International Financial Reporting Standards (IFRS)

Issues and solutions for the pharmaceuticals and life sciences industries

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Foreword

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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 2019 to reflect changes in IFRS and interpretations as at that date. 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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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 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 one country, Agara. It is now progressing through the additional development procedures and clinical trials necessary to gain approval in another 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 one country, Spartek, and is progressing through the additional development procedures necessary to gain approval in another country, Oceana.

Experience shows that significant additional clinical trials will be necessary to meet the Oceanese 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 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 in paragraph 57 of IAS 38, and that certain development costs must therefore be capitalised, because regulatory approval has been obtained. Management is unsure about 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 developing the asset and that 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.

1.5 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 about whether the product will be commercially successful.

1.6 Capitalisation of development costs for biosimilars

Background

A pharmaceutical manufacturer is developing a biosimilar product and has submitted its application to the FDA, which included robust analytical studies and data comparing the proposed product to the existing FDA-approved reference product to demonstrate biosimilarity. The FDA has reviewed the product's structural and functional characterisations and requested the manufacturer to move forward with comparative Phase I clinical studies. Management does not anticipate any significant difficulties with 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.

Should management start capitalising development costs at this point?

Solution

No, management should not capitalise additional development expenditure, because the product has not met all of the capitalisation criteria. It cannot demonstrate that it has met the criterion of technical feasibility. The abbreviated pathway for biological products does not mean that a lower approval standard is applied to biosimilar or interchangeable products. The manufacturer must still demonstrate that the product is biosimilar to the reference product, and it must complete the requested Phase I, and later Phase III, clinical trials to support approval.

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 product. However, a strong indication that an entity has met all of the above criteria arises when it obtains regulatory approval of the biosimilar product. 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.

1.7 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].

1.8 Accounting for development expenditure once capitalisation criteria are met

Background

Pharmaceutical entity Delta 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.

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 Delta capitalise these costs?

Solution

Delta 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.

1.9 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 in 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.

1.10 Costs 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.

1.11 Development costs for a 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 in 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, 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.

1.12 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. Such costs should not be recognised in the carrying amount of an asset under paragraph 20 of IAS 38. Patent defence costs should be expensed as incurred.

1.13 Priority review vouchers

Background

Pharmaceutical entity Egram developed a vaccine for a rare paediatric disease. It was awarded a paediatric priority review voucher ('PRV') by the FDA when it received marking approval. The PRV entitles the holder to request priority review by the FDA of any future drug application that would otherwise get a standard review. The holder can use the PRV on one of its own applications, or it can sell it to another company. The PRV does not guarantee that the FDA will approve the drug application. Egram sold the PRV to pharmaceutical entity Fiorel for C65 million.

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 Fiorel account for the acquired PRV?

Solution

The PRV is identifiable, because it can be sold or transferred to another company and it arises from a legal right. The PRV will allow Fiorel to fast track a review with the FDA, saving costs and potentially accelerating the time to market. Fiorel therefore has the power to obtain future economic benefits.

The recognition criteria in paragraph 25 of IAS 38 are met when an intangible is separately acquired. The C65 million reflects the expectation of future economic benefits and the cost can be reliably measured. Fiorel should therefore recognise the PRV on its balance sheet at cost.

Fiorel will subsequently need to assess whether the useful life of the PRV is finite or indefinite under paragraph 88 of IAS 38. The PRV has a finite life, which ends at the point when the priority review has been committed and used with the FDA, or when the PRV is sold to another company. The asset is consumed on a unit of production basis (when used), and so that would be the most appropriate amortisation method. As such, the PRV will be amortised in full when Fiorel uses the voucher for a priority review.

1.14 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 and 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.

1.15 Partial 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 C3 million, including C0.2 million relating to the Asian marketing rights and 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 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 C2.8 million (C3.0 million – C0.2 million). The fair value of C0.2 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 C2.3 million [C2.8 – (0.5 – ((0.2/3) × 0.5))].

1.16 Intangible asset derecognition on out-licence of rights

Background

Pharma Co A enters into a contract with Pharma Co B with the following terms:

- Pharma Co A grants Pharma Co B an exclusive perpetual licence to sell and market an arthritis drug in the US.
- Pharma Co A retains the rights to sell and market the drug in the rest of the world.
- Pharma Co A will continue to manufacture the arthritis drug.
- Pharma Co B will purchase the drug from Pharma Co A at cost plus a fair value mark-up.

The consideration payable by Pharma Co B under this agreement comprises:

- An up-front payment of C10 million.
- A milestone payment of C5 million payable when sales exceed C 30 million.
- Royalties of 5% payable on sales.

Pharma Co A has a capitalised intangible asset of LCC15 million in relation to the intellectual property for arthritis drug. The relative value of the US market to the rest of the world is 40%.

Relevant guidance

An intangible asset should be derecognised [IAS 38 para 112]:

a. on disposal; or

b. when no future economic benefits are expected from its use or disposal.

The gain or loss arising from the derecognition of an intangible asset should be determined as the difference between the net proceeds, if any, and the carrying amount of the asset. Gains should not be classified as revenue. [IAS 38 para 113].

The amount of gain or loss arising from the derecognition of an intangible asset is determined in accordance with the requirements for determining the transaction price in paragraphs 47–72 of IFRS 15. [IAS 38 para 116].

An entity should recognise revenue for a sales-based royalty in exchange for a licence of intellectual property only when (or as) the later of the following events occurs [IFRS 15 para B63]:

a. the subsequent sale or usage occurs; and

b. the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied). [IFRS15 para B63].

How should Pharma Co A account for the disposal of the US rights to the arthritis drug?

Solution

Pharma Co A has granted Pharma B a right-of-use licence for the US rights to the arthritis drug. The gain or loss arising from the disposal is the difference between the proceeds and the carrying amount of the asset.

Judgement is required to determine the portion of the carrying amount of the intangible asset to derecognise, relative to the amount retained.

Pharma Co A has determined that 40% of the carrying amount of the intangible asset should be derecognised, since this is the relative value of the US rights out-licenced compared to the rights retained in the rest of the world.

The proceeds to include in the gain or loss arising from the derecognition of the intangible asset are determined in accordance with IFRS 15. The consideration for the contract comprises a fixed element (the up-front payment) and two variable elements (the milestone payment and the royalties). Initially, only the fixed consideration is recognised as proceeds. The sales milestone and royalties are recognised when the subsequent sale occurs, using the royalty exception applicable to licences. Therefore, the variable consideration is excluded from the calculation of the gain or loss arising on the derecognition of the intangible asset. The variable consideration is recognised in the income statement when the underlying sales are made.

A gain is recognised on disposal of the US rights of C4 million (that is, Up-front payment of C10 million minus carrying amount of intangible asset disposed of amounting to C6 million (calculated as C15 million × 40%)).

Note: Cash flows from future milestones and royalties in relation to the derecognised rights should not be used, in ongoing impairment calculations, to support the carrying value of the remaining intangible that has not been derecognised.

1.17 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 IFRS 9 and IFRS 15 is explained in **Solution 5.14**.

1.18 In-licence of technology

Background

Pharmaceutical entities Regal and Simba enter into an agreement in which Regal will in-license Simba's know-how and technology (which has a fair value of C3 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 10 years. The agreement stipulates that Regal will make a non-refundable payment of C3 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 C3 million. The intangible asset should be amortised from the date when it is available for use (see **Solution 1.28**). 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 5.15** for Simba's accounting under IFRS 15.

1.19 In-licence of marketing rights for a drug in development

Background

Pharmaceutical entities 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. Up-front payment of C20 million on signing of the contract;

b. milestone payment of C50 million on, Phase III clinical trial approval; and

c. milestone payment of C80 million on securing final regulatory approval.

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 where the purchase consideration is in the form of cash or other monetary assets. [IAS 38 para 26].

Solution

Sargent has assessed that the C20 million Up-front 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 C20 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 judgemental 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 whether the payment is due only on a verifiable outcome, or wether it 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 that any of the milestone is for prepaid development services.

There is a policy choice on how to treat variable payments for intangible assets: either a cost accumulation approach or a financial liability approach.

Industry practice is generally to follow a cost accumulation approach to variable payments for the acquisition of intangible assets. Contingent consideration is not considered on initial recognition of the asset, but it is added to the cost of the asset initially recorded, when incurred.

1.20 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 US 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 up-front payment of C10 million on signing the contract.
- A milestone payment of C20 million on regulatory approval.
- Royalties of 15% payable on sales.
- A sales milestone of C20 million in the first year that annual sales exceed C500 million.

The up-front payments and milestones are non-refundable in the event that the contract is cancelled after 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 where 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 account for the in-licence?

Solution

The up-front purchase of the compound is a separately acquired intangible, which is capitalised under paragraph 25 of IAS 38. Biotech has no further performance obligations for development services. The intangible is recognised at cost of L10 million.

The future milestones must be assessed to determine whether 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 judgemental 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 whether the payment is due only on a verifiable outcome, or whether it 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.

There is a policy choice on how to treat variable payments for intangible assets: either a cost accumulation approach or a financial liability approach.

Industry practice is generally to follow a cost accumulation approach to variable payments for the acquisition of intangible assets. Contingent consideration is not considered on initial recognition of the asset, but it is added to the cost of the asset initially recorded, when incurred.

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

See **Solution 5.18** for IFRS 15 guidance.

1.21 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 up-front payment of C10 million.
- Milestone of C20 million payable for enrolling 1,000 patients for Phase III trials.
- Milestone of C10 million on regulatory approval.
- Royalties of 25% payable on sales.

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 where 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 account for the in-licence?

Solution

Pharma needs to assess whether the up-front payment is for the acquisition of an intangible or for prepaid R&D. There is no separate payment for R&D services, and so it is likely that the up-front payment is, at least in part, a prepayment for R&D. Any prepayment recognised is released to the income statement over the development period.

The future milestones must be assessed to determine whether 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 judgemental 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 whether the payment is due only on a verifiable outcome, or whether it 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 C10 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.

See Solution 5.19 for IFRS 15 guidance.

1.22 Up-front payments to conduct research

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, up-front payment of C3 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 up-front 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 up-front payment is recognised as a prepayment in the income statement over the period of the research activity.

1.23 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 C100,000 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.

1.24 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:

a. C2 million on signing the agreement.

b. C3 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 up-front 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 up-front 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 need 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.

1.25 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. C5 million on signing the agreement, as an advance payment. Tintoretto is required to refund the entire payment if it fails 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 the advance payment 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 C5 million as prepaid expense initially, and it should recognise the prepaid to R&D expense over the term of the agreement on successful completion of Phase II.

1.26 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 it 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 expensed over the service period.

1.27 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 in 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; and
- competitors in the market place.

1.28 Commencement of amortisation

Background

A pharmaceutical entity acquired a compound in Phase III for C5 million on 1 January 20X3. The entity receives regulatory and marketing approval on 1 March 20X4 and it 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 the entity 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)].

1.29 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.

1.30 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 up-front 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.

1.31 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 where 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.

1.32 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;
- changes 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.

1.33 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 on 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?

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.

1.34 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.

1.35 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.

1.36 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 IG5].

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.

1.37 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.

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?

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.

1.38 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 whether 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.

1.39 Reversals of impairment losses (cost model)

Background

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.

1.40 Impairment testing and useful life

Background

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.

2 Manufacturing & supply chain

2.1 Treatment of trial batches in development

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 (that is, 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

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 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

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 that is, (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 property, plant or equipment (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?

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 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.

2.4 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 at which 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.

2.5 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.

2.6 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.

2.7 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 in 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 purpose. 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 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 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.

2.8 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.

2.9 Exclusive supply agreements

Background

Caravaggio enters into a two-year collaboration agreement with an experienced drug manufacturer, Supplier, to exclusively manufacture two well-established drug compounds for the US. Caravaggio and Supplier form a joint steering committee where Caravaggio, in an advisory capacity, can provide feedback to Supplier and address any queries raised by Supplier. The contract explicitly specifies the manufacturing facility, and Supplier does not have the right to substitute the specified facility. The contract specifies the monthly volumes of the two drug compounds that need to be delivered by Supplier. Supplier only has one production line to fulfil the contractual requirements. The specified volume cannot be changed by Caravaggio during the term of the arrangement. Supplier operates the manufacturing facility and makes all manufacturing decisions, including how and when the drug compounds are to be produced to meet the specified volume requirements.

Relevant guidance

A contract is, or contains, a lease if there is an identified asset and the contract conveys the right to control the use of the identified asset for a period of time in exchange for consideration. An entity assesses whether a contract is, or contains, a lease at the inception date. [IFRS 16 paras 9–11].

To assess whether a contract conveys the right to control the use of an identified asset (as described in paras B13–B20 of IFRS 16) for a period of time, an entity should assess whether, throughout the period of use, the customer has both of the following:

a. the right to obtain substantially all of the economic benefits from use of the identified asset (as described in paras B21–B23); and

b. the right to direct the use of the identified asset (as described in paras B24–B30).

Does the contract with Supplier contain a lease?

Solution

No. Although the asset is identified, Caravaggio lacks control of the right to use asset during the period of use, and so the contract does not contain a lease. The asset is identified, because the manufacturing facility is explicitly specified in the contract and Supplier has only one manufacturing production line available to fulfil the contract and no substitution rights. However, Caravaggio does not have the right to control the use of the manufacturing facility throughout the two-year period of use, despite receiving substantially all of the economic benefits from the use of the manufacturing facility. This is because Supplier is entitled to make all operating decisions, such as determining how and when the facility is operated during the period of use, the detailed production schedule for the two drug compounds, and the batch size. Therefore, Supplier has the right to control the use of the identified asset during the period of use.

The solution might be different if Caravaggio was able to change purchase volumes and/or had the ability to make key operating decisions in the manufacturing facility. Contract manufacturing agreements can take many different forms and will require careful assessment of the facts and circumstances and relevant rights at the inception of each arrangement.

2.10 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 whether the raw materials have an alternative manufacturing use.

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

- 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.

3

Funding for R&D

3.1 Capitalisation of interest on loans received to fund R&D

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 it is 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 specifies criteria for the recognition of interest as an element of the cost of an internally generated intangible asset. [IAS 38 para 66].

Can Pilax capitalise the interest incurred for borrowings obtained to finance R&D activities?

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:

a. Randolph will keep any trial results, if compound X fails in Phase III, and Tiepolo will transfer the underlying intellectual property (IP).

b. 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 Tiepolo account for the funding received?
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 should adjust the carrying amount 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. [IFRS 9 para B5.4.6].

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 income statement.

In case of success – An adjustment to the liability in accordance with paragraph B5.4.6 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 judgemental area. Each structure should be evaluated on its specific facts and circumstances.

3.3 Loans and grants from government/charitable organisations to fund R&D

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 Warhol decides to exploit and commercialise the results of the research project. The repayment terms require Warhol to repay an amount equal to 10% of sales per year if it 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 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. [IAS 20 para 10A].

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. 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.

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, and 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 [IFRS 10 para 7]:

a. power over the investee;

b. exposure, or rights, to variable returns from its involvement with the investee; and

c. the ability to use its power over the investee to affect the amount of the investor's returns.

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 where 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 combinations & asset acquisitions

4.1 Acquisition of a single compound

Background

Atom Inc is interested in a single compound, 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 interest in 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 where 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.

Please note that this solution is based on IFRS 3 prior to the ‘definition of a business’ amendment. The amendment is effective on 1 January 2020 and early application is permitted.

4.2 Acquisition of compound and scientists transfer

Background

Alpha owns the right to several drug compound candidates that are currently in Phase I. Alpha's activities consist of research and development that is being performed on the early-stage drug compound candidates. Alpha employs management and administrative personnel, as well as scientists who are vital to performing the research and development. Delta acquires the rights to the drug compound candidates, along with the scientists formerly employed by Alpha 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 Delta account for the transaction as a business combination?

Solution

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

Delta 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 Delta 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.

Please note that this solution is based on IFRS 3 prior to the 'definition of a business' amendment. The amendment is effective on 1 January 2020 and early application is permitted.

4.3 Accounting for acquired IPR&D

Background

Pharmaceutical Company Alpha owns the rights to several product (drug compound) candidates. Its only activities consist of research and development performed on the product candidates. Delta, also in the pharmaceutical industry, acquires Alpha, including the rights to all of Alpha's product candidates, testing and development equipment, and it hires all of the scientists formerly employed by Alpha, who are integral to developing the acquired product candidates. Delta 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 should be regarded by the entity as having an indefinite useful life where 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 a finite 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 Delta 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. Delta 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 in 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.

4.4 Acquisition of a Biotech entity – one IPR&D project (amended IFRS 3)

Background

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

Pharma Co has decided to early adopt the amendments to the definition of a business under IFRS 3 for this transaction.

Relevant guidance

The amended model introduces an optional concentration test that, if met, eliminates the need for further assessment. [IFRS 3 para B7A].

Under the concentration test, companies consider whether substantially all of the fair value of the gross assets acquired is concentrated in a single asset (or a group of similar assets). If so, the assets acquired would not represent a business and no further analysis is required. [IFRS 3 B7B].

Is the arrangement the acquisition of a business under the amended definition of a business in IFRS 3?

Solution

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

4.5 Acquisition of a Biotech entity – more than one IPR&D project (amended IFRS 3)

Background

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

Pharma Co has decided to early adopt the amendments to the definition of a business under IFRS 3 for this transaction.

Relevant guidance

The optional concentration test includes the concept of aggregating 'similar' assets. [IFRS 3 para B7B]. However, a group of intangibles are not similar if they have significantly different risk characteristics. [IFRS 3 para B7B(f)(vi)].

A transaction is not automatically a business combination if the optional concentration test does not result in the asset classification. An entity would then need to assess the transaction under the framework in IFRS 3. [IFRS 3 para B7].

IFRS 3 requires a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs.

If a set of activities does not have outputs, an acquired process is considered substantive where [IFRS 3 para B12B]:

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

Is the arrangement the acquisition of a business under the amended definition of a business in IFRS 3?

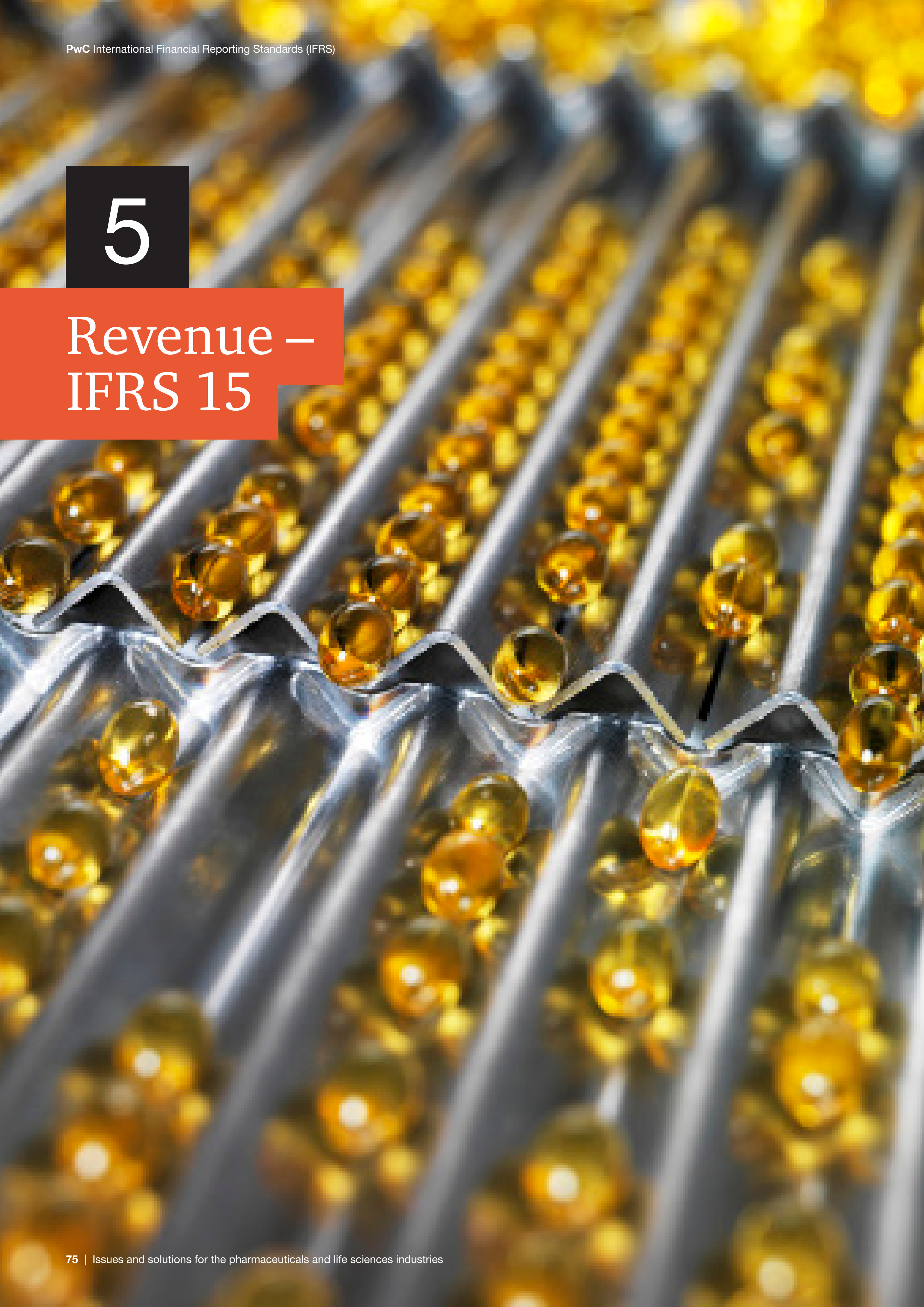
Solution

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

The concentration test is not applied, because the fair value of the assets acquired is not concentrated in a single identifiable asset or a group of similar identifiable assets. Further analysis is required, following the framework without outputs, to assess whether a process is acquired and whether the process is substantive. A business is acquired, because the organised workforce is a substantive process that is critical to the ability to develop and convert the inputs (that is, workforce, IPR&D and tangible assets) into outputs.

5

Revenue – IFRS 15



5.1 Contract term

Background

Biotech enters into a 10-year term licence arrangement with Pharma under which Biotech transfers to Pharma the exclusive rights to sell product using its intellectual property in a particular territory. The intellectual property is considered a right of use licence and there are no other performance obligations in the arrangement. Pharma makes a non-refundable up-front payment of C25 million and is obligated to pay an additional C1 million at the end of each year throughout the stated term.

Pharma can cancel the contract for convenience at any time but, on cancellation, it must return its rights to the licensed intellectual property to Biotech. On cancellation, Pharma does not receive any refund of amounts previously paid.

Relevant guidance

Some contracts with customers might have no fixed duration and can be terminated or modified by either party at any time. Other contracts might automatically renew on a periodic basis that is specified in the contract. An entity should apply the guidance in the revenue standard to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. [IFRS 15 para 11].

What is the contract term for the purposes of IFRS 15?

Solution

In the scenario above, Biotech would likely conclude that the contract term is 10 years, due to the substantive termination penalty that Pharma would incur if the contract were cancelled prematurely. The substantive termination penalty in this arrangement is Pharma's obligation to transfer an asset to Biotech through the return of its exclusive rights to the licensed intellectual property without refund of amounts paid. Furthermore, since the additional annual payments are due over a 10-year period, it is likely that Biotech will conclude that the arrangement contains a significant financing component. Therefore, Biotech would recognise C25 million, plus the present value of the C1 million payments due at the end of each year throughout the stated term, on transferring control of the right of use licence.

The assessment of whether a substantive termination penalty is incurred on cancellation could require significant judgement for arrangements that include a licence of intellectual property. Factors to consider include the nature of the licence, the payment terms (for example, how much of the consideration is paid up-front), the business purpose of contract terms that include termination rights, and the impact of contract cancellation on other performance obligations, if any, in the contract. If management concludes that a termination right creates a contract term shorter than the stated term, management should assess whether the arrangement contains a renewal option that provides the customer with a material right.

5.2 Contract modifications

Background

Pharma A has an arrangement with Pharma B, whereby Pharma A has provided a licence to its oncology drug and is performing R&D services. Pharma A received a large up-front payment of C50 million, and it receives reimbursement at cost for R&D services throughout the contract term up to a specified budget of C30 million. Pharma A is recognising revenue over time in a cost-to-cost model as a single performance obligation, because the parties concluded that the licence and the R&D services were not distinct.

Pharma A and Pharma B enter into an amendment, to increase the budget for R&D on the oncology drug to C40 million. As a result, Pharma A now expects to incur C10 million of additional R&D costs and to be reimbursed an additional C10 million by Pharma B. No other changes were made as part of this amendment.

Relevant guidance

A contract modification is a change in the scope or price (or both) of a contract that is approved by the parties to the contract. In some industries and jurisdictions, a contract modification might be described as a change order, a variation or an amendment. A contract modification exists where the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. A contract modification could be approved in writing, by oral agreement or implied by customary business practices. [IFRS 15 para 18].

An entity should account for a contract modification as a separate contract if both of the following conditions are present [IFRS 15 para. 20]:

a. The scope of the contract increases because of the addition of promised goods or services that are distinct.

b. The price of the contract increases by an amount of consideration that reflects the entity's stand-alone selling prices of the additional promised goods or services and any appropriate adjustments to that price to reflect the circumstances of the particular contract.

How should Pharma A account for the modification?

Solution

Pharma A should account for the contract modification (to expand efforts and increase the transaction price) as if it were a part of the existing oncology contract, and it should adjust revenue on a cumulative catch-up basis to reflect the related impact in accordance with paragraph 21 of IFRS 15.

The pricing on the extension (that is, zero margin) would not appear to represent the stand-alone selling price for the additional R&D efforts. As a result, the contract modification would not meet the conditions to be accounted for as a separate contract in accordance with paragraph 20 of IFRS 15. Pharma A is merely extending the existing oncology program and, therefore, the modification would likely not constitute a separate performance obligation in the context of the contract.

Pharma A would (1) adjust the measure of progress by reflecting the additional costs that it expects to incur in the denominator of the cost-to-cost model, (2) increase the transaction price by the additional consideration that it now expects to receive, subject to the constraint, and (3) reflect the impact as a cumulative catch-up adjustment to revenue.

5.3 Scope considerations when accounting for collaboration arrangements

Background

A biotech entity, Biotech, enters into an arrangement with a pharmaceutical entity, Pharma. Biotech grants an IP licence to a drug compound to Pharma and will perform manufacturing services on the compound. Biotech receives an up-front payment of C40 million, per-unit payments for manufacturing services performed, and a milestone payment of C150 million on regulatory approval.

Relevant guidance

An entity should account for a contract with a customer only when all of the following criteria are met [IFRS 15 para 9]:

a. the parties to the contract have approved the contract (in writing, orally, or in accordance with other customary business practices) and are committed to perform their respective obligations.
b. the entity can identify each party's rights regarding the goods or services to be transferred.
c. The entity can identify the payment terms for the goods or services to be transferred.
d. the contract has commercial substance (that is, the risk, timing, or amount of the entity's future cash flows is expected to change as a result of the contract).
e. it is probable that the entity will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

'Customer' is defined as: "A party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration". [IFRS 15 App A].

Is this arrangement within the scope of IFRS 15 ?

Solution

Determining whether an arrangement is within the scope of IFRS 15 can be a difficult judgement. In the scenario above, the arrangement appears to be within the scope of the revenue standard, because Biotech and Pharma have a vendor-customer relationship. Biotech is providing a licence and manufacturing services to Pharma, and those goods and services are the outputs of Biotech's ordinary activities. Also, the two companies do not share in the risks and benefits that result from the activities under the arrangement.

Identifying the customer is straightforward in many instances, but in some instances a careful analysis needs to be performed to confirm whether a customer relationship exists. For example, a contract with a counterparty to participate in an activity where both parties share in the risks and benefits of the activity (such as developing an asset) is unlikely to be within the scope of the revenue guidance, because the counterparty is unlikely to meet the definition of a customer. An arrangement where, in substance, the entity is selling a good or service is likely to be within the scope of the revenue standard, even if it is termed a 'collaboration' or something similar. The revenue standard applies to all contracts, including transactions with collaborators or partners, if they are a transaction with a customer.

5.4 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 (such as 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 promised.

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 the different types of obligations 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, or 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 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.

Contractual obligation	Likelihood of being a separate PO
• Marketing contributions	Likely
• Delivery of investigational products and clinical trial supplies	Likely
• Participation in a steering committee	Potentially
• Provision of information	Unlikely
• Patent defence	Unlikely

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.

5.5 Assessing distinct promises – (licence and manufacturing)

Background

Alpha, a pharmaceutical company, enters into an agreement with Delta to provide it with a licence related to a mature product for a period of 10 years. For the first three years, Alpha will continue to manufacture the drug, while Delta is developing its manufacturing facilities in order to continue to manufacture the product. Since the licence is related to a mature product, it is not expected that the underlying product will change over the licence period. The manufacturing could be performed by another contract manufacturing organisation (CMO).

Relevant guidance

Licences transferred together with other services, such as manufacturing, must first be assessed to determine whether 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 [IFRS 15 para 27]:

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.

The following are indicators that an entity's promise is not separately identifiable from other promises [IFRS 15 para 29]:

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.

Should Alpha consider the licence a distinct performance obligation in this arrangement?

Solution

Determining whether a licence and manufacturing services are distinct will depend on the facts and circumstances surrounding the licence and the related manufacturing services. Alpha will need to determine whether the customer can benefit from the licence on its own, as well as whether the licence is separately identifiable from the manufacturing services. In this scenario, Alpha is likely to judge that there are two performance obligations. The manufacturing services can be performed by a CMO, so Delta could benefit from the licence on its own. This would be the case even if Delta was contractually obligated to manufacture the product with Alpha for the defined period.

In a scenario where the licence that Delta obtained was solely limited to a right to distribute Alpha's product, and Delta could not use the underlying IP to manufacture products on its own, the licence would be merely a mechanism for Delta to sell what it had purchased, and it would not be distinct.

5.6 Accounting for reimbursement of costs

Background

Biotech enters into a licence arrangement with Pharma to develop a potential drug that is currently in the pre-clinical stage. Biotech agrees to provide Pharma with a perpetual licence to Biotech's proprietary IP and perform R&D services for Pharma relating to the completion of clinical trials to develop the potential drug. Biotech determines that the licence to the proprietary IP and the R&D services are not distinct, and they are accounted for as a single performance obligation that is satisfied over time.

Revenue is recognised using a cost-to-cost model. Biotech receives an up-front payment of C100 million at the inception of the arrangement, and it receives 100% reimbursement for all R&D costs incurred.

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 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].

At the inception of the arrangement, should Biotech include an estimate of cost reimbursement for the R&D in the transaction price?

Solution

Biotech should generally include a best estimate of R&D reimbursements in the transaction price, at the inception of the arrangement. In most circumstances, the R&D reimbursements included in the estimated transaction price would be aligned with the measure of progress used in the denominator of the cost-to-cost model (assuming that is the most relevant measure). In this scenario, if Biotech expects to incur R&D costs of C60 million to fulfil the performance obligation, it should include that same amount in the transaction price, assuming it is contractually entitled to an equal reimbursement.

Actual reimbursements might vary from initial estimates; however, the contract requires Pharma to reimburse Biotech for 100% of costs incurred. The related R&D services revenue would be recognised only as the costs are incurred and, therefore, Biotech would not be exposed to a significant reversal of cumulative revenue at any point in time in the arrangement. Biotech should revise its estimates of the R&D reimbursements included in the transaction price to reflect its best estimate at each reporting period.

5.7 Estimating variable consideration where there are contingent payments

Background

Research Co, a contract research organisation, enters into an arrangement with Company Pharma, a pharmaceutical company, to perform a clinical trial on a Phase III drug candidate. Research Co will receive fixed consideration of C20 million plus an additional milestone or bonus payment of C2 million if it screens 100 patients to enrol in the clinical trial in the first two months of the contract term. Research Co has extensive experience in enrolling patients and completing similar types of trial in the same field that Company Pharma's drug candidate is targeting. Research Co believes that (1) there is a large population of patients to potentially screen for the clinical trial, and (2) its past experience of screening patients has significant predictive value.

Relevant guidance

If the consideration promised in a contract includes a variable amount, an entity should estimate the amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer. [IFRS 15 para 50].

An entity should estimate an amount of variable consideration by using either the expected value or most likely amount method, depending on which method the entity expects to better predict the amount of consideration to which it will be entitled. [IFRS 15 para 53].

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].

At the inception of the arrangement, should Research Co include the C2 million contingent payment in the transaction price?

Solution

Since there is a binary outcome of the contingent payment (that is, Research Co either will or will not screen 100 patients in the first two months), the most likely amount method would generally be used to estimate the variable consideration.

In the scenario above, Research Co has extensive experience which it believes has predictive value. In addition, screening patients is largely in Research Co's control and the contingency is expected to be resolved in a relatively short period of time. Therefore, Research Co would likely include the C2 million contingent payment in the transaction price at inception.

Research Co would then consider the variable consideration constraint, and it is likely to conclude that it is highly probable that there will not be a significant reversal of cumulative revenue, due to the large up-front payment (C20 million) and the fact that the contingency is likely to be resolved in two months. Assuming the performance obligation is satisfied over time, the entire C22 million would be included in the transaction price and not 'held back' due to the constraint.

5.8 Revenue recognition for sales 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 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 and the country's government have not renegotiated the payment terms. Tiepolo has an unconditional right to receive payment.

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)].

How should Tiepolo's management account for the sales to the governmental entity in this country in Southern Europe under IFRS 15?

Solution

Tiepolo's management must first determine whether it is appropriate to recognise new sales to this country. 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 affect the amount of revenue that can be recognised. This is because the receivable will be discounted at initial recognition if there is a significant financing component.

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.

5.9 Rebates on volume purchases

Background

Alpha has a multi-year contract with Delta to sell pharmaceutical drugs, and it agrees to pay Delta an annual rebate if Delta completes a specified cumulative level of purchases during any year of the contract period. The contract specifies that the amount of rebate will vary based on a tiered structure agreed to in the contract as follows (note that the rebate earned is not retroactive to prior purchases):

Purchases	Rebate	Probability
1-1,000 units	0%	15%
1,001-2,000 units	2%	60%
Greater than 2,000 units	5%	25%

The unit price for each product is C100. Based on historical experience of rebates due to Delta, Alpha has assigned probabilities to each possible outcome.

Relevant guidance

If the consideration promised in a contract includes a variable amount, an entity should estimate the amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer. [IFRS 15 para 50].

An entity should estimate an amount of variable consideration by using either the expected value or the most likely amount method, depending on which method the entity expects to better predict the amount of consideration to which it will be entitled. [IFRS 15 para 53].

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].

Consideration payable to a customer includes cash amounts that an entity pays, or expects to pay, to the customer (or to other parties that purchase the entity's goods or services from the customer). Consideration payable to a customer also includes credit or other items (for example, a coupon or voucher) that can be applied against amounts owed to the entity (or to other parties that purchase the entity's goods or services from the customer). An entity should account for consideration payable to a customer as a reduction of the transaction price and, therefore, of revenue unless the payment to the customer is in exchange for a distinct good or service (as described in paras 26–30 of IFRS 15) that the customer transfers to the entity. If the consideration payable to a customer includes a variable amount, an entity should estimate the transaction price (including assessing whether the estimate of variable consideration is constrained) in accordance with paragraphs 50–58 of IFRS 15. [IFRS 15 para 70].

How should Alpha account for the rebate expected to be paid to the customer at the end of the year?

Solution

Alpha determines that the 'expected value' method best predicts the amount of consideration to which it will be entitled. Alpha concludes that it is probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty is resolved.

Under the expected value approach, Alpha estimates the rebate to be 2.45% ((0% rebate x 15% likelihood) + (2% rebate x 60% likelihood) + (5% rebate x 25% likelihood)), based on a probability-weighted assessment of each possible scenario. Therefore, as each unit is shipped during the year, Alpha will recognise a rebate accrual of C2.45 and revenue of C97.55. At the end of each reporting period, Alpha should revise the estimate of sales and true up the calculation and rebate that will be due at the end of the arrangement. This true-up would include a cumulative adjustment on shipments throughout that reporting period.

Companies might have rebate programs that require payments to government health systems. In cases where the government health system is considered the customer, the guidance above would generally apply.

5.10 Outcome-based pay-for-performance arrangements

Background

Umbrella Insurance Company and Rembrandt Pharmaceuticals put in place a reimbursement scheme in territory X for the 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.

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 Rembrandt recognise revenue under a pay-for-performance arrangement?

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 estimates the total transaction price at the start of the contract using the expected value method, which it judges to be most appropriate. However, 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 would constrain the transaction price to nil initially.

If Rembrandt is 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, it should re-evaluate the application of the constraint, which could result in the expected value of consideration being allocated to each each drug.

5.11 Contract manufacturing

Background

Vendor is hired by Customer to manufacture a batch of 100,000 units of a drug with specific package labelling. The initial contract term is six months. Once bottled and labelled, there are significant practical limitations that preclude Vendor from redirecting the product to another customer. Vendor also has an enforceable right to payment for performance completed to date if the contract is cancelled for any reason other than a breach or non-performance.

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].

A practical limitation on an entity's ability to direct an asset for another use exists if an entity would incur significant economic losses to direct the asset for another use. A significant economic loss could arise because either the entity would incur significant costs to rework the asset, or it would only be able to sell the asset at a significant loss. For example, an entity might be practically limited from redirecting assets that have design specifications that are unique to a customer or are located in remote areas. [IFRS 15 para B8].

When and how should Vendor recognise revenue?

Solution

Vendor should recognise revenue on transfer of control of the product to the distributor, which in this scenario would be over time as the units are being manufactured. Management has concluded that the drug to be manufactured by Vendor has no alternative use to Vendor (that is, the bottled and labelled product imposes a practical limitation that precludes Vendor from redirecting it to another customer). A practical limitation on an entity's ability to direct an asset for another use exists if the entity would incur significant economic losses to direct the asset for another use. Vendor has an enforceable right to demand payment if Customer cancels the contract. Therefore, Vendor should record revenue over time as the units are being manufactured.

5.12 Contract for development services

Background

Alpha, a small pharmaceutical company, contracts with a much larger pharmaceutical company, 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. Beta X owns Alpha's work-in-progress at all points in the contract.

BetaX will make 20 equal quarterly non-refundable payments of C250,000 (totalling C5 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 C4 million.

Alpha has completed many similar contracts, and it has a track record of reliably estimating costs to complete. Alpha incurs costs of C400,000 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. This is because BetaX controls an asset (that is, the work-in-progress) at any stage during the contract. Alpha is enhancing that asset through its development services.

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 C500,000, costs of C400,000 and profit of C100,000 for the first quarter. The unbilled C250,000 of revenue should be recognised as a contract asset on Alpha's balance sheet.

5.13 Development services with up-front 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. C3 million on signing of the agreement;

b. C1 million upon successful completion of Phase III clinical trial approval; and

c. C2 million on securing regulatory approval.

Devox expects to incur costs totalling C3 million up to the point of securing regulatory approval. Devox management has concluded that it is not probable that 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

Management has reviewed the contract and concluded 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 up-front payment) and two contingent amounts (dependent on clinical trial and regulatory approval). The contingent amounts are variable consideration. Devox uses the most likely outcome to estimate variable consideration and concludes that the most likely amount is zero. Therefore, 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 up-front 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 up-front fee and any element of variable consideration that is no longer constrained). At the end of each reporting period, the company would re-assess its 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. This could result in a cumulative catch-up of revenue for the performance to date.

5.14 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 at fair value through other comprehensive income, under IFRS 9.

Relevant guidance

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. The financial asset should be subsequently measured at fair value at each reporting date, with any gains or losses recognised in other comprehensive income.
[IFRS 9 paras 5.2.1, 5.7.1 and 5.7.5].

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, because control has transferred. A gain or loss on disposal will also be recognised. 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:

- 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. [IFRS 9 para 5.1.1]. The fair value would be based on the quoted share price multiplied by the quantity of shares. IFRS 15 does not specify the measurement date for non-cash consideration. The shares could be measured on the date of the contract inception, the date when the licence is transferred, or the date when the shares are received. Therefore, management should apply judgement to determine the measurement date.

The shares should subsequently be measured at fair value at each reporting date, with any gains or losses recognised in other comprehensive income. [IFRS 9 paras 5.7.1, 5.7.5].

5.15 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 10 years. Simba receives a non-refundable up-front payment of C3 million for access to the technology. Simba will also receive a royalty of 20% from sales of the AIDS drug.

Relevant guidance

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

IFRS 15 identifies two types of licences: 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 [IFRS 15 para. B58]:

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.

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 [IFRS 15 para B63]:

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).

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

Solution

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 up-front payment) and variable elements (the royalties).

The up-front 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.

See Solution 1.18 for Regal's accounting.

5.16 Contingent payments based on first commercial sale

Background

In June 20x7, Alpha enters into an arrangement to license IP to Delta. The IP relates to an unapproved drug that will be further developed by Delta. The licence is a right to use license and is transferred at contract inception and there are no other performance obligations in the contract. In exchange for the licence, Alpha will receive:

- an up-front payment of C50 million; and
- a milestone payment of C30 million on first commercial sale of a product by Delta.

In December 20x8, the drug is approved by the FDA, and the first commercial sale occurs in February 20x9. Assume that, as of 31 December 20x8, it is probable that a commercial sale will occur.

Relevant guidance

Notwithstanding the guidance in paragraphs 56–59 of IFRS 15, an entity should recognise revenue for a sales-based or usage-based royalty promised in exchange for a licence of intellectual property only when (or as) the later of the following events occurs [IFRS 15 para B63]:

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).

How should Alpha account for the C30 million milestone payment triggered on first commercial sale?

Solution

The C30 million milestone payment is contingent on Delta's sale of the drug, thus, it is reasonable to conclude that the exception for sales- and usage-based royalties received in exchange for licences of IP applies.

Under the royalty exception, the milestone is recognised at the later of (1) when the subsequent sales or usage occurs, and (2) full or partial satisfaction of the performance obligation to which some or all of the sales-based royalty has been allocated.

The milestone payment should be recognised as revenue in the period that the first commercial sale occurs (that is, in February 20X9). Alpha should consider providing disclosure about the milestone and the related accounting policies in the December 20X8 financial statements, if material.

5.17 Licence of intellectual property is predominant

Background

Pharma licenses its patent rights to an approved, mature drug compound to Customer for a licence term of 10 years. Pharma also promises to provide training and transition services relating to the manufacturing of the drug for a period not to exceed three months. The manufacturing process is not unique or specialised, and the services are intended to help Customer to maximise the efficiency of its manufacturing process. Pharma concludes that the licence and the services are distinct. The only compensation for Pharma in this arrangement is a percentage of Customer's sales of the product.

Relevant guidance

Notwithstanding the guidance in paragraphs 56–59 of IFRS 15, an entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a licence of intellectual property only when (or as) the later of the following events occurs [IFRS 15 para B63]:

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).

The guidance for a sales-based or usage-based royalty applies where the royalty relates only to a licence of intellectual property or where a licence of intellectual property is the predominant item to which the royalty relates (for example, the licence of intellectual property might be the predominant item to which the royalty relates where the entity has a reasonable expectation that the customer would ascribe significantly more value to the licence than to the other goods or services to which the royalty relates). [IFRS 15 para 63A].

Does the sales-and usage-based royalty exception apply to this arrangement?

Solution

Yes. The sales- and usage-based royalty exception applies because the licence of IP is predominant in the arrangement. In this scenario, the Customer would ascribe significantly more value to the licence than to the three months of training and transition services. Pharma would recognise revenue as Customer's sales occur, assuming this approach does not accelerate revenue ahead of performance.

5.18 Out-licence of development-phase compound where the licensee does 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 US 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 US.
- 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 rights to develop and sell the product in the rest of the world and will seek to license these rights to another pharmaceutical company.

The consideration payable by Pharma includes:

- An Up-front payment of C10 million on signing the contract.
- A milestone payment of C20 million on regulatory approval.
- Royalties of 15% payable on sales.
- A sales milestone of C20 million in the first year that annual sales exceed C500 million.

The up-front payments and milestones are non-refundable in the event that the contract is cancelled after 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 [IFRS 15 para B58]:

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.

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].

How should Biotech recognise revenue under the out-licencing agreement?

Solution

The out-licence is within the scope of IFRS 15, because Biotech's ordinary business activities are to develop new drugs for out-licensing; the objective being that Pharma Co completes the clinical research, obtains regulatory approval and takes the drug to market. 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 up-front 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 Up-front payment, which is recognised at a point in 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 US, 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.

If Biotech had recognised an intangible asset for Syndrome Q, the portion of the carrying amount of the intangible asset relating to the US rights disposed of should be derecognised **(see Solution 1.16).**

See Solution 1.20 for the accounting of Pharma.

5.19 Out-licence of development-phase compound where the licensor 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 Up-front payment of C10 million.
- A milestone payment of C20 million payable on successful completion of a Phase III trial.
- A milestone payment of C10 million on regulatory approval.
- Royalties of 25% payable on sales.

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 whether 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 [IFRS 15 para 27]:

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.

The following are indicators that an entity's promise is not separately identifiable from other promises [IFRS 15 para 29]:

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 identifies two types of licences: 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 [IFRS 15 para B63]:

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).

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

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

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 granted a 'right to use' licence, and it has also promised to provide development services. No other deliverables are identified. 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 licence and the development services are both capable of being distinct, because 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 that there are two performance obligations.

Measuring and allocating the transaction price

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

Initially, only the 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 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 that they relate to the outcome of transferring the licence. [IFRS 15 para 85(a)]. This is also consistent with the IFRS objective of allocating the transaction price to each performance obligation based on the stand-alone selling price. [IFRS 15 para 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 up-front 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, as described in **Solution 5.18**. 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 5.12**. Biotech determines an appropriate measure of progress, and it recognises revenue accordingly.

The royalties are recognised as revenue when the subsequent sales are made.

See Solution 1.21 for the accounting of Pharma.

6

Presentation and disclosure

6.1 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 format, the costs are recognised as part of costs of goods sold.

The 'function of expenses' 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 'function of expenses' 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.

6.2 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. If the analysis of expenses is presented by nature, promotional costs should be classified as advertising and promotional costs; however, more detailed analysis might be provided. If the analysis of expenses is presented by function, promotional costs should be included within sales and marketing expenses, and further disclosure might be warranted.

6.3 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 prepayment and expensed immediately when the advertisement airs in 20X5. Costs for hits to the company's internet site should be expensed, based on the click-through rate in 20X5.

6.4 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 sales transaction, should be classified as marketing expense. 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 where the product is packaged as sample product.

6.5 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

Where 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 the 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.

6.6 Segmental reporting of internal research and development

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.

6.7 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 [IFRS 8 para 13]:

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.

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. The activities meet the quantitative threshold for percentage of total revenues, and they otherwise meet the criteria for an operating segment.

6.8 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; and 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 Manet disclose R&D expenses and capital expenditure separately in its 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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