be recognised, for a performance obligation satisfied over time, only if the entity can reasonably measure its progress towards complete satisfaction of the performance obligation (this requires reliable information). [IFRS 15 para 44].

An entity might not be able to reasonably measure the outcome of a performance obligation. An entity should recognise revenue to the extent of the costs incurred until it can reasonably measure the outcome of the performance obligation. [IFRS 15 para 45].

_How should Alpha recognise the payments that it receives from BetaX to conduct development?_

**Solution**

Alpha identifies that it has promised to supply development services to BetaX. Alpha concludes that the control of development services is transferred over time, because BetaX controls an asset, which Alpha is enhancing through its development services. This is because BetaX owns the work-in-progress at any stage during the contract.

Alpha determines that an appropriate measure of progress is an input method, based on an estimate of total costs. Alpha can reasonably measure its progress towards completion. Alpha recognises revenue of LC500,000, costs of LC400,000 and profit of LC100,000 for the first quarter. The unbilled LC250,000 of revenue should be recognised as a receivable on Alpha’s balance sheet.
6.2 Development services with upfront and contingent payments

**Background**

CareB has appointed Devox to develop an existing compound on its behalf. Devox will have no further involvement in the compound after regulatory approval. CareB will retain full ownership of the compound (including intellectual rights) at all stages during the development contract and after regulatory approval is obtained. Devox will not participate in any further marketing or production arrangements. A milestone plan is included in the contract. CareB agrees to make the following non-refundable payments to Devox:

a) LC3 million on signing of the agreement;

b) LC1 million approval of Phase III clinical trial approval; and

c) LC2 million on securing regulatory approval.

Devox expects to incur costs totalling LC3 million up to the point of securing regulatory approval. Management cannot reliably estimate whether the compound will obtain Phase III clinical trial approval or regulatory approval.

**Relevant guidance**

The transaction price includes some or all of an amount of variable consideration only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. [IFRS 15 para 56].

Revenue is recognised over time if any of the following criteria is met: 1) the customer simultaneously receives and consumes the benefits provided by the entity’s performance as the entity performs; 2) the entity’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or 3) the entity’s performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date. [IFRS 15 para 35].

**How should Devox recognise revenue for this contract?**

**Solution**

Devox concludes that it has contracted to supply development services, which is a single performance obligation, the control of which is transferred over time.

The consideration that Devox receives includes a fixed amount (the upfront payment) and two contingent amounts (dependent on clinical trial and regulatory approval). The contingent amounts are variable consideration, and they are included in the transaction price when Devox can conclude that it is highly probable that there will not be a subsequent reversal of a significant amount of revenue. It is unlikely that Devox can include these amounts in the transaction price until the contingencies are resolved. The nature of the contingencies are such that the resolution is outside Devox’s control and thus in most cases it would not be possible for Devox to conclude that no reversal is highly probable.

The upfront payment is initially deferred. This amount has been received, but Devox has not transferred any goods or services to the customer.

Revenue for the services provided is recognised using an appropriate measure of progress; that is, the percentage of completion at the reporting date is applied to the total transaction price at that date (including the fixed upfront fee and any element of variable consideration that is no longer constrained). At the end of each reporting period, the company would re-assess their estimate of the variable consideration that is no longer constrained. For example, if it is highly probable that the milestone payments will be received, these amounts are included in the transaction price, which will result in a cumulative catch up of revenue for the performance to date.
6.3 Receipts for out licensing

Background

Pharmaceutical entities Regal and Simba enter into an agreement in which Regal will license Simba’s know-how and technology to manufacture a compound for AIDS. Regal will use Simba’s technology in its facilities for a period of ten years. Simba receives a non-refundable upfront payment of LC3 million for access to the technology. Simba will also receive a royalty of 20% from sales of the AIDS drug if it is successful.

Relevant guidance

A promise to grant the licence is a separate performance obligation, if it is distinct.

IFRS 15 identifies two types of licence: a right to access, that transfers over time; and a right to use, that transfers at a point in time. The promise is to provide a right to access if all of the following criteria are met:

The contract requires, or the customer reasonably expects, that the entity will undertake activities that significantly affect the intellectual property to which the customer has rights;

The rights granted by the licence directly expose the customer to any positive or negative effects of the entity’s activities identified in paragraph B58(a); and

Those activities do not result in the transfer of a good or a service to the customer as those activities occur. [IFRS 15 para B58].

If these are not met, it is a right to use a licence, and it is recognised when the licence is granted to the customer. [IFRS 15 para B61].

Revenue in the form of a sales-based or usage-based royalty, in exchange for a licence of intellectual property, is recognised only when (or as) the later of the following events occurs:

1. The subsequent sale or usage occurs; and

2. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied). [IFRS 15 para B63].

How should Devox recognise revenue for this contract?

How should Simba account for a non-refundable upfront fee received for licensing out its know-how and technology and the royalty to be received on sales?
Simba concludes that it has a single performance obligation under the contract to issue the licence.

Simba concludes that it has granted a ‘right to use’ licence, and revenue is recognised at the point in time that the licence is granted to Regal. In this case, the IP licensed to Regal has significant stand-alone functionality (being the technology), and Simba does not perform any activities that affect that functionality.

The consideration for the licence comprises a fixed element (the upfront payment) and variable elements (the royalties).

The upfront fee is not variable, and it is recognised when control of the licence transfers. This is when Regal obtains the rights to use the underlying IP.

Simba applies the exception for variable consideration related to sales- or usage-based royalties received in exchange for a licence of intellectual property. Royalties are not included in the transaction price until Regal makes sales, regardless of whether or not Simba has predictive experience with similar arrangements.
6.4 Post-development phase obligations

Background

A medium-sized pharmaceutical company (Med Co) received regulatory approval for its new drug against high blood pressure (Benirol). Med Co decided to outsource certain work streams (e.g. provision of information, patent defence and marketing support), and it entered into a collaboration agreement with a well-known post-development services group (Service Co). Service Co is trying to identify what performance obligations have been agreed.

Relevant guidance

Performance obligations identified in a contract with a customer might include promises that are implied by an entity’s usual practices, policies or statements. Such promises might create a valid expectation of the customer that the entity will transfer a good or service to the customer. [IFRS 15 para 24].

Performance obligations do not include activities that are necessary for the entity to fulfil a contract. Only activities that transfer a good or service to a customer are considered. [IFRS 15 para 25].

What are some examples of performance obligations that could be provided by Service Co?

Solution

The assessment of different types of obligation that might arise under a contract requires judgement. There are a number of factors that should be considered as a minimum, when forming that judgement:

- **Is the obligation substantive or perfunctory?** This requires an assessment as to whether the obligation is significant, whether it results in the transfer of a significant good or service to the customer, and whether it is incidental and of little consequence from a revenue recognition perspective. For example, an agreement to answer another party’s questions about a compound that they had purchased could be viewed as part of normal good relationship management (that is, perfunctory); whereas an agreement to supply 500 million free sample tablets would appear to be a substantive obligation.

- **Is the obligation a separate performance obligation?** If the obligation is a separate performance obligation, revenue can only be recognised when control of that performance obligation has been transferred.

<table>
<thead>
<tr>
<th>Contractual obligation</th>
<th>Likelihood of being a separate PO</th>
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</thead>
<tbody>
<tr>
<td>Marketing contributions</td>
<td>Likely</td>
</tr>
<tr>
<td>Delivery of investigational products and clinical trial supplies</td>
<td>Likely</td>
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<tr>
<td>Participation in a steering committee</td>
<td>Potentially</td>
</tr>
<tr>
<td>Provision of information</td>
<td>Unlikely</td>
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<tr>
<td>Patent defence</td>
<td>Unlikely</td>
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</table>

If a contractual obligation is not considered to be a separate performance obligation under the terms of the contract, there might still be accounting implications. The obligation might represent a cost that needs to be provided for, or the obligation might need to be combined with another promise in the contract as part of a larger performance obligation.
### Background

The Umbrella Insurance Company and Rembrandt Pharmaceuticals put in place a reimbursement scheme in Territory X for treatment of Alzheimer’s with Rembrandt’s newly developed and approved product. Umbrella will only pay, under the scheme, for the drug in Territory X for those patients in whom Rembrandt’s product is shown to effectively slow down the progression of Alzheimer’s. The contract stipulates specific indicators which show that progression has slowed. Umbrella will only pay if all indicators have been evidenced. Umbrella will only pay for the drug when it is shown to have achieved the required outcome.

The outcome, at the inception of this arrangement, is unknown. Rembrandt’s product has already been subject to clinical trials during the approval process, but the patient population used in the clinical trials is different from the population in Territory X.

### Relevant guidance

Revenue is recognised over time if any of the following criteria is met: 1) the customer simultaneously receives and consumes the benefits provided by the entity’s performance as the entity performs; 2) the entity’s performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or 3) the entity’s performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date. [IFRS 15 para 35].

If a performance obligation is not satisfied over time, it is satisfied when the customer obtains control of the promised asset. [IFRS 15 para 38]. The transaction price includes some or all of an amount of variable consideration only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. [IFRS 15 para 56].

**How should pharmaceutical entities recognise revenue under pay-for-performance arrangements?**

### Solution

*Rembrandt has promised to provide Alzheimer’s drugs to patients. Rembrandt assesses that each drug is a separate performance obligation satisfied at a point in time. The consideration for the contract is variable. Rembrandt does not know if it will receive payment.*

*Rembrandt estimates the total transaction price at the start of the contract using the expected value method, which it judges to be most appropriate. It might be that, given the differences in population between the original trial and Territory X, Rembrandt cannot assert that it is highly probable that any consideration will be received, and so it constrains the transaction price to nil initially.*

*It is expected that Rembrandt will be able to build a sufficient record of outcomes over time, such that it improves its ability to predict how many patients in the population of Territory X will benefit from the drug; and thus the expected value of consideration to be allocated to each packet of pills might no longer need to be constrained.*
6.6 **Out-licence of development-phase compound where the licensee continues to do the development work**

### Background

Biotech Co has successfully developed a drug for Syndrome Q through Phase II trials. Biotech and a large pharmaceutical company (Pharma Co) have agreed the following terms:

- Biotech grants a licence to Pharma to manufacture, sell and market the product in the USA for the treatment of Syndrome Q. Biotech retains the patents and underlying intellectual property associated with the product.
- Pharma is to fund and perform all Phase III clinical development work on a drug developed by Biotech to obtain regulatory approval in the USA.
- There is a development committee that oversees the development of the product. The development committee makes all strategic decisions regarding the product. Biotech is not required to attend the committee, but it has the right to, and expects to, attend.
- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.
- Biotech retains the right to sell the product in the rest of the world.

The consideration payable by Pharma includes:

- An upfront payment of LC10 million on signing the contract.
- A milestone payment of LC20 million on regulatory approval.
- Royalties payable on sales of 15%.
- A sales milestone of LC20 million in the first year that annual sales exceed LC500 million.

The upfront payments and milestones are non-refundable in the event that the contract is cancelled when the payments have been made.

### Relevant guidance

IFRS 15 identifies two types of licence: a right to access, that transfers over time; and a right to use, that transfers at a point in time. The promise is to provide a right to access if all of the following criteria are met:

a) The contract requires, or the customer reasonably expects, that the entity will undertake activities that significantly affect the intellectual property to which the customer has rights;

b) The rights granted by the licence directly expose the customer to any positive or negative effects of the entity’s activities identified in paragraph B58(a); and

c) Those activities do not result in the transfer of a good or a service to the customer as those activities occur. [IFRS 15 para B58].

If these are not met, it is a right to use a licence, and it is recognised when the licence is granted to the customer. [IFRS 15 para B61].

The transaction price includes some or all of an amount of variable consideration only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. [IFRS 15 para 56]. There is an exception to this rule. Revenue for a sales-based or usage-based royalty in exchange for a licence of intellectual property is recognised only when (or as) the later of the following events occurs:

a) The subsequent sale or usage occurs; and

b) The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied). [IFRS 15 para B63].

This exception only applies to a licence of intellectual property or when a licence of intellectual property is the predominant item to which the royalty relates.

**How should Biotech recognise revenue under the out-licence?**
Solution

Biotech collaborates with Pharma on the steering committee, and it also shares the risks and rewards of development through the milestone and royalty arrangements. The out-licence is within the scope of IFRS 15, because Biotech licenses its IP to Pharma, and this is an output of its ordinary business activities.

The guarantee that Biotech has given to defend the patent from unauthorised use is not considered to be a promised good or service under the contract.

Biotech has a seat on a development committee, but it is not required to attend. This is not a performance obligation to Pharma, because it does not transfer a good or service.

Accounting for the out-licence

Biotech has granted a ‘right to use’ licence, and revenue is recognised when the licence is granted to Pharma. The IP licensed to Pharma has significant stand-alone functionality (being a patented drug formula), and Biotech does not perform any activities that affect that functionality. The participation of Biotech in the development committee does not affect the functionality of the patent.

The consideration for the licence comprises a fixed element (the upfront payment) and two variable elements (the milestone payments and the royalties).

Variable consideration

When the contract is signed, Biotech estimates the consideration for the contingent regulatory approval-based milestone, and it determines that the most likely amount is zero. The most likely amount method of estimation is considered to be the most predictive of the outcome, since the outcome is binary (either regulatory approval is granted or it is not). The transaction price is therefore initially the upfront payment which is recognised at a point of time.

The transaction price should be re-assessed at each reporting date. Biotech will include the regulatory approval milestone payment in the total estimated transaction price when it is highly probable that the resulting revenue recognised would not have to be reversed in a future period. This is unlikely to be before regulatory approval is granted. This amount will be recognised as revenue when it is included in the transaction price. This is because the transaction price relates to the licence which has already been granted to the customer.

Biotech applies the exception for variable consideration related to sales- or usage-based royalties received in exchange for licences of intellectual property. Royalties are not included in the transaction price until Pharma makes the relevant sales in the USA, regardless of whether or not Biotech has predictive experience with similar arrangements.

The additional consideration that might arise from the ‘sales milestone’ is not received until an annual sales threshold is met. Biotech concludes that this ‘milestone’ is, in substance, a sales-based royalty, since it is receivable only when underlying sales are made. As such, revenue for this milestone is recognised if and when the annual sales threshold is met in accordance with the exception for royalties.

See Solution 1.16 for the accounting of Pharma.
6.7 **Out-licence of development-phase compound where the licensee continues to do the development work**

**Background**

Biotech is a well-established company that has the expertise to perform clinical trials. Biotech enters into a contract with Pharma Co with the following terms:

- Biotech grants Pharma a licence to manufacture, sell and market product.
- Biotech is responsible for performing Phase III clinical trials and obtaining regulatory approval.
- Biotech gives Pharma a guarantee to defend the patent from unauthorised use.
- Biotech is not involved in the manufacture, selling or marketing of the product.

The consideration payable by Pharma under this agreement comprises:

- An upfront payment of LC10 million.
- A milestone payment of LC20 million payable on successful completion of a Phase III trial.
- A milestone payment of LC10 million on regulatory approval.
- Royalties payable on sales of 25%.

Royalties on a similar licence, at the same stage of development, would typically be in the range of 23% to 26% of sales.

**Relevant guidance**

Licences transferred together with other services, such as R&D, must first be assessed to determine if the licence is distinct and therefore a separate performance obligation. Goods and services that are distinct are accounted for separately. A good or service is distinct if both of the following criteria are met:

a) The customer can benefit from the good or service, either on its own or together with other resources that are readily available to the customer; and

b) The entity’s promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. [IFRS 15 para 27].

The following are indicators that an entity’s promise is not separately identifiable from other promises:

a) The entity provides a significant service of integrating the goods or services with other goods or services promised in the contract into a bundle.

b) One or more of the goods or services significantly modifies or customises, or is significantly modified or customised by, one or more of the other goods or services promised in the contract.

c) The goods or services are highly interdependent or highly interrelated. [IFRS 15 para 29].

IFRS 15 identifies two types of licence: a right to access, that transfers over time; and a right to use, that transfers at a point in time. [IFRS 15 para B58].

The transaction price includes some or all of an amount of variable consideration only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. [IFRS 15 para 56]. There is an exception to this rule. Revenue for a sales-based or usage-based royalty in exchange for a licence of intellectual property is recognised only when (or as) the later of the following events occurs:
The subsequent sale or usage occurs; and
The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied). [IFRS 15 para B63].

This exception only applies to a licence of intellectual property or when a licence of intellectual property is the predominant item to which the royalty relates.

How should Biotech recognise revenue under the out-licence?

Solution

The out-licence is within the scope of IFRS 15, because Biotech, licenses its IP to Pharma, and this is an output of its ordinary business activities. Pharma is considered a customer of Biotech.

Identifying performance obligations

Biotech has promised to provide Pharma with a licence, and it has also promised to provide development services. No other deliverables are identified.

The licence and the development services are both capable of being distinct as Pharma can benefit from both on their own. Biotech could have provided the licence without any development services. The next phase of development is Phase III trials, and there are several other entities that could have provided these services. Biotech could have provided the licence without the development services, and Pharma would have been able to benefit from it by obtaining development services from another provider.

The licence and development services are separately identifiable. This is because the services are not integrated with (and do not modify) the original licence, and the licence and services are not highly interrelated or interdependent. Biotech has therefore judged there are two performance obligations.

Measuring and allocating the transaction price

The consideration for the contract comprises a fixed element (the upfront payment) and two variable elements (the milestone payments and the royalties).

Initially only fixed consideration is included in the transaction price. The amount of the variable consideration for both milestone payments (Phase III and regulatory approval) included in the transaction price is determined to be zero at inception, based on the most likely amount and the application of the variable consideration constraint.

Biotech first needs to determine how to allocate the variable consideration. Biotech concludes in this arrangement that the sales based royalties are linked to the commercial success of the IP and relate to the outcome of transferring the licence. [IFRS 15.85a.] This is also consistent with the allocation objective to allocate transaction price to each performance obligation based on the stand alone selling price [15.85(b)].

Biotech concludes that the milestone payments relate to both performance obligations and not specifically to the licence, given the nature of the service being delivered and the fact that Biotech assesses that an allocation of the upfront payment alone would be unlikely to cover the costs of development.

The total transaction price is then allocated to the licence and the development services, based on their estimated stand-alone selling prices.

Biotech reconsiders, at each reporting date, whether or not the variable consideration is included in the transaction price. Changes to the transaction price are allocated to the two performance obligations in the same ratio as was determined initially, based on stand-alone selling prices.

Recognising revenue

Control of the licence transfers at a point in time, for the reasons described in Solution 6.6. This is when Pharma obtains the rights to use the underlying IP. Control of the development services is transferred over time, for similar reasons to those described in Solution 6.1. Biotech determines an appropriate measure of progress, and it recognises revenue accordingly.

The royalties are recognised as revenue when the subsequent sales are made.
6.8 Revenue recognition to customers with a history of long delays in payment

**Background**

Tiepolo Pharma sells prescription drugs to a governmental entity in a country in Southern Europe.

Tiepolo has historically experienced long delays in payment for sales to this entity, due to slow economic growth and high debt levels in the country.

Tiepolo and the country’s government have not renegotiated the payment terms. Tiepolo has an unconditional right to receive payment.

Tiepolo currently has outstanding receivables from sales to this entity over the last three years, and it continues to sell products at its normal market price. Tiepolo has not entered into any factoring arrangements for the settlement of these receivables.

**Relevant guidance**

An entity should account for a contract with a customer when the criteria set out in paragraph 9 of IFRS 15 are met. The most relevant criterion in this situation is that the entity should account for the contract when it is probable that the entity will be able to collect the consideration to which it is entitled. In evaluating collectability, the entity should only consider the client’s ability and intention to pay.

The transaction price includes some or all of an amount of variable consideration only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. [IFRS 15 para 56].

The promised consideration is variable if other facts and circumstances indicate that the entity’s intention, when entering into the contract, is to offer a price concession. [IFRS 15 para 52(b)].

**Solution**

Tiepolo’s management must first determine that it is appropriate to recognise new sales to country A. Revenue should be recognised only when it is probable that the entity will collect the consideration to which it is entitled.

Slow payment does not, on its own, preclude revenue recognition. However, it might well impact the amount of revenue that can be recognised, because the receivable will be discounted at initial recognition, if there is a significant financing component.

Revenue should be recognised only to the extent that it is probable that the entity will collect the consideration to which it is entitled.

When assessing whether the entity will collect the consideration, the entity needs to determine whether it expects to provide a price concession and accept a lower amount of consideration. If so, the consideration is variable [IFRS 15 para 52(b)], and the entity will need to estimate the variable consideration in accordance with paragraph 53 of IFRS 15 and determine the amount that it expects to receive, subject to the constraint set out in paragraph 56 of IFRS 15.

If the entity concludes that it will receive an amount which is less than the invoiced amount, it has to evaluate whether it granted an implicit price concession or whether the receivable is impaired.
6.9 **Sale of an intangible asset in exchange for listed shares**

**Background**

Pharmaceutical company Jerome agrees to acquire a patent from pharmaceutical group Kupla in order to develop a more complex drug.

Jerome will pay for the patent by:

- Issuing shares (which are listed) to Kupla representing 5% of the total issued share capital; and
- If Jerome is successful in developing a drug and bringing it to the market, Kupla will also receive a 5% royalty on all sales.

The transaction represents an acquisition of an intangible asset by Jerome and a disposal of an intangible asset by Kupla. The transfer of the intangible asset and the transfer of shares occur on the same date.

Kupla’s management expects to classify the shares as:

- Available for sale, under IAS 39; or
- At fair value through other comprehensive income, under IFRS 9.

**Relevant guidance**

**IAS 39 guidance**

An entity should initially measure a financial asset that is available for sale at its fair value plus transaction costs directly attributable to the acquisition [IAS 39 para 43]. The fair value of a financial asset is determined using IFRS 13 and the guidance provided by paragraphs AG66–AG82 of Appendix A to IAS 39.

**IFRS 9 guidance**

An entity should initially measure a financial asset at fair value through other comprehensive income at its fair value plus transaction costs directly attributable to the acquisition. [IFRS 9 para 5.1.1]. The fair value of a financial asset is determined using IFRS 13.

**IFRS 15 guidance**

Non-cash consideration is measured at fair value [IFRS 15 para 66]. Variable consideration should be estimated and included in the transaction price to the extent that it is highly probable that a significant reversal in the amount of the cumulative revenue recognised will not occur. [IFRS 15 paras 50, 56]. The transaction price, taking into account the estimate and any constraint of variable consideration, should be re-assessed at each reporting date [IFRS 15 para 59].

**How should Kupla’s management account for the shares and royalties that it receives?**
Solution

Kupla should derecognise the patent and recognise the shares. A gain or loss on disposal will also be recognised. [IAS 38 para 113]. IAS 38 requires the consideration to be measured in accordance with IFRS 15. This should be calculated for the purpose of calculating the net gain on disposal of the patent. There are two elements to the consideration:

- Shares received. The shares received represent non-cash consideration and are measured at fair value.
- Royalties are variable consideration. Since this transaction is a sale of IP and not a licence, the sales- and usage-based royalty exemption does not apply. If Kupla can estimate a minimum amount of royalties that it expects to receive, and it is highly probable that the amount will not reverse in the future, this estimated amount is included in the transaction price, and thus the gain or loss on disposal. Kupla revises the estimate for variable consideration at each reporting date.

Shares

Kupla should initially recognise the shares received at their fair value plus transaction costs that are directly attributable to the acquisition. [IAS 39 para 43; IFRS 9 para 5.1.1]. The fair value would be based on the quoted share price multiplied by the quantity of shares.

The shares should subsequently be measured at fair value at each reporting date, with any gains or losses recognised in other comprehensive income. [IAS 39 para 55; IFRS 9 para 5.7.1]. Impairment losses are recognised in profit or loss when IAS 39 is applied. Impairment requirements do not apply to equity instruments under IFRS 9.
7. **Presentation and disclosure**
7.1 Accounting for promotional campaigns

Background
A pharmaceutical company has developed a new drug that simplifies the long-term treatment of kidney disease. The company’s commercial department has incurred significant costs with a promotional campaign, including TV commercials and presentations in conferences and seminars for doctors.

Relevant guidance
An intangible asset is an identifiable non-monetary asset without physical substance. An asset is a resource that is controlled by the entity as a result of past events and from which future economic benefits are expected to flow to the entity. [IAS 38 para 8].

How should these costs be accounted for and presented in the income statement?

Solution
The company should not recognise its advertising and promotional costs as an intangible asset, even though the expenditure incurred might provide future economic benefits; it should charge all promotional costs to the income statement. Expenditure on advertising and promotional activities should be expensed when incurred. [IAS 38 para 69(c)].

The presentation of promotional costs in the income statement will depend on the analysis of expenses (that is, by nature or by function) preferred by management. Promotional costs should be classified as advertising and promotional costs if the analysis of expenses is presented by nature; however, more detailed analysis might be provided. Promotional costs should be included within sales and marketing expenses if the analysis of expenses is presented by function, and further disclosure might be warranted.
7.2 Advertising and promotion costs

Background

Kandinsky Medical recently completed a major study, comparing its Alzheimer’s drug to competing drugs. The results of the study were highly favourable, and Kandinsky has invested in a significant new marketing campaign. The campaign will be launched at the January 20X5 International Alzheimer’s Conference. Kandinsky has also paid for direct-to-consumer (DTC) television advertising, which will appear in February 20X5. Related DTC internet advertising will likewise begin in February, and will be paid for, based on ‘click-through’ to its Alzheimer’s site.

Relevant guidance

Expenditure is incurred, in some cases, to provide future economic benefits, but no asset is acquired or created. The expenditure is recognised as an expense when it is incurred. An expenditure that is recognised as an expense when it is incurred includes expenditure on advertising and promotional activities. [IAS 38 para 69].

How should expenditure on advertising and promotional campaigns be treated before the campaign is launched?

Solution

The company should not recognise its advertising and promotional costs as an intangible asset, even though the expenditure incurred might provide future economic benefits; it should charge all promotional costs to the income statement. Expenditure on advertising and promotional activities should be expensed when incurred. [IAS 38 para 69(c)].

All costs to develop and produce the marketing campaign and related materials, including the television advertisement, internet advertisement and website, should be expensed immediately. Amounts paid to television broadcast providers should be accounted for as a pre-payment and expensed immediately when the advertisement first airs in 20X5. Costs for hits to the company’s internet site should be expensed, based on the click-through rate in 20X5.
7.3  Accounting for the cost of free samples

**Background**

Goya Laboratories is eager to increase knowledge of its new generic pain medication within hospitals. Accordingly, Goya’s sales force distributes free samples of the pain medication during sales calls and at certain hospital conventions.

**Relevant guidance**

An entity might classify expenses according to nature or function/cost of sales methods. [IAS 1 paras 102, 103]. Functions are defined as cost of sales, distribution activities or administrative activities. [IAS 1 para 103].

*How should Goya classify, and account for, the costs of free samples distributed in order to promote a product?*

**Solution**

The cost of product distributed for free, and not associated with any sale transaction, should be classified as marketing expenses. Goya should account for the sample product given away at conventions and during sales calls as marketing expense. The product costs should be recognised as marketing expense when the product is packaged as sample product.
7.4 Classification of co-promotion royalties

Background

Mondrian Pharma uses the sales force of Matisse Inc for co-promotion of its transplantation drug in the US. The co-promotion agreement requires Mondrian to pay Matisse 25% of net sales in the US for its marketing efforts. The agreement is material to both parties.

Relevant guidance

When items of income and expense are material, their nature and amount should be disclosed separately. [IAS 1 para 97]. An entity should present an analysis of expenses recognised in profit and loss, using a classification based on either the nature or function within the entity, whichever provides information that is reliable and more relevant. [IAS 1 para 99].

How should Mondrian classify co-promotion payments?

Solution

If expenses are presented by function, Mondrian should classify the co-promotion payments as marketing and sales expenses. If Mondrian presents expenses by nature, the co-promotion payments should be classified as third-party marketing expenses and presented separately on the face of the income statement.
### Background

Pharmaceutical entity Alpha produces and sells a portfolio of drugs that comprises three separate divisions. It funds the majority of its R&D activities internally, in order to develop new drugs for all three divisions. It does not provide any significant R&D services to external parties. The operational results for its R&D activities, for all of these divisions, are regularly reviewed by the entity’s chief operating decision-maker (CODM). In addition, the CODM regularly reviews a divisional report, with three separate divisional operating profit and loss statements, to make operational decisions. There are three divisional heads that are directly accountable to, and maintain regular contact with, the CODM to discuss operating activities (included in R&D activities), financial results, forecasts and plans for their division.

### Relevant guidance

An operating segment is a component of an entity that engages in business activities from which it might earn revenues or incur expenses, whose operating results are regularly reviewed by the entity’s CODM, to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available. [IFRS 8 para 5].

Operating segments normally have segment managers who report to the CODM. [IFRS 8 para 9].

If the CODM reviews two or more overlapping sets of components for which managers are held responsible, the entity should determine the operating segments based on which set would help users to evaluate the nature and financial effects of the business activities of the entity. [IFRS 8 para 10].

**Should R&D activities be reported as a segment?**

### Solution

The CODM reviews different sets of overlapping information. Management should consider qualitative factors in determining the appropriate operating segments. These should include an assessment of whether the resultant operating segments are consistent with the core principle of IFRS 8, whether the identified operating segments could realistically represent the level at which the CODM is assessing performance and allocating resources, and whether the identified operating segments enable users of its financial statements to evaluate its activities and financial performance, and the business environment in which it operates.

Alpha’s R&D activities are not reported as a separate operating segment. The divisions have heads directly accountable to, and maintaining regular contact with, the CODM to discuss operating activities, financial results, forecasts and plans for their division. Division segments are consistent with the core principle of IFRS 8, because they enable users of their financial statements to evaluate the activities and financial performance and the business environment of the pharmaceutical entity.
7.6 Segmental reporting of research and development services

**Background**

Entity B has R&D facilities, which it uses to perform contract investigation activities for other laboratories and pharmaceutical companies. Approximately 65% of the laboratory’s revenues are earned from external customers – and these external revenues represent 15% of the organisation’s total revenues. The R&D facilities’ operating results are regularly reviewed by entity B’s chief operating decision-maker (CODM), to make decisions about resources to be allocated to the segment and to assess its performance.

**Relevant guidance**

An operating segment is a component of an entity that engages in business activities from which it might earn revenues or incur expenses, whose operating results are regularly reviewed by the entity’s CODM, to make decisions about resources to be allocated to the segment and to assess its performance, and for which discrete financial information is available. [IFRS 8 para 5].

An entity should report separately the information about an operating segment that meets any of the following quantitative thresholds:

a) Its reported revenue, including both sales to external customers and inter-segment sales or transfers, is 10% or more of the combined revenue (internal and external) of all operating segments.

b) The absolute amount of its reported profit or loss is 10% or more of the greater, in absolute amount, of (i) the combined reported profit of all operating segments that did not report a loss, and (ii) the combined reported loss of all operating segments that reported a loss.

c) Its assets are 10% or more of the combined assets of all operating segments. [IFRS 8 para 13].

*Should entity B report its R&D activities as a business segment?*

**Solution**

Entity B’s management should report its R&D activities as a separate reportable segment. It meets the quantitative threshold for percentage of total revenues, and it otherwise meets the criteria for an operating segment.
7.7 Disclosure of R&D when reported to CODM

Background
Manet Corp is a pharmaceutical company with several operating segments. In the biotech segment, 18% of the segment expenses relate to R&D; 30% of all segment capital expenditure is capitalised R&D costs.

R&D capitalised and expensed is reported to the CODM, by operating segment, to make decisions about resources to be allocated.

Relevant guidance
An operating segment is a component of an entity that engages in business activities from which it might earn revenues or incur expenses, whose operating results are regularly reviewed by the entity’s CODM, to make decisions about resources to be allocated to the segment and to assess its performance, and for which discrete financial information is available. [IFRS 8 para 5].

An entity should disclose material expenses about each reportable segment if the specified amounts are included in the measure of segment profit or loss reviewed by the CODM. [IFRS 8 para 23(f)].

An entity should also disclose non-current assets if these are included in the measure of segment assets reviewed by the CODM or are otherwise regularly provided to the CODM. [IFRS 8 para 24(b)].

Should pharmaceutical entities disclose R&D expenses and capital expenditure separately in their segment reporting?

Solution
R&D capitalised and expensed during the year should be disclosed for all reportable segments, because this information is reported to the CODM to make decisions about resources to be allocated.
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Questions?

PwC clients who have questions about this publication should contact their engagement partner.

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