International Financial Reporting Standards (IFRS)

Issues and solutions for the pharmaceuticals and life sciences industries – Volume I & II updates

Pharmaceuticals and life sciences

July 2012

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Foreword

The *IFRS Issues and solutions for the pharmaceuticals and life sciences industries* represents an authoritative analysis of accounting issues that the industry faces. This edition has been updated since 2005 to reflect changes in IFRS and interpretations and takes account of changes in the business environment including solutions for value based pricing arrangements and long dated receivables. The solutions are based on a specified set of circumstances but each situation faced by companies must be evaluated on its own facts which may differ from those in these solutions.

I hope you continue to find this publication useful in understanding the accounting for the transactions you encounter in your business. Further, I hope that by encouraging debate of these topics, we will encourage consistent practices by the pharmaceuticals and life sciences industries in financial reporting under IFRS. This consistency will be critical to the acceptance and usefulness of pharmaceuticals and life sciences entities' financial statements.

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Research and development → Manufacture → Sales and marketing

1. Capitalisation of internal development costs: Timing – Scenario 1

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 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 38.57]:

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.

There is no definitive starting point for the capitalisation of internal development costs. Management must use its judgment, 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 files its submission to the regulatory authority for final approval. It is the clearest point at which the technical feasibility of completing the asset is proven [IAS 38.57 (a)], and this is the most difficult criterion to demonstrate.

In many (but not all) circumstances, filing the submission to the regulatory authority for final scientific regulatory approval will therefore represent the starting point for capitalisation.

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 the capitalisation criteria laid down by the IFRS. In particular the technical feasibility of the project is not yet proven.

2. Capitalisation of internal development costs: Timing - Scenario 2

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 the late stages of Phase III testing. It is structurally similar to drugs the entity has successfully developed in the past with very low levels of side effects, and management believes it will be favourably treated by the regulatory authority because it meets currently unmet clinical need. The entity has also started producing inventory.

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38.57]:

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.

There is no definitive starting point for the capitalisation of internal development costs. Management must use its judgment, 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 files its submission to the regulatory authority for final approval. It is the clearest point at which the technical feasibility of completing the asset is proven [IAS 38.57 (a)], and this is the most difficult criterion to demonstrate.

In many (but not all) circumstances, filing the submission to the regulatory authority for final scientific regulatory approval will therefore represent the starting point for capitalisation.

Should management start capitalising the development costs?

Solution

Yes, management should capitalise subsequent internal development costs because the project has met the criteria.

3. Capitalisation of internal development costs when regulatory approval has been obtained in a similar market - Scenario 1

Background

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

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

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38.57]:

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 the development costs be capitalised?

Solution

The company should capitalise any additional development costs. The criterion of technical feasibility in Country Belan has been met, as registration is highly probable and there are likely to be low barriers to obtaining regulatory approval.

4. Capitalisation of internal development costs when regulatory approval has been obtained in a similar market - Scenario 2

Background

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

Experience shows that significant additional clinical trials will be necessary to meet the Oceanese scientific 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 38.57]:

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 the development costs be capitalised?

Solution

The company should not capitalise additional development expenditure. It cannot show that it has met the criterion of technical feasibility, because in this case, registration in another market requires significant further clinical trials and as a result, approval in one market does not necessarily predict approval in the other.

The existence of substantive risk to a performance obligation to obtain the additional scientific regulatory approval indicates these development costs may not be capitalised.

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 IAS 38 paragraph 57 can be satisfied.)

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38.57]:

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 capitalise the development costs at this point?

Solution

There is no definitive starting point for capitalisation; management should use its judgment, based on the facts and circumstances of each development project. In this scenario, it is probable that commercial regulatory approval will be achieved and, since the remaining criteria of IAS 38.57 have been met, management should start capitalising internal development costs [IAS 38.57]. It may still be appropriate to expense the costs if there are uncertainties whether the product will be commercially successful. For example, the solution might be different for a biological compound generic ('bio similar') when uncertainty exists over being able to successfully manaufacture the product.

6. Accounting for development expenditure once capitalisation criteria are met –Scenario 1

Background

Pharmaceutical entity MagicCure has obtained scientific regulatory approval for a new respiratory drug and 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. 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 38.66].

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 38.67].

7. Accounting for development expenditure once capitalisation criteria are met - Scenario 2

Background

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

Relevant guidance

Development costs are capitalised as an intangible asset if the criteria specified in IAS 38 are met. 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 38.66].

Should the management of DeltaB capitalise these costs?

Solution

DeltaB should not capitalise the expenditure it incurs to add new functionality, because new functionality will require filing for new scientific regulatory approval. This requirement implies that technical feasibility of the modified device has not been achieved.

8. Examples of development costs

Background

A laboratory is developing a drug to cure SARS. Management has determined that it meets the criteria of IAS 38.57, and that certain development costs must therefore be capitalised because regulatory approval has been obtained. Management is unsure what costs to include.

Relevant guidance

Development is the application of research findings or other knowledge to a plan or design for the production of a new product before commercial production or use of the product has begun [IAS 38.8].

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

Solution

Management should consider the following development costs, assuming the criteria for capitalising development costs have been met [IAS 38.57]:

- *employee benefits for personnel involved in the investigation and trials, including employee benefits for dedicated internal employees;*
- *compensation paid to patients or their relatives;*
- *directly attributable costs such as fees to transfer a legal right and the amortisation of patents and licences that are used to generate the asset;*
- *overheads that are directly attributable to develop the asset and can be allocated on a reasonable and consistent basis, such as allocation of depreciation of property, plant and equipment (PPE) or rent;*
- *legal costs incurred in presentations to authorities;*
- *insurance costs for the risks of unexpected side-effects in patients participating in trials;*
- *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.*

9. Useful economic lives of intangibles

Background

A laboratory has capitalised the costs incurred in the development of a new drug. These costs have met the capitalisation criteria under IAS 38.57 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 38.97].

Useful life is defined as the period of time over which an asset is expected to be used by the entity [IAS 38.8].

Management should assess the useful life of an intangible asset both initially and on an annual basis [IAS 38.88] [IAS 38.104].

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. In addition to these factors, it should consider industry-specific factors, such as the following:

- *duration of the patent right or license of the product;*
- *redundancy of a similar medication/device due to changes in market preferences;*
- *impact of bad publicity on a brand name (for example, a significant fall in sales arising from side- effects or a recall of a products available on the market);*
- *unfavourable court decisions on claims from product users;*
- *regulatory decisions over patent rights or licences;*
- *development of new drugs treating the same disease;*
- *changes in the environment that make the product ineffective (for example, a mutation in the virus that is causing a disease, which renders it stronger); and*
- *changes or anticipated changes in participation rates or reimbursement policies of insurance companies, Medicare or governments for drugs and other medical products.*

10. Commencement of amortisation

Background

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

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 38.97].

When should it begin amortising its intangible assets?

Solution

Amortisation should begin from 1 March 20X4, because this is the date from which the asset is available for use. Prior to that date, the intangible asset should be tested for impairment at least annually, irrespective of whether any indication of impairment exists [IAS 36.10 (a)].

See also

Solution 18 (Complex arrangements for in-licensing agreements including capitalisation)

11. Indefinite-life intangible assets

Background

Management of a pharmaceutical entity has acquired an intangible asset that it believes has an indefinite useful life and has decided not to amortise it.

Relevant guidance

An intangible asset can be regarded as having an indefinite useful life when there is no foreseeable limit on the period during which the asset is expected to generate positive cash flows for the entity [IAS 38.88].

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

Solution

Yes, management can regard an asset as having an indefinite life in accordance with IAS 38. However, even though the asset is not amortised, management is required to test it for impairment, by comparing its recoverable amount with its carrying value annually and whenever there is an indication the intangible asset may be impaired [IAS 36.10 (a)].

Pharmaceutical intangible assets that might be regarded as having an indefinite life could include acquired over-the-counter brands or generic products. Technological and medical advances will reduce the number of situations where an indefinite life would apply. As a result of limited patent lives, only in exceptional cases would the active ingredient of pharmaceutical products have unrestricted economic lives.

12. 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 36.9].

What indicators of impairment should management consider?

Solution

Paragraph 12 of IAS 36 provides a minimum number of potential indications management should consider when assessing intangible asset impairment. Management of pharmaceutical entities should also consider other pharmaceutical-specific indicators, including:

- *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 publicity over brand names;*
- *change in the economic lives of similar assets;*
- *litigation;*
- *relationship with other intangible or tangible assets; and*
- *changes or anticipated changes in participation rates or reimbursement policies of insurance companies, Medicare and governments for drugs and other medical products.*

13. Exchange of intangible assets with no continuing involvement

Background

Pharmaceutical entity Egram is developing a hepatitis vaccine compound. Pharmaceutical entity Fiorel is developing a measles vaccine compound. 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. The fair value of Egram's compound has been assessed as 3 million. The carrying value of the compound is 0.5 million.

Relevant guidance

An intangible asset may 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 38.45].

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 38.46]:

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 38.47].

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

Solution

Egram's management should recognise the compound received at the fair value of the compound given up, which is 3 million. Management should also recognise a gain on the exchange of 2.5 million (3 million – 0.5 million) because there is no continuing involvement.

14. Exchange of intangible assets with continuing involvement

Background

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

Relevant guidance

An intangible asset may 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 38.45].

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 38.46]:

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 38.47].

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

Solution

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

15. Accounting for receipt of listed shares in exchange for a patent

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 right it acquires by giving Kupla 5% of its shares (which are listed). The listed shares represent the fair value of the patent. If Jerome is successful in developing a drug and bringing it to the market, Kupla will also receive a 5% royalty on all sales. Kupla's management expects to classify the shares as available for sale.

Relevant guidance

An entity should initially measure a financial asset that is available for sale at its fair value plus transaction costs directly attributable to the acquisition [IAS 39.43]. The fair value of a financial asset is determined using paragraphs AG69-AG82 of Appendix A of IAS 39 [IAS 39.48].

A financial instrument is regarded as quoted in an active market if quoted prices are readily and regularly available from an exchange. Published price quotations in an active market are the best evidence of fair value. They are therefore used to measure the financial asset or financial liability [IAS 39.AG71].

Revenue from royalties shall be recognised on an accrual basis in accordance with the substance of the relevant agreement [IAS 18.30].

How should Kupla's management account for the shares it receives?

Solution

Kupla's management should initially recognise the shares received as available-for-sale securities at their fair value plus transaction costs that are directly attributable to the acquisition [IAS 39.43]. Kupla's management should also derecognise the patent that is transferred to Jerome, and should recognise the gain arising from the sale of the patent. The fair value of the shares received represents the amount of the consideration received [IAS 18.12].

Kupla should not yet recognise any asset relating to the future royalty stream from the potential sales of the drug, because this stream of royalties is contingent upon the successful development of the drug. The revenue will be recognised on an accrual basis, as the royalties are earned [IAS 18.30 (b)].

16. Accounting for receipt of unlisted shares in exchange for a patent

Background

Pharmaceutical company Rossel agrees to acquire a patent from pharmaceutical group Kupla in order to try to develop a more complex drug. Rossel will pay for the right it acquires by giving Kupla 10% of the shares in an unlisted subsidiary. If Rossel is successful in developing the drug and bringing it to the market, Kupla will receive a 5% royalty on all sales. Management expects to classify these shares as available-for-sale.

Relevant guidance

An entity should initially measure an available-for-sale financial asset at its fair value plus transaction costs directly attributable to the acquisition [IAS 39.43]. In determining the fair value of a financial asset an entity shall apply paragraphs AG69-AG82 of Appendix A of IAS 39 [IAS 39.48].

How should Kupla's management initially recognise the shares it receives from Rossel in a collaboration agreement?

Solution

Kupla's management should initially recognise the shares received as available-for-sale securities at their fair value plus transaction costs that are directly attributable to the acquisition [IAS 39.43]. Kupla should determine the fair value of the unlisted shares using an appropriate valuation technique – for example, discounted cash flow models, earning multiples or ratios for similar listed entities. Kupla's management should also derecognise the patent that is transferred to Rossel and should recognise the gain arising from the sale of the patent. The fair value of the shares received represents the amount of the consideration received [IAS 18.12].

Kupla should not yet recognise any asset relating to the future royalty stream from the potential sales of the drug, because this stream of royalties is contingent upon the successful development of the drug. The revenue will be recognised on an accrual basis, as the royalties are earned [IAS 18.30 (b)].

17. Accounting for receipt of shares subject to trading restrictions in exchange for a patent

Background

Pharmaceutical company Landra acquires a patent from pharmaceutical group Mixan in order to develop a more complex drug. Landra pays for the right it acquires by giving Mixan 15% of its listed shares. This does not give Mixan significant influence over Landra. The shares received by Mixan will have the following restriction: during the first two years, Mixan can only sell the shares to a third party at a price fixed in the agreement with Landra. Mixan's management expects to classify these shares as available-for-sale.

Relevant guidance

An entity should initially measure an available-for-sale financial asset at its fair value plus transaction costs directly attributable to the acquisition [IAS 39.43]. In determining the fair value of a financial asset an entity shall apply paragraphs AG69-AG82 of Appendix A of IAS 39 [IAS 39.48].

A financial instrument is regarded as quoted in an active market if quoted prices are readily and regularly available from an exchange. Published price quotations in an active market are the best evidence of fair value. They are therefore used to measure the financial asset or financial liability [IAS 39.AG71].

How should Mixan's management account for the shares it receives?

Solution

Mixan's management should initially measure the listed shares received as available-for-sale securities at their quoted market price plus costs directly attributable to the acquisition. This is the best representation of their fair value [IAS 39.AG71]. The existence of restrictions over the shares does not preclude measuring the shares at their quoted market price.

Following the rules for available-for-sale securities, Mixan should subsequently measure the shares at fair value at each balance sheet date. Movements in fair value should be recognised in other comprehensive income, except for impairment losses and foreign exchange gains and losses, which are charged to the income statement. Management should also provide relevant disclosures relating to the key characteristics of the shares (i.e. restrictions). Mixan should derecognise the intangible asset represented by the patent transferred to Landra and recognise any resulting gain or loss in the income statement.

18. Complex arrangements for in-licensing agreements including capitalisation

Background

Pharmaceutical entities Regal and Simba enter into an agreement in which Regal will licence Simba's know-how and technology (which has a fair value of LC 3 million) to manufacture a compound for AIDS. It cannot use the know-how and technology for any other project. 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. Regal will use Simba's technology in its facilities for a period of three years. Simba will have to keep the technology updated and in accordance with Regal's requirements. The agreement stipulates that Regal make a non-refundable payment of LC 3 million to Simba for access to the technology. Simba will also receive a 20% royalty from sales of the protein compound.

Relevant guidance

An intangible asset should be recognised if [IAS 38.21]:

a. it is probable that the future economic benefits from the asset flow to the entity; and
b. the cost of the asset can be measured reliably.

Research constitutes original and planned investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding [IAS 38.8].

No intangible assets arising from research should be recognised. Expenditure on research should be recognised as an expense when it is incurred [IAS 38.54]

How should Regal's management account for the in-licensing agreement?

Solution

Regal's management should recognise an intangible asset for the use of Simba's technology. The right should be measured at its cost of LC 3 million. The intangible asset should be amortised from the date it is available for use (Solution 10). Here, the technology 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), as it is an expense directly related to the production of the compound.

The price an entity pays to acquire an intangible asset reflects expectations about the probability that the expected future economic benefits from the asset will flow to the entity. The effect of probability is therefore reflected in the cost of the asset. The probability recognition criterion is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

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.

When the drug is sold, Regal pays Simba 20% of sales. These payments are presented in the income statement (by nature as part of operating expenses or by function as cost of sales). The method of presentation of expenses in the income statement should be applied consistently [IAS 1.45].

19. Upfront payments to conduct research with access to the 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, upfront payment of LC 3 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 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 38.54].

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

Solution

Astro will have access to the research being carried out over a two-year period. The upfront payment should therefore be deferred as a pre-payment and recognised in the income statement over the life of the research. If the research terminates early, Astro should write off the remainder of the pre-payment immediately. The costs of carrying out the research should be classified as research and development expenditure in the income statement.

20. Payments made to conduct research

Background

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraines over a five-year period. Alpha is engaged only to provide development services and will periodically have to update BetaX with the results of its work. BetaX has exclusive rights over the development results. It will make 20 equal non-refundable payments of LC 0.25 million (totalling LC 5 million), if Alpha can demonstrate compliance with the development programme. Payments do not depend upon the achievement of a particular outcome. Alpha's management estimates the total cost will be LC 4 million.

In the first quarter of year one, Alpha incurs costs of LC 0.4 million, 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

Research expenditure should not be capitalised as an intangible asset. Expenditure on research should be expensed when incurred [IAS 38.54].

How should BetaX recognise the payments it makes Alpha?

Solution

BetaX should recognise an expense of LC 250,000 each quarter for as long as it engagess Alpha to continue performing the research. These payments should be presented in the income statement (by nature as part of operating expenses or by function as research and development expenditure). The method of presentation of expenses in the income statement should be applied consistently [IAS 1.45].

21. Payments received to conduct development

Background

Alpha, a small pharmaceutical company, contracts with the much larger BetaX to develop a new medical treatment for migraine over a five-year period. Alpha is engaged only to provide development services and will periodically have to update BetaX with the results of its work. BetaX has exclusive rights over the development results. It will make 20 equal non-refundable payments of LC 0.25 million (totalling 5 million), if Alpha can demonstrate compliance with the development programme. Payments do not depend upon the achievement of a particular outcome. Alpha's management estimates the total cost will be 4 million.

In the first quarter of year one, Alpha incurs costs of LC 0.4 million, 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 the gross inflow of economic benefits during the period, arising in the course of the ordinary activities when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7].

Revenue is recognised only to the extent of recoverable expenses if the outcome of the transaction involving the rendering of services cannot be estimated reliably [IAS 18.26].

How should Alpha recognise the payments it receives from BetaX to conduct development?

Solution

Alpha should recognise the revenue for the payments in accordance with the percentage of completion model, based on an estimate of total costs [IAS18.20] or on a straight-line basis [IAS 18.25], whichever provides the most rational recognition of revenue. In this case, a percentage of completion model based on the estimate of total costs appears to be the most appropriate, given the circumstances.

As Alpha has met its obligations and the project is developing in line with the estimates and is forecast to be profitable, Alpha should recognise revenue of LC 500,000, costs of LC 400,000 and profit of LC 100,000 for the first quarter. The unbilled LC 250,000 of revenue should be recorded as a receivable on Alpha's balance sheet, as contract work in progress. Alpha's management should assess the amount due from BetaX for recoverability in accordance with IAS 18 [IAS 18.28].

22. Upfront payments received to conduct development: Interim recognition

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), even after scientific 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. 3 million on signing of the agreement;
b. 1 million on filing for stage 3 clinical trial approval; and
c. 2 million on securing scientific regulatory approval.

In addition, CareB will reimburse Devox for any expenditure incurred above 3 million.

Devox expects to incur costs totalling 3 million up to the point of securing scientific regulatory approval. But management cannot reliably estimate whether the compound will obtain stage 3 clinical trial approval or scientific regulatory approval.

Relevant guidance

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7].

Revenue is recognised only to the extent of recoverable expenses, if the outcome of the transaction involving the rendering of services cannot be estimated reliably [IAS 18.26].

How should Devox recognise the initial payment it has received from CareB?

Solution

Devox should record the initial payment as deferred income. This deferred income will subsequently be recognised as revenue over the expected contract period, on a basis that is consistent with the services being provided. When the payment is initially received, the earnings process has not been completed. The future milestone payments are not included in the determination of revenue, as their receipt cannot be reliably estimated and no earnings process has been completed.

23. Upfront payments received to conduct development: Interim recognition

Background

Devox is now in the process of fulfilling the contract with CareB outlined in Solution 22. It has incurred 2 million in development costs from the inception of the contract on 1 March 20X1 through to 31 December 20X1, as projected in the original development plan. Devox estimates that the level of costs incurred approximates the amount of services delivered under the contract.

Relevant guidance

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7].

Revenue is recognised only to the extent of recoverable expenses, if the outcome of the transaction involving the rendering of services cannot be estimated reliably [IAS 18.26].

How should it recognise deferred income and costs incurred to conduct development for another party?

Solution

Devox should by now have recognised some of the deferred income it initially recorded as revenue. Since it has incurred 2 million in development costs to date and expects to incur another 1 million, it should have recognised a comparable ratio of deferred income – i.e. 66.7% or 2 million – as revenue. The future milestone payments are not included in the determination of revenue, as their receipt cannot be reliably estimated and no earnings process has been completed.

24. Upfront payments received to conduct development: Completion

Background

Scientific approval has been achieved for the compound on which Devox is working (Solutions 22 and 23). CareB has paid the 1 million and the 2 million milestone payments specified in the development contract, in addition to the 3 million it paid on signing the contract. Devox has incurred costs of 3 million to reach this point, in line with original expectations.

Relevant guidance

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7].

Revenue is recognised only to the extent of recoverable expenses, if the outcome of the transaction involving the rendering of services cannot be estimated reliably [IAS 18.26].

How should deferred income, milestone receipts and costs incurred to conduct development for another party be recognised?

Solution

Devox should recognise any remaining deferred income associated with the initial receipt of 3 million as revenue. It records the 1 million and 2 million milestone payments it received as income since the earnings processes relative to these payments have been fully completed.

25. Donation payment for research

Background

Pharmaceutical entity Sherriff has made a non-refundable gift of 3 million to a university. The donation is to be used to fund research activities in the area of infectious diseases over a two-year period. Sherriff has no right to access the research findings.

Relevant guidance

An intangible asset is an identifiable, non-monetary asset without physical substance [IAS 38.8]. An asset is a resource that is controlled by an entity as a result of past events, and from which future economic benefits are expected to flow to the entity [Framework 4.4 (a)].

Sherriff proposes to recognise the donation as an intangible asset.

Solution

Management should not recognise the donation as an intangible asset as Sherriff has no control over the research and any benefit from the research are expected to flow to the entity. The donation should be expensed when incurred (normally when committed) in the income statement as a charitable donation.

26. Loans received to fund research and development purposes

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 criteria for capitalisation are met after filing for scientific regulatory approval because they are confident approval will be received. Pilax capitalises borrowing costs on qualifying assets as required by IAS 23.

Relevant guidance

An entity shall 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 shall recognise other borrowing costs as an expense in the period in which it incurs them [IAS23.8]. A qualifying asset is an asset that necessarily takes a substantial period of time to prepare for its intended use or sale [IAS 23.5].

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 38.66]. Allocations of overheads are made on bases similar to those used in allocating overheads to inventories. IAS 23 'Borrowing Costs' specifies criteria for the recognition of interest as an element of the cost of an internally generated intangible asset [IAS 38.66].

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.

27. Segmental reporting of internal research and development

Background

Pharmaceutical entity Alpha produces and sells a portfolio of drugs that is comprised of 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 are regularly reviewed by the entity's chief operating decision maker (CODM). In addition the CODM regularly reviews a divisional report with three separate division 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, financial results, forecasts, or plans for their division.

Relevant guidance

An operating segment is a component of an entity that engages in business activities from which it may earn revenues and incur expenses, whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available [IFRS 8.5].

Although a function may not earn revenues, if its activities serve as an integral component of the entity's business it can still be disclosed as an operating segment.

If the chief operating decision maker uses more than one set of segment information, other factors may identify a single set of components as constituting an entity's operating segments, including the nature of the business activities of each component, the existence of managers responsible for them, and information presented to the board of directors [IFRS 8.8].

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 it operates in.

Alpha's R&D activities won't be 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, or plans for their division. Division segments are consistent with the core principle of IFRS 8 because it enables users of its financial statements to evaluate the activities and financial performance, and the business environment of the pharmaceutical entity.

28. 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. 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 the Entity B's chief operating decision maker (CODM) to make decisions about resources to be allocated to the segment and assess its performance.

Relevant guidance

An operating segment is a component of an entity that engages in business activities from which it may earn revenues and incur expenses, whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available [IFRS 8.5].

Single operating segments or aggregations of operating segments (where permitted) must be treated as reportable segments where they exceed certain quantitative thresholds. An entity is allowed, however, to report segment information for smaller operating segments or aggregations of operating segments if it wishes to do so [IFRS 8.11].

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

(a) Its reported revenue, including both sales to external customers and intersegment sales or transfers, is 10 per cent 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 per cent 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 per cent or more of the combined assets of all operating segments [IFRS 8.13].

Should it report its R&D activities as a business segment?

Solution

Entity B's management should report its R&D activities as a separate reportable segment. It meets the quantitative threshold for percentage of total revenues and it otherwise meets the criteria for an operating segment.

29. Segmental reporting for external research and development expenditure

Background

Manet Corp. is a pharmaceutical company with several operating segments. Eighteen percent of the segment expenses in the biotech segment are R&D. Thirty percent 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 may earn revenues and incur expenses, whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available [IFRS 8.5].

Certain other profit or loss information should also be separately disclosed. This comprises specified amounts for each reportable segment if they are either included in the measure of profit or loss that is reported to the CODM or they are otherwise provided to the CODM, even if not included in that measure of profit or loss.

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

Solution

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

30. Treatment of trial batches in development

Background

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

Relevant guidance

Inventories are assets that are [IAS 2.6]:

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

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

Solution

Management should initially recognise the raw materials acquired for the production of trial batches as inventory, until they are moved into actual production. As 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.

31. 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 has no foreseeable future alternative use.

Relevant guidance

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 36.59].

What impairment indicators should a pharmaceutical entity consider?

Solution

Management should consider the general internal and external indicators given in paragraph 12 of IAS 36, when assessing whether PPE should be tested for impairment. In addition, pharmaceutical entities should also consider industry-specific factors such as the following:

- *patent expiry date;*
- *failure of the machinery to meet regulatory requirements;*
- *technical obsolescence of the PPE (for example, because it cannot accommodate new market preferences);*
- *changes in medical treatments*
- *market entrance of competitive products;*
- *product recall;*
- *organisational restructuring or reorganisation*
- *relationship with other tangible and intangible assets; and*
- *changes or anticipated changes in third-party reimbursement policies that will impact the price received for the sale of product manufactured by PPE.*

32. 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 (approval for the use of the machine) from the relevant regulatory authorities. The validation of the machinery is a separate process from the regulatory approval of the new formulation of aspirin.

Relevant guidance

The cost of an item of PPE includes the asset's purchase price and any directly attributable costs of bringing the asset to its working condition as well as any demolition or restoration costs [IAS 16.16].

Examples of costs that should not be capitalised as PPE are the costs of opening a new facility, 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. 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).

33. 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 shall be measured at the lower of cost and net realisable value [IAS 2.9]. An entity should not carry its inventory at values in excess of amounts expected to be realised from its sale or use [IAS 2.28]. Management should make a new assessment of the net realisable value in each subsequent period [IAS 2.33].

Is the inventory used to manufacture the product impaired?

Solution

Pharmaceutical entities should consider industry- specific factors when assessing whether inventories are impaired. Suspending production and a product recall are indicators that the carrying value of raw material inventory used to manufacture the drug may not be recoverable.

34. Treatment of development supplies

Background

A laboratory has purchased 10,000 batches of saline solution. These batches will be used as supplies in trials on patients during various Phase III clinical tests. They can also be used as supplies for other testing purposes, but have no other uses. Management is considering whether the batches should be recorded as an asset.

Relevant guidance

Inventories are assets that are [IAS 2.6]:

- held for sale in the ordinary course of business;
- in the process of production for a sale in the ordinary course of business; or
- materials or supplies to be used in the production process or rendering services.

An asset is recognised in the balance sheet when it is probable that the future economic benefits will flow to the entity and the asset has a cost or value that can be measured reliably [Framework 4.44].

Should costs associated with supplies used in clinical testing be accounted for as inventories?

Solution

The batches do not meet the definition of inventory, because they can only be used for development. However the batches do meet the definition of an asset. They should therefore be recorded at cost and accounted for as supplies used in the development process (e.g. as part of other current assets). When supplies are used, the associated cost forms part of the development expense.

35. Advertising and promotional expenditure

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 38.8].

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 may 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 38.69(c)].

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

36. Presentation of co-marketing expenses

Background

Pharmaceutical entities Gena and Himen have entered into a co-marketing agreement for a compound XY, developed by Himen, for a period of ten years. The agreement is material for both parties. Under the terms of the agreement, Gena has made an upfront payment and milestone payments based on the achievement of certain goals, such as receipt of approval from the regulatory authorities. In return, Himen has granted Gena exclusive marketing rights for XY in Japan.

Himen will manufacture the product and sell it to Gena at cost plus a normal manufacturing margin. Gena will also pay Himen 20% of its net sales of XY and will share a portion of any potential product liability. The promotion and commercialisation of drugs are Gena's main activities, although in this case they are performed jointly with a third party.

Relevant guidance

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities of an entity, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7]. The nature and amount of items of income or expense that are material should be disclosed separately [IAS 1.97].

Industry practice is to consider a sales-agency only relationship as co-promotion, whereas physical sales of product between two companies for resale would be considered co-marketing.

How should Gena present its co-marketing expenditure in its financial statements?

Solution

Gena should present the payments received from customers as sales revenue, and the cost of purchasing XY from Himen as inventory and then cost of goods sold. The co-marketing amounts paid to Himen of 20% of net sales of the product should be presented as selling and distribution expenses (if the income statement is presented by function) or as royalty expenses (if the income statement is presented by nature) in Gena's accounts. If they are a material element of the respective cost, they should be separately identified as co-marketing activities. The accounting for the upfront payment and milestone payments based on the achievement of certain goals is discussed in Solution 51 (Collaboration agreement to develop a drug).

37. Presentation of co-marketing income

Background

Pharmaceutical entities Gena and Himen have entered into a co-marketing agreement for a compound XY, developed by Himen, for a period of ten years. The agreement is material for both parties. Under the terms of the agreement, Gena has made an upfront payment and milestone payments based on the achievement of certain goals, such as receipt of approval from the regulatory authorities. In return, Himen has granted Gena exclusive marketing rights for XY in Japan.

Himen will manufacture the product and sell it to Gena at cost plus a normal manufacturing margin. Gena will also pay Himen 20% of its net sales of XY and will share a portion of any potential product liability. The promotion and commercialisation of drugs are Gena's main activities, although in this case they are performed jointly with a third party.

Relevant guidance

Revenue is the gross inflow of economic benefits during the period, arising in the course of the ordinary activities of an entity, when those inflows result in increases in equity. The increases in equity should not relate to contributions from equity participants [IAS 18.7]. The nature and amount of items of income or expense that are material should be disclosed separately [IAS 1.97].

Industry practice is to consider a sales-agency only relationship as co-promotion, whereas physical sales of product between two companies for resale would be considered co-marketing.

How should Himen present the co-marketing income it receives from Gena in its financial statements?

Solution

Himen should present 100% of the sales of the product XY to Gena as sales revenue, and the corresponding costs of production as cost of goods sold. The co-marketing income, at 20% of Gena's sales, should be presented as co-marketing revenue and disclosed separately as a component of revenue. The accounting for the upfront payment and milestone payments based on the achievement of certain goals is discussed in Solution 51 (Collaboration agreement to develop a drug).

38. Development of alternative indications

Background

Arts Pharma markets a drug approved for use as a painkiller. Recent information shows the drug may 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 38R.57]:

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

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

Solution

Arts should begin capitalisation of development costs as soon as the criteria of IAS 38.57 are met. Entities involved in developing new drugs or vaccines usually expense development expenditure before submission of a filing for regulatory approval. However, there is no definitive starting point for capitalising development costs of alternative indications. Management must use its judgment, 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 final submission for regulatory approval.

Management should consider, amongst other factors, the risks associated with demonstrating effectiveness of the new indication, whether a significantly different dosage may be needed for the other indication (potentially requiring new side effect studies) and whether the new indication will target a different group of patients (e.g., children vs. adults). If these considerations indicate the uncertainties are comparable to a new drug and commercialisation is substantially dependent upon regulatory approval, the entity should begin to capitalise development costs no later upon regulatory approval.

39. Line extension development costs

Background

Degas Pharma owns a drug that has historically been approved for its pain-reducing effect on adults. Management now intends to obtain scientific approval to use the drug for the treatment of children. Degas has commenced additional development procedures necessary to gain approval for this line extension. Regulatory approval is needed for this line extension and the probability of obtaining approval is comparable to that of a new drug.

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38.57]:

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 the asset; and
f. the ability to measure reliably the expenditure attributable to the intangible asset.

Line extensions include a variety of circumstances, such as extension of an approved formulation to children, use of a new formulation (e.g., use of an inhaler vs. injection, syrup vs. tablets) and/or different dosages.

Should management capitalise the development costs relating to the line extension?

Solution

Degas should begin capitalisation of development costs as soon as the criteria of IAS 38.57 are met, which is no later than upon regulatory approval. Technical feasibility of line extensions is usually the most difficult criterion to demonstrate. Degas' management should consider whether the existing approval indicates that technical feasibility of the line extension has been achieved.

Degas' management should also consider the results of the development process underlying the earlier approval and the historical success of having comparable line extensions approved. If the regulatory uncertainties are comparable to those for a new drug, Degas should capitalise development costs no later than upon regulatory approval.

40. Cost incurred for performance comparisons

Background

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

Relevant guidance

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

The cost of an internally generated intangible asset comprises all directly attributable cost incurred to create, produce and prepare the asset for its intended use [IAS38.66]. In some cases, expenditure is 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 38R.69].

Should costs incurred to compare various drugs with the intent 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 as 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.

41. Development costs for limited markets

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 filed for initial regulatory approval, and believes that all other capitalisation criteria under IAS 38.57 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 [IAS 38.57]:

a) 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;

An intangible asset shall 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 38.21].

Should the development costs for a limited market be capitalised?

Solution

IAS 38.57 requires all of the capitalisation criteria to be met, including the economic benefit criterion. Da Vinci pursues development of a drug if the market potential is sufficient to obtain future economic benefits. However, Da Vinci has decided to pursue this drug for reputational reasons. Da Vinci should recognise development costs for this drug when the criteria in IAS 38 are met, but the amount capitalised should be limited to no more than the amount recoverable following commercialisation.

Da Vinci will need to assess the capitalised costs for any indication of impairment at each reporting date [IAS 36.9] and test for impairment annually as long as the asset is not available for use [IAS 36.10].

42. 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, plus paying a 25% premium on a quarterly basis as the work is completed.

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

Research expenses are recognised as incurred [IAS 38.54]. Examples of research activities include the search for alternatives for materials, devices, products, processes, systems or services [IAS 38.56 (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 38.59(d)].

How should Whistler Corp. 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.

43. Fixed-fee 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 pay Ruskin LC3 million upon completion of the contracted work. The payment is based on delivery of the research services; there is no success-based contingency.

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

Research expenses are recognised as incurred [IAS 38.54]. Examples of research activities include the search for alternatives for materials, devices, products, processes, systems or services [IAS 38.56 (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 38.59(d)].

How should Whistler Corp. account for contracted research arrangements?

Solution

Whistler should accrue the contract research costs over the expected period of the research. The costs are expensed as accrued and recorded as research expense. The activity is within the definition of research. It will not result in the design or testing of a chosen alternative for new improved materials, devices, products, processes, systems or services that could be capitalised as a development intangible asset. The structuring of the payments does not alter the accounting treatment.

44. 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 has to pay costs for its attorneys and other legal charges.

Relevant guidance

The nature of intangible assets is such that, in many cases, there are no additions to such an asset or replacements of part of it. Accordingly, most subsequent expenditure is likely to maintain the expected future economic benefits embodied in an existing intangible asset rather than to meet the definition of an intangible asset and the recognition criteria in this Standard [IAS 38.20].

Pharmaceutical companies spend significant amounts of money to enforce their patents (or keep others from using their patented know-how). Significant costs are also incurred in defending patent infringement lawsuits. These costs are necessary to maintain the flow of economic benefits from patented products and technologies.

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

Solution

Velazquez should not capitalise patent defence costs as they maintain rather than increase the expected future economic benefits from an intangible asset. They therefore should not be recognised in the carrying amount of an asset under IAS 38.20. Accordingly, patent defence costs have to be expensed as incurred.

45. 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 program. Sisley pays Wright on a cost-plus basis for the research, plus LC 100,000 per development candidate which Sisley elects to pursue further. Sisley concludes that the expenditure doesn't 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) shall be recognised. Expenditure on research (or on the research phase of an internal project) shall be recognised as an expense when it is incurred [IAS 38.54].

An intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate select criteria [IAS 38.57].

Expenditure on an intangible item that was initially recognised as an expense shall not be recognised as part of the cost of an intangible asset at a later date [IAS 38.71].

How should Sisley account for the payments to Wright?

Solution

Costs incurred for research should not be capitalised. Accordingly, Sisley's payments relating to the cost-plus portion of the contract should be expensed. Sisley's payments relating to the successful development 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.

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

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

The cost of a separately acquired intangible asset comprises [IAS 38.27]:

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 shall only be recognised if, amongst other criteria, the technical feasibility of a development project can be demonstrated [IAS 38.57].

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

Solution

Tiepolo owns the compound. Tintoretto performs development on Tiepolo's behalf. No risks and rewards of ownership are to be transferred between the parties. By making the initial upfront payment and the subsequent milestone payment to Tintoretto, Tiepolo does not acquire a separate intangible asset, which could be capitalised. The payments represent funding for R&D by a third party, which needs to be expensed over the development period provided that the recognition criteria in IAS 38.57 for internally generated intangible assets are not met.

47. 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 effectively out-licenses Tiepolo's compound to Tintoretto. Tiepolo and Tintoretto will set up a development steering committee to jointly perform the development and will participate in the funding of the development costs according to specific terms. Tiepolo agrees to make the following payments to Tintoretto:

a. LC5 million on signing the agreement as an advance payment. Tintoretto has to refund the entire payment in the event of failure to successfully complete Phase II.
b. 50% of total development costs on successful completion of Phase II (after deducting the advance payment).

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

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

The cost of a separately acquired intangible asset comprises [IAS 38.27]:

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 shall only be recognised if, amongst other criteria, the technical feasibility of a development project can be demonstrated [IAS 38.57].

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

Solution

Tintoretto becomes party to substantial risks in the development of Tiepolo's compound, as 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. As a result, the advance payment and the milestone payment should be expensed as incurred. Tiepolo should not expense the refundable advance payment before successful completion of Phase II is probable. Tiepolo should record the LC 5 million as prepaid expense initially and recognise the prepaid to R&D expense over the term of the agreement upon successful completion of Phase II.

48. Development services on third-party IP with a call option to in-license priced at a multiple of development expense

Background

Tiepolo Pharma contracts with Randolph Ventures to develop multiple late stage pharmaceutical compounds for the US market. The only additional development for US would be a clinical trial (e.g. a Phase III study). The compounds are owned by third parties that do not have the expertise to perform the clinical trial. Randolph Ventures has a separate agreement with the third party owners that allows Randolph to offer the arrangement to Tiepolo. Tiepolo will conduct all development activities on behalf of Randolph Ventures for cost plus a 15% mark-up, which approximates to the current market price for third party development work. Tiepolo Pharma also obtains a call option to exclusively in-license any of the products from the third-party owner of the compound for predetermined royalty rates. The call option is only exercisable upon successful approval by the FDA in the US. Tiepolo has no rights to the results of the phase III study if it does not exercise the option. Besides the predetermined royalty rates, the exercise price is at 140% of the development costs for the Phase III study and payable to Randolph Ventures. The 140% of the development costs price gives Randolph Ventures a risk adjusted rate of return on its investment. Tiepolo management's policy is not to capitalise development cost prior to approval by the regulatory agency as in general the future economic benefits are not assured and thus the criteria of IAS 38.57 are not fulfilled.

Can Tiepolo's management capitalise the call option exercise payment to Randolph?

Relevant guidance

Normally, the price an entity pays to acquire separately an intangible asset reflects expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. In other words, the effect of probability is reflected in the cost of the asset. Therefore, the probability recognition criterion in paragraph 21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

An intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:

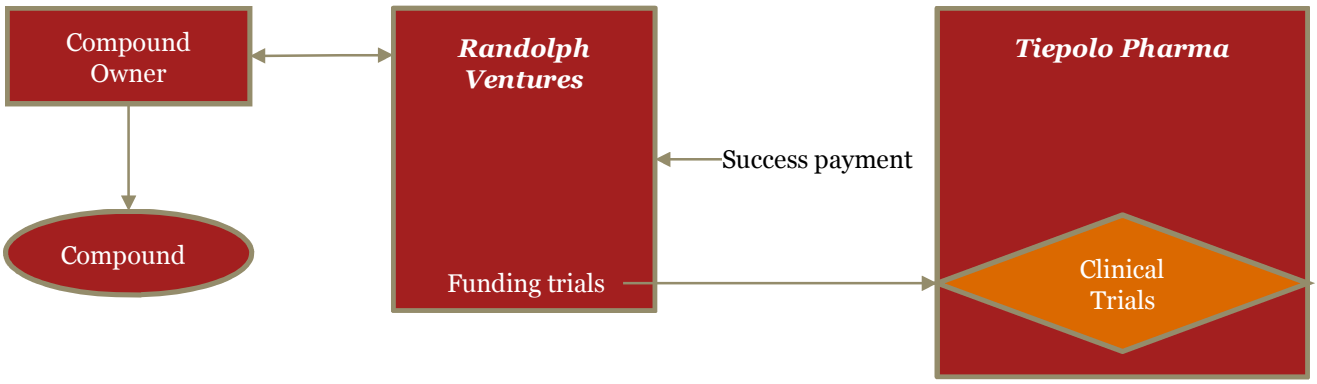
a. the technical feasibility of completing the intangible asset so that it will be available for use or sale.
b. its intention to complete the intangible asset and use or sell it.
c. its ability to use or sell the intangible asset.
d. how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.
e. the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
f. its ability to measure reliably the expenditure attributable to the intangible asset during its development [IAS 38.57].

Expenditure on an intangible item that was initially recognised as an expense shall not be recognised as part of the cost of an intangible asset at a later date [IAS 38.71].

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;

c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably [IAS 18.20].



Solution

The fixed price call option in substance gives Tiepolo control over the compound at inception of the agreement. It follows that the development work performed on the compound is internal.

Separately acquired intangible assets are capitalised because the probability of success is incorporated in the price paid. The call option to acquire the compounds is economically correlated to the development of the compounds. Economically the price is a predefined amount to compensate past development reimbursements. It is priced at 140% of the development costs to give Randolph Ventures a risk adjusted rate of return on its investment. The development costs arise before the capitalisation threshold is met. At inception of the option the potential future benefits of the owner of the compound are limited. Under economically favourable conditions (i.e. positive Phase III result) a third party is likely to exercise the option. Thus the entire exercise price of the call option could not be capitalised as IAS 38.71 states that expenditure on intangible assets originally recognised as expenses shall not be recognised as part of cost of an intangible asset. The conditions for in-licensing have been fixed at the inception of the option. Thus the exercise price for the option consists of 100% development costs plus a 40% premium of the inherent risk absorbed by Randolph Ventures. It would be appropriate to consider the full exercise price to be expense and to classify the expense in accordance with the entities accounting policy.

The call option does not meet the definition of a derivative and therefore does not need to be fair valued at each reporting date. This is because the call option value changes in response to a variable specific to one of the parties of the contract (e.g., the value changes in response to the success of Tiepolo's development activities) [IAS 39.9(a)].

R&D funding vehicles are a complex and judgmental area. Each structure should be evaluated on its specific facts and circumstances. The solutions 48-51 are not intended to provide any definitive rules, but rather illustrate some of the form and substance considerations that might arise.

49. Development services on third-party IP with a market price call option to in-license

Background

Tiepolo Pharma contracts with Randolph Ventures to develop multiple late stage pharmaceutical compounds for the Japanese market. The products have already received regulatory approval in other markets (i.e., US or Europe). The only additional development work required for Japan is a clinical trial (e.g., a Phase III study in Japan). The compounds are owned by third parties that do not have the expertise in the Japan market. Randolph Ventures has a separate agreement with the third party owners that allows Randolph to offer the arrangement to Tiepolo. Tiepolo will conduct all development activities on behalf of Randolph Ventures for cost plus a 15% mark-up, which approximates to the current market price for third party development work. Tiepolo Pharma also obtains a call option to exclusively in-license any of the products from the third-party owner of the compound. The call option is only exercisable upon successful approval in Japan. The exercise price is fair market value at the date of exercise and payable to Randolph Ventures. Tiepolo's management believes at least one of the compounds will be favourably treated by the regulatory authority because it meets a strong therapeutic need and the compound has been successfully developed in other markets. Tiepolo management´s policy is not to capitalise development cost prior to approval by the regulatory agency as in general the future economic benefits are not assured and thus the criteria of IAS 38.57 are not fulfilled.

How should Tiepolo's management account for the development and in-licensing option agreement?

Relevant guidance

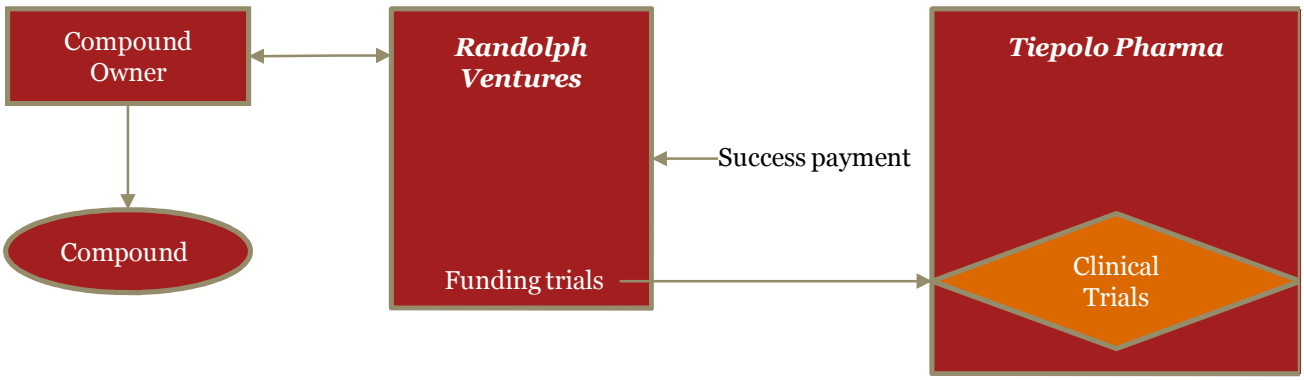
An intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:

a. the technical feasibility of completing the intangible asset so that it will be available for use or sale.
b. its intention to complete the intangible asset and use or sell it.
c. its ability to use or sell the intangible asset.
d. how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.
e. the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
f. its ability to measure reliably the expenditure attributable to the intangible asset during its development [IAS 38.57].

Expenditure on an intangible item that was initially recognised as an expense shall not be recognised as part of the cost of an intangible asset at a later date [IAS 38.71].

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably [IAS 18.20].



Solution

Tiepolo Pharma has a contract to conduct development services. The call option to acquire the compounds has nil value and is independent from the development services because the strike price is at fair market value. A price at fair market value of the compound indicates the option is an independent purchase of an intangible asset that is not linked to a return on invested funding for development work. The payments to reimburse development costs would be recorded as revenue as they are earned. The cost to of the development services would be recorded as cost of services in the statement of profit or loss. When the option is exercised the amount paid for the IP could be capitalised as regulatory approval has been obtained and future economic benefits are expected the asset criteria are fulfilled.

R&D funding vehicles are a complex and judgmental area. Each structure should be evaluated on its specific facts and circumstances. The solutions 48-51 are not intended to provide any definitive rules, but rather illustrate some of the form and substance considerations that might arise.

50. Development services on own IP with a development expense based put option

Background

Tiepolo Pharma is developing a pharmaceutical compound (compound X), which has successfully passed through phase II clinical trials. Before Tiepolo Pharma begins phase III clinical trials for its own compound Randolph Ventures offers Tiepolo Pharma to fund the phase III clinical trial studies and all registration costs. The study results and documentation will be the property of Randolph Ventures, but Tiepolo Pharma has an obligation to acquire the studies and documentation after successful registration of compound X for 175% of the estimated total development costs.The 175% of the estimated total development costs price gives Randolph Ventures a risk adjusted rate of return on its investment. Randolph Ventures subcontracts Tiepolo Pharma as a contract research provider to perform the necessary development activities for phase III clinical trials on its behalf. Tiepolo Pharma will plan and carry out the necessary clinical development project, which will be monitored by an independent advisory panel. This panel will decide whether the development of the compound will be continued until registration based on scientific data and potential revenue. Tiepolo Pharma will decide whether to stop development of the compound due to safety reasons. Randolph Ventures will fund 100% of Tiepolo Pharma´s development costs until the panel has decided to stop the project.

Relevant Guidance

An intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:

a. the technical feasibility of completing the intangible asset so that it will be available for use or sale.
b. its intention to complete the intangible asset and use or sell it.
c. its ability to use or sell the intangible asset.
d. how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.
e. the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
f. its ability to measure reliably the expenditure attributable to the intangible asset during its development [IAS 38.57].

Expenditure on an intangible item that was initially recognised as an expense shall not be recognised as part of the cost of an intangible asset at a later date [IAS 38.71].

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably [IAS 18.20].

A financial liability is any liability that is a contractual obligation to deliver cash or another financial asset to another entity [IAS 32.11].

A financial instrument may 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) that are beyond the control of both the issuer and the holder of the instrument, such as a change in a stock market index, consumer price index, interest rate or taxation requirements, or the issuer's future revenues, net income or debt to equity ratio. 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). Therefore, it is a financial liability of the issuer unless:

a. the part of the contingent settlement provision that could require settlement in cash or another financial asset (or otherwise in such a way that it would be a financial liability) is not genuine;
b. the issuer can be required to settle the obligation in cash or another financial asset (or otherwise to settle it in such a way that it would be a financial liability) only in the event of liquidation of the issuer; or
c. the instrument has all of the features and meets the conditions in paragraphs 16A and 16B [IAS 32.25].

Paragraph 25 requires that if a part of a contingent settlement provision that could require settlement in cash or another financial asset (or in another way that would result in the instrument being a financial liability) is not genuine, the settlement provision does not affect the classification of a financial instrument. Thus, a contract that requires settlement in cash or a variable number of the entity's own shares only on the occurrence of an event that is extremely rare, highly abnormal and very unlikely to occur is an equity instrument. Similarly, settlement in a fixed number of an entity's own shares may be contractually precluded in circumstances that are outside the control of the entity, but if these circumstances have no genuine possibility of occurring, classification as an equity instrument is appropriate [IAS 32.AG28].

1. Has Tiepolo lost control of compound X?

2. Is the payment for the studies and documentation the acquisition of an intangible asset?

3. How should Tiepolo account for the funding received?

Solution

1. Has Tiepolo lost control of compound X?

Tiepolo Pharma has a contract to conduct development services and the obligation to acquire the outcome of the phase III studies (i.e. the research results) if the study result is successful and the registration of the compound in the relevant indication is highly probable. Economically the price is a predefined amount to compensate past development costs of Randolph Ventures. It is priced at 175% of the development costs. Thus at inception of the contract the potential future economic benefits of the owner of the phase III study is limited. Furthermore, there is no alternative use for the study outcome without the patented IP for the underlying compound. Tiepolo has not lost control of compound X.

2. Is the payment for the studies and documentation the acquisition of an intangible asset?

Separately acquired intangible assets are capitalised because the probability of success is incorporated in the price paid. Economically the price is a predefined amount to compensate past development expenditures. It is priced at 175% of the development costs to give Randolph Ventures a risk adjusted rate of return on its investment. The development costs arise before capitalisation threshold met. Thus the entire payment for the studies and documentation could not be capitalised as IAS 38.71 states that expenditure on intangible assets originally recognised as expenses shall not be recognised as part of cost of an intangible asset. It would be appropriate to consider the 175% as expense and to classify the expense in accordance with the entity's accounting policy.

3. How should the funding received be accounted for?

Economically the "offer" to provide a phase III study for a service fee is priced on the estimated development costs plus a risk premium for a negative study result. However, Tiepolo has no control over the rendering of the development services because the independent advisory panel decides about the continuation of the development project. Tiepolo has the obligation to pay 175% of the development costs to Randolph Ventures and Tiepolo has no option to avoid this payment if the compound obtains registration. Thus Randolph Ventures is only acting as a service provider under predetermined conditions. As a consequence the funding of Randolph Ventures for the development services for Tiepolo Pharma is a financial liability with a contingent settlement provision and a predefined payback structure.

The financial liability with a contingent settlement provision to Randolph Ventures consists of two components. The two components are reimbursement of development expense and a 75% risk premium.

The reimbursement component should be accounted for as a contingent financial liability to Randolph Ventures because Tiepolo has no influence on the decision to stop the development project (only the advisory panel can stop the project). A reasonable assumption is that the recognition of the liability should be measured at least at the cash amount received because the probability of success within a study cannot be reliably measured. As the phase III study is without alternative use for Randolph Ventures, Tiepolo has to report all development costs as own development expenses. Any liability recorded for funding received that relates to the reimbursement of development expense component would be reversed as contra-development expense upon development work being abandoned prior to approval.

The premium component of the contingent settlement provision should be recognised at fair value as funding is received and disclosed as a contingent financial liability. The premium has to be recognised at the net present value as expense if uncertainty of the study results is resolved (in general after the finalisation of the study). Any liability recorded for the risk premium component would be reversed as contra-expense upon development work being abandoned prior to approval through the same line item that it was previously recorded.

R&D funding vehicles are a complex and judgmental area. Each structure should be evaluated on its specific facts and circumstances. The solutions 48-51 are not intended to provide any definitive rules, but rather illustrate some of the form and substance considerations that might arise.

51. Collaboration agreement to develop a drug - Separable arrangements

Background

Sargent and Chagall enter into a collaboration deal in which Sargent will pay Chagall for developing and manufacturing a new antibiotic originally discovered by Chagall. Sargent will have exclusive marketing rights to the antibiotic if it is approved. The contract terms require the following payments:

a. upfront payment of LC5 million on signing of the contract;
b. milestone payment of LC5 million on filing for phase III clinical trial approval;
c. milestone payment of LC7 million on securing final regulatory approval; and
d. LC11.5 per unit, which equals the estimated cost plus 15%, once commercial production begins.

The cost-plus 15% is consistent with Sargent's other recently negotiated supply arrangements for drugs with comparable manufacturing complexity.

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

The cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets [IAS 38.26].

How should Sargent account for collaboration agreements to develop a new drug compound?

Solution

There is no indication that the agreed prices for the various elements are not at fair value. In particular, the terms for product supply at cost plus 15% are consistent with Sargent's other supply arrangements. Therefore, Sargent should capitalise the upfront purchase of the compound and subsequent milestone payments as incurred, and consider impairment at each financial reporting date. Amortisation should begin once regulatory approval has been obtained. Costs for the products have to be accounted for as inventory and then expensed as costs of goods sold as incurred.

If the contract terms did not represent fair value, the payments would have to be allocated to the development and production supply components of the arrangement using fair value as the allocation key.

52. Exchange of listed shares for a patent

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. Buonarroti must recognise the patent in its balance sheet.

Relevant guidance

For equity-settled, share-based payment transactions, the entity shall measure 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, the entity shall measure their value by reference to the fair value of the equity instruments granted [IFRS 2.10].

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

Solution

Buonarroti should recognise the patent at its fair value. Thebest indicator of fair value is the publically traded price of the shares on the acquisition date.

The seller of the patent would record the shares received in exchange for the patent at their fair value at the date of exchange and record a gain/loss in the income statement for the sale of the patent.

53. Accounting for acquired early-stage projects

Background

Picasso Pharma has acquired a new drug compound, which is currently in phase I clinical development. Picasso has capitalised the costs for 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 shall be amortised on a systematic basis over its useful life. Amortisation shall begin when the asset is available for use in the manner intended by management [IAS 38.97].

How should Picasso amortise an intangible asset related to an acquired early-stage project when utilising the results for development of a drug other than the drug for which the project was originally acquired?

Solution

Picasso should not amortise the intangible asset subsequent to its acquisition, as 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 therapy.

54. Cost of collaboration arrangements

Background

Pollock Corp. and Vermeer enter into a collaboration arrangement. Pollock receives an upfront payment from Vermeer for an anti-infective product currently in development and subsequent milestone payments. Vermeer receives the right to sell the product and will pay Pollock a royalty share. The cost to market the product is borne by Vermeer.

Relevant guidance

The price 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 IAS 38.21(a) is always considered to be satisfied for separately acquired intangible assets [IAS 38.25].

How should the costs of collaboration agreements be accounted for?

Solution

Vermeer should capitalise the upfront and milestone payments as they represent a separately acquired intangible asset for in-process development. The development intangible must be assessed for any indication of impairment at each reporting date, based upon the progress of development, and tested for impairment annually as long as the asset is not available for use. Amortisation begins once the asset is available for use, which would be once the anti-infective has been given regulatory approval. The asset is amortised over the product's expected life.

Royalty payments to Pollock made after completion of the development should be recognised by Vermeer as cost of goods sold, as the sales of the drug are recognised.

In these arrangements, consideration must also be given as to whether the contractual payments all represent fair value. If Vermeer pays significant milestone premiums but pays a relatively smaller royalty, the fair values should be assessed and part of the milestone may need to be recognised as a prepaid royalty, as it potentially represents part of the royalty expense.

55. Production technology development expenditure

Background

Gauguin SA is developing a technology to enable production of its new bio-pharmaceutical vaccine. The technology to produce the vaccine will require FDA approval and has no alternative use. Gauguin incurs both technology development costs and validation costs leading up to the approval.

Relevant guidance

Development costs are capitalised as an intangible asset if all of the following criteria are met [IAS 38.57]:

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.

The cost of an item of property, plant and 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. 16].

Before any inventory produced using a new production method can be sold, relevant regulatory authorities must approve the production process. How should Gauguin account for the expenditures?

Solution

Consistent with its handling of the product development costs, Gauguin's management does not believe the production technology has achieved technological feasibility prior to filing for final regulatory approval. Accordingly, internal development costs for the production technology and validation prior to final filing are expensed. With filing for final regulatory approval, Gauguin has demonstrated the probability of the technology's approval and further product and technology development costs must be capitalised as intangible assets.

56. Bifurcating components of a collaboration agreement

Background

Monet Pharma acquires the marketing rights in certain territories for an AIDS product developed by Renoir. The collaboration includes the following terms:

a. upfront payment of LC20 million on signing of the contract
b. no milestone payments.

Supply of the product at LC80 per unit, where the estimated cost per unit is LC100.

Relevant guidance

The cost of inventories shall comprise all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition [IAS 2. 10].

Trade discounts, rebates and other similar items are deducted in determining the costs of purchasing inventory [IAS 2.10].

Normally, the price an entity pays to acquire separately an 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 is always satisfied for separately acquired intangible assets [IAS 38.25].

The cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets [IAS 38.26].

How should Monet account for collaboration agreements that contain several components?

Solution

Monet's management has to assess whether the agreed terms reflect the fair value of the components of this arrangement. In this case, the supply price does not cover the estimated costs, so the agreed amounts do not reflect fair value. As a result, Monet should estimate the fair values for the two components of the agreement. The fair value of product supply can be estimated at cost plus a profit margin consistent with the manufacturing complexity inherent in production of the drug. This should be multiplied by the expected supply amounts and a separate inventory prepayment should be recorded separately from the acquired marketing rights. The remaining upfront payment should be capitalised as an acquired marketing intangible by Monet and amortised over the expected life of the developed AIDS product.

57. Development loan – Market terms

Background

Warhol Inc. lends LC1 million to Lichtenstein Inc., a small biotech entity, for development of a new active substance. The loan agreement contains the usual market conditions for unsecured loans with significant credit risk and has to be paid back in five years. Lichtenstein has no material sources of cash in-flows other than those resulting from successful development of the substance. Warhol has no other relationships with Lichtenstein.

Relevant guidance

An asset is recognised in the balance sheet when it is probable that the future economic benefits will flow to the entity and the asset has a cost or value that can be measured reliably [Framework 4.44].

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market [IAS 39.9].

How should a lender account for development loans?

Solution

Warhol must recognise the fair value of the loan as a financial asset in accordance with IAS 32/39 and reassess the carrying value at each reporting date. The best evidence of fair value is normally the transaction price [IAS 39.43, AG64]. It is necessary to consider other relationships between Warhol and Lichtenstein when using the transaction price as fair value. The financial asset is classified as a loan and receivable asset, measured at amortised cost. The contractual interest and five year capital repayment dates mean that the loan has fixed or determinable payments.

Warhol should evaluate the loan at the end of each reporting period for impairment indicators. Specifically, the progress of Lichtenstein's development project may be an indication that Lichtenstein may be in financial difficulties [IAS 39.59].

Additionally, Warhol should evaluate whether the agreement conveys control over Lichtenstein. If so, Lichtenstein should be consolidated in Warhol's financial statements, causing the inter-company loan to be expensed as development expenditure as it is consumed, rather than as described above.

58. Sales target milestone with fair royalty

Background

Rembrandt Pharmaceuticals acquired the rights to sell an anti-obesity drug in the United Kingdom from Watteau Ltd. through a development agreement. The development agreement required Rembrandt to make several milestone payments to Watteau, including a LC25 million payment if cumulative sales of the anti-obesity drug reach LC250 million. A royalty payment schedule is also included in the agreement. The royalty payment rate represents fair value relative to comparable in-licensing arrangements.

Upon filing for regulatory approval, Rembrandt projects lifetime sales of the drug in the UK to be over LC500 million.

Relevant guidance

A provision shall be recognised when [IAS 37.14]:

a. an entity has a present obligation as a result of a past event;
b. it is probable that an outflow of resources will be required to settle the obligation; and
c. a reliable estimate can be made of the amount of the obligation.

How should Rembrandt account for milestone payments based upon the achievement of sales targets?

Solution

Because the agreement includes a market-rate royalty payment, the sales milestone is considered to be a contingent milestone for development services provided by Watteau. The payment should be accounted for as an increase to the product rights intangible asset. The entire sales target milestone must be accrued as a provision once achievement of the target is probable and the payment will be required to be made.

The milestone payment becomes probable and should be accrued when:

- *The product has been approved and there is a substantive track record of sales*
- *Rembrandt's current sales forecasts indicate that the sales milestone will be achieved within the foreseeable future.*

Consideration must be given as to whether the contractual payments represent fair value. If the relative weighting of the milestone payments indicates fair values that are clearly different from the actual payments, they should be allocated in accordance with that fair value weighting.

Note: *The obligation to make payments linked to future sales may give rise to a liability in accordance either with IAS 32/39 or IAS 37. The above analysis is predicated on existing accounting standards and industry practice at the date of this publication. This topic is being considered by the IFRS Interpretations Committee and could be effected by any additional guidance or amendments issued from the IFRS Interpretations Committee project.*

59. Annual sales target milestone with fair royalty

Background

Rembrandt Pharmaceuticals acquired the rights to sell an anti-obesity drug in the United Kingdom from Watteau Ltd. through a development agreement. The development agreement required Rembrandt to make several milestone payments to Watteau, including a LC25 million payment in any year that annual sales of the anti-obesity drug reach LC100 million. A royalty payment schedule is also included in the agreement. The royalty payment rate represents fair value relative to comparable in-licensing arrangements.

Upon filing for regulatory approval, Rembrandt forecasts that the lifetime sales of the drug in the UK will be more than LC500 million over the remaining 10-year patent life. The sales are expected to develop quickly after launch, and taper and then decline rateably with the introduction of generic competitor drugs. Based upon its forecasts at launch, Rembrandt's achievement of sales in excess of LC100 million in any year is considered unlikely.

Relevant guidance

A provision shall be recognised when [IAS 37.14]:

a. an entity has a present obligation as a result of a past event;
b. it is probable that an outflow of resources will be required to settle the obligation; and
c. a reliable estimate can be made of the amount of the obligation.

How should Rembrandt account for milestone payments based upon the achievement of sales targets?

Solution

Because the agreement includes a market-rate royalty payment, any sales milestone payment should be considered a contingent milestone for development services provided by Watteau. However, the sales milestone should be accrued only when achievement of the LC100 million sales level is probable. Based upon Watteau's forecasts upon launch, no sales milestones should be accrued.

If the forecasts develop favourably and the LC100 million annual sales level becomes probable, the provision should be accounted for as an increase to the product rights intangible asset. This assessment should be made for the current period and all future periods.

The milestone payment becomes probable and should be accrued when:

- *The product has been approved and there is a substantive track record of sales*
- *Rembrandt's current sales forecasts indicate that the sales milestone will be achieved within the foreseeable future.*

Consideration must be given as to whether the contractual payments represent fair value. If the relative weighting of the milestone payments indicate fair values clearly different from the actual payments, they should be allocated in accordance with that fair value weighting.

***Note:** The obligation to make payments linked to future sales may give rise to a liability in accordance either with IAS 32/39 or IAS 37. The above analysis is predicated on existing accounting standards and industry practice at the date of this publication. This topic is being considered by the IFRS Interpretations Committee and could be effected by any additional guidance or amendments issued from the IFRS Interpretations Committee project.*

60. Sales target milestone with below-market royalty

Background

Rembrandt Pharmaceuticals acquired the rights to sell an anti-obesity drug in the United Kingdom from Watteau Ltd. through a development agreement. The development agreement required Rembrandt to make several milestone payments to Watteau, including a LC25 million payment if cumulative sales of the anti-obesity drug reached LC250 million. While a royalty payment schedule is included in the agreement, the royalty payment rate is less than comparable in-licensing arrangements.

Upon filing for regulatory approval, Rembrandt projects that the lifetime sales of the drug in the UK will be over LC500 million.

Relevant guidance

A provision shall be recognised when [IAS 37.14]:

a. an entity has a present obligation as a result of a past event;
b. it is probable that an outflow of resources will be required to settle the obligation; and
c. a reliable estimate can be made of the amount of the obligation.

How should Rembrandt account for milestone payments based upon the achievement of sales targets?

Solution

The milestone serves as a proxy for sales royalties in this arrangement, as the sales royalty payments required by the arrangement are less than fair value. The milestone accrual should be recorded as a royalty expense if the income statement is presented by nature of expenses, or as cost of goods sold if presented by function.

As the sales milestone represents a royalty, sales of the product is the past event that would require its accrual. Once Rembrandt begins selling the drug, the forecast sales milestone should be accrued rateably over the initial LC250 million in sales, as Rembrandt expects to exceed the milestone target level.

Consideration must be given as to whether the contractual payments represent fair value. If the relative weighting of the milestone payments indicates fair values clearly different from the actual payments, they should be allocated in accordance with that fair value weighting.

***Note:** The obligation to make payments linked to future sales may give rise to a liability in accordance either with IAS 32/39 or IAS 37. The above analysis is predicated on existing accounting standards and industry practice at the date of this publication. This topic is being considered by the IFRS Interpretations Committee and could be effected by any additional guidance or amendments issued from the IFRS Interpretations Committee project.*

61. Sales target milestone with no royalty

Background

Rembrandt Pharmaceuticals acquired the rights to sell an anti-obesity drug in the United Kingdom from Watteau Ltd. through a development agreement. The development agreement required Rembrandt to make several milestone payments to Watteau, including a LC25 million payment if cumulative sales of the anti-obesity drug reached LC250 million. Contrary to other similar product acquisitions, the agreement does not require any royalty payments. Otherwise, each milestone payment represents fair value relative to the stage of development or marketing, based upon comparable in-licensing arrangements.

Upon filing for regulatory approval, Watteau forecasts that the lifetime sales of the drug in the UK will be over LC500 million.

Relevant guidance

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied [IAS 18.20]:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

Contingent assets are not recognised in financial statements, since this may result in the recognition of income that may never be realised. However, when the realisation of income is virtually certain, then the related asset is not a contingent asset and its recognition is appropriate [IAS 37.33].

How should Watteau account for milestone receipts based upon the achievement of sales targets?

Solution

Consideration must be given as to whether the contractual payments represent fair value. If the relative weighting of the milestone payments indicates fair values clearly different from the actual payments, they should be allocated in accordance with that fair value weighting. The absence of a royalty stream, where other comparable agreements contain them suggests the components of the arrangement may not be at fair value and that the sales milestone or an element of it serves as a proxy for royalties.

However, Watteau should not record any proportion of the sales milestone as royalty income until receipt is virtually certain. Accordingly, the sales milestone should be accrued only once cumulative sales reach LC250 million.

Rembrandt should account for the sales milestone as though it were an agreement with a below market royalty.

62. Validation costs

Background

Delacroix SA scrapped the first validation batch produced by its new plant because it did not meet predetermined 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 16.16]. 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 16.22].

How should Delacroix account for first validation batch?

Solution

Delacroix SA must expense the first validation batch as validation cost. This cost should be recorded as a component of R&D expense.

63. Impairment of development costs prior to use

Background

Dali Pharmaceuticals has capitalised external development costs as an intangible asset relating to a compound that has not been approved. Subsequently, Dali identified side effects associated with the compound that indicate its value is severely diminished and an impairment charge must be recognised.

Relevant guidance

In an income statement in which expenses are classified by nature, impairment is shown as a separate line item. By contrast, if expenses are classified by function, impairment is included in the function(s) to which it relates [IAS 1 .IG.5].

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. If presenting the income statement by nature of expense, Dali should classify the charge as an impairment charge.

64. 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

In an income statement in which expenses are classified by nature, impairment is shown as a separate line item. By contrast, if expenses are classified by function, impairment is included in the functional line items to which it relates [IAS 1 .IG.5].

Where should Dali classify impairment charges on development intangible assets which are currently marketed?

Solution

The reduction in economic value of a marketed product represented by impairment is similar economically to an accelerated consumption of economic benefits and is therefore best represented as an accelerated amortisation charge. Accordingly, 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. If presenting the income statement by nature of expense, Dali should classify the charge as an impairment charge.

65. Single market impairment accounting

Background

By way of a collaboration agreement, Veronese SpA acquired the rights to market a topical fungicide cream in Europe. The acquired rights apply broadly to the entire territory. For unknown reasons, patients in Greece prove far more likely to develop blisters from use of the cream, causing Veronese to withdraw the product from that country. As fungicide sales in Greece were not expected to be significant, loss of the territory, taken in isolation, does not cause the overall net present value from sales of the drug to be less than its carrying value.

Relevant guidance

An entity shall assess at each reporting date whether there is any indication that an asset may be impaired. If any such indication exists, the entity shall estimate the recoverable amount of the asset [IAS 36.9].

In assessing whether there is any indication that an asset may be impaired, an entity shall 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 36.12 (f)].

How should Veronese account for the rescission of a drug's marketing approval in a specific territory?

Solution

The cash-generating unit for the marketing right should be viewed as sales from Europe. Accordingly, withdrawal from one territory does not cause the asset's value in use to be less than its carrying value and no impairment loss should be recognised.

However, Veronese's management should carefully consider whether the blistering in one jurisdiction is indicative of potential problems in other territories. If the issue cannot be isolated, a broader impairment analysis should be performed, including the potential for more wide-ranging sales losses.

Additionally, if Veronese has capitalised any development costs specifically for achieving regulatory approval in Greece, these capitalised development costs must be written off with the withdrawal of the product from the territory.

66. Impairment of an acquired early - Stage project

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 shall be amortised on a systematic basis over its useful life. Amortisation shall begin when the asset is available for use in the manner intended by management [IAS 38.97].

An impairment loss shall be recognised on an intangible asset accounted for under the cost method, when the recoverable amount of the intangible asset is less than its carrying amount [IAS36.59]. The recoverable amount of an asset is the higher of its fair value less cost to sell and its value in use [IAS 36.18].

How should Seurat amortise an intangible asset related to an acquired early-stage project when utilising the results for development of a drug other than the drug for which the project was originally acquired?

Solution

Seurat should not start to amortise the intangible asset when it is acquired, as it is not ready for use. The poor results of the clinical trials indicate that the intangible asset may be impaired. Management must perform an impairment test on the intangible asset and may have to write it down to the higher of the compound's fair value less cost to sell or the value in use of the directly related technology.

Amortisation of any remaining carrying value of the intangible asset should occur over the estimated development period of Seurat's other drug, as the intangible is linked to the technology being used in the development of a new drug.

67. 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 recorded an impairment of the capitalised development intangible asset due to a reduction in the amounts it estimated that it could recover as a result of this rival drug. Subsequently, the competing drug was removed from the market because of safety concerns. The market share and forecast cash flows generated by Ruben's 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 shall not exceed its carrying amount adjusted for amortisation or depreciation had no impairment loss been recognised for the asset in prior years. That increase is a reversal of an impairment loss [IAS 36.114].

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 36.115].

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

Solution

The value in use calculation resulting in the impairment loss included an estimate of market share. An identifiable change in estimate exists and the previously recorded impairment should be reversed. Rubens should recalculate the value in use of the drug. 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.

68. 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. Although positive margins are forecast to continue, management identifies this as an indicator of impairment. Management may exit the market for this drug earlier than previously contemplated.

Relevant guidance

An entity shall assess at each reporting date whether there is any indication that an asset may be impaired. If so, the entity shall estimate the recoverable amount of the asset [IAS 36.9].

The recoverable amount is defined as the higher of an asset's fair value less costs to sell and its value in use [IAS36.18]. 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 36.19].

If there is an indication that an asset may be impaired, this may 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 36.17].

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

Solution

Fra Angelico must evaluate the carrying value of the antidepressant's cash-generating unit (including the production line) for impairment relative to its value in use resulting from sales of the antidepressant. Given the margin achieved on the remaining sales, the value in use exceeds the asset's carrying value and Fra Angelico determines that no impairment is required. However, Fra Angelico reduces the remaining useful life to the revised period over which sales are expected.

69. 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 do not forecast any significant sales once the patent expires.

Relevant guidance

The depreciable amount of an intangible asset with a finite useful life shall be allocated on a systematic basis over its useful life. The amortisation method used shall reflect the pattern in which the asset's future economic benefits are expected to be consumed [IAS38.97].

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 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 38.98].

The useful life of an intangible asset that arises from legal rights shall not exceed the period of the legal rights, but may be shorter depending on the period over which the entity expects to use the asset [IAS 38.94].

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

Solution

Raphael should 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. Use of the straight-line method reflects consumption of benefits available from the patent, which is based upon the passage of time. If the time over which the 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.

70. Amortisation life of development – Intangible assets

Background

Raphael & Co. has begun commercial production and marketing of an approved product. The production is done using a licensed technology that will be used in the production of other products for 20 years. The patent underlying the new product will expire in 10 years. An upfront payment for the 20 year license 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 shall be allocated on a systematic basis over its useful life. The amortisation method used shall reflect the pattern in which the asset's future economic benefits are expected to be consumed [IAS 38.97].

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 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 38.98].

The useful life of an intangible asset that arises from legal rights shall not exceed the period of the legal rights, but may be shorter depending on the period over which the entity expects to use the asset [IAS 38.94].

What is the appropriate method of amortising the capitalised costs?

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 upon 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.

71. 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 as an intangible asset. Amortisation of the development costs is being recorded 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 may also warrant the inclusion of other amounts, such as distribution costs [IAS 2.38].

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 2.39]. Under the function of expenses income statement, the costs are recognised as part of costs of goods sold.

The function of expense or 'cost of sales' method classifies expenses according to their function as part of cost of sales or, for example, the costs of distribution or administrative activities. At a minimum, an entity discloses its cost of sales under this method separately from other expenses [IAS 1.103].

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

Solution

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

72. 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 is released to production based upon orders from the manufacturing and development departments.

Relevant guidance

Inventories are assets that are [IAS 2.6]:

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. When the material is consumed in the production of sample products, the material should be accounted for as a marketing expense at the point where it is packaged for use as a sample. When the material is released to production for use in manufacturing of drugs in development, the material should be accounted for consistently with the treatment of other R&D expense related to the product.

73. Pre-launch inventory produced before filing

Background

Van Eyck Ltd. has an asthma drug in development. Management has determined that the drug has not yet met the criteria in IAS 38.57 to allow capitalisation of development costs. Management believes there is a 40% likelihood that development will succeed and filing for final regulatory approval will occur in the near term. Although approval is not yet probable, 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 filing for final regulatory approval and continues after the filing.

Relevant guidance

Inventories are assets that are [IAS 2.6]:

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 2.28].

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 2.33].

What is the carrying amount of pre-launch inventory?

Solution

Consistent with its handling of development costs, Van Eyck's management does not believe the asthma drug has achieved technological feasibility prior to filing for final regulatory approval.

Accordingly, inventory manufactured prior to this filing is immediately provided for and written down to zero, the probable amount expected to be realised from its sale at the time of production. The write-down should be recorded in cost of goods sold or as R&D expense according to their policy.

With the filing for final regulatory approval, Van Eyck has demonstrated the probability of the technological feasibility of the drug and begins to capitalise the inventory costs. The provision recorded prior to filing should also be reversed, up to no more than the original cost. The reversal should also be recorded through cost of goods sold.

74. Treatment of inventory of 'in-development' drugs

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 gets scientific regulatory approval. The doses cannot be used for any other purpose. Management is considering whether the doses should be recorded as inventory.

Relevant guidance

Inventories are assets that are [IAS 2.6]:

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 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.

75. 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 the generic version was the chemical equivalent of the original drug and that economic benefits were probable. Deeming that it had met the recognition criteria of IAS 38.57, it therefore began to capitalise development costs in May 20X3.

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

Relevant guidance

Inventories are assets that are [IAS2.6]:

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

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

Solution

Pre-launch inventory should be recorded as inventory at the lower of its cost or net realisable value. Management's conclusion to capitalise development costs is an indication that the generic drug is economically viable and therefore the cost of the pre-launch inventory costs will be realised through future sales.

The marketing approval for after year-end is a subsequent event that confirms that management's year end assessment.

76. Net costs of validation batches sold

Background

Durer Pharma produces sample products for validation of a new oncology production line at a cost of LC 100,000. Based upon the sample production run, Durer receives regulatory approval for the production line and plans to sell the validation batch for LC 75,000.

Relevant guidance

Examples of directly attributable costs to be capitalised as property, plant and equipment are costs of testing whether the asset is functioning properly, after deducting the net proceeds from selling any items produced while bringing the asset to that location and condition (such as samples produced when testing equipment) [IAS 16.17(e)].

How should Durer treat costs to produce product used to validate a plant if the product can subsequently be sold?

Solution

Durer Pharma should capitalise the LC 25,000 net cost of the validation batch (cost of LC 100,000 less net selling price of validation batch of LC 75,000) as PPE. The remaining LC 75,000 should be capitalised as inventory and expensed when the batch is sold.

77. Net gain on sale of validation batches sold

Background

Durer Pharma produces sample products for validation of a new oncology production line at a cost of LC100,000. Based upon the sample production run, Durer receives regulatory approval for the production line and plans to sell the validation batch for LC150,000.

Relevant guidance

Examples of directly attributable costs to be capitalised as property, plant and equipment are costs of testing whether the asset is functioning properly, after deducting the net proceeds from selling any items produced while bringing the asset to that location and condition (such as samples produced when testing equipment) [IAS 16.17(e)].

How should Durer treat costs to produce product used to validate a plant if the product can subsequently be sold?

Solution

Once earned, Durer's net gain of LC 50,000 relating to PPE validation should be accounted for as a reduction of the cost of the oncology production line.

78. 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 2.2].

A 'biological asset' is a living animal or plant [IAS 41.5].

A biological asset shall be measured on initial recognition and at each balance sheet date at its fair value less estimated point-of-sale costs [IAS 41.12].

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

Solution

Caravaggio should account for its production of vaccine cultures at cost as a component of inventories, following the guidance of IAS 2. A virus is not a living plant or animal and is therefore outside the scope of IAS 41.

79. 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 three years. Simba will have to keep the technology updated and in accordance with Regal's requirements only during this three- year period. Simba obtains a non-refundable upfront payment of LC3 million for access to the technology. Simba will also receive a royalty of 20% from sales of the AIDS compound, if Regal successfully develops a marketable drug.

The 20% royalty is in line with other comparable royalty arrangements entered into by Regal.

Relevant guidance

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied [IAS 18.20]:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

When services are performed by an indeterminate number of acts over a specific period of time, revenue is recognised on a straight-line basis over the specific period, unless there is evidence that some other method better represents the stage of completion. When a specific act is more significant than any other acts, the recognition of revenue is postponed until the significant act is executed [IAS 18.25].

How should Simba account for a non-refundable up-front fee received for licensing out its know-how and technology to a third party??

Solution

Simba's management should recognise the non-refundable upfront fee received over a straight-line basis of three years. The LC3 million upfront fee is a service fee for granting a third party access to its technology and to keep it updated in accordance with its requirements for a period of three years. This is the case even if the technology maintenance requirements are not expected to be significant.

Management should recognise the royalty receipts as revenue when earned. If it is material to Simba's financial statements, the royalty should be presented as a separate class of revenue.

80. Receipts for conducting development

Background

Cezanne, a pharmaceutical research company, contracts with Botticelli to develop a new medical treatment for asthma over a five-year period. Cezanne is engaged only to provide development services and will periodically have to update Botticelli on the results of its work. Botticelli has exclusive rights over the development results. Botticelli will make five annual payments of LC1 million (totalling LC5 million). Half the money is non-refundable, and half is refundable if the new drug does not obtain regulatory approval. Cezanne's management estimates that the total costs will be LC4 million, and that it will incur those costs equally over the development period, i.e. LC0.8 million per annum.

After year three, the project is going well. Cezanne has spent LC2.4 million and has received the first three instalments totalling LC3 million from Botticelli.

After year four, the project is still on track. Cezanne has spent LC3.2 million and has received four instalments totalling LC4 million from Botticelli. Whether the product will obtain regulatory approval is still uncertain.

Relevant guidance

An entity shall recognise revenue from a transaction associated with the rendering of services, when the outcome of the transaction can be reliably estimated. This is the case when all of the following conditions are satisfied [IAS 18.20]:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

How should a Cezanne recognise revenue for contract development, if the payments received are partially refundable?

Solution

Cezanne could make a loss of LC1.5 million (costs of LC4.0 million offset by revenues of LC2.5 million) if regulatory approval is not received. The contract is not onerous when it is signed, even though achievement of regulatory approval cannot be considered highly probable at that point. A loss should not be recorded as an onerous contract liability until is apparent that Cezanne is committed to incur the loss and results indicate the development will fail. The risks of success and failure are generally factored into price negotiations such that at the outset of a contract the expected revenues, on a weighted average probability basis, exceed the expected costs of fulfilling the contract [IAS 37.10].

For the cumulative years one-three, Cezanne should recognise costs of LC2.4 million, revenue of LC1.5 million (percentage of completion times the non-refundable portion of the payments). The cash received in excess of recognised revenue of LC1.5 million (LC1 million per year for three years less LC1.5 million in cumulative revenue) must be deferred, as revenue can only be recognised to the extent that it is probable the earnings process has been completed.

In year four, Cezanne should recognise the costs incurred of LC0.8 million as expenses, revenue of LC0.5 million. LC0.5 million of cash received in year 4, in excess of the recognised revenue should be deferred, as obtaining regulatory approval is not yet probable.

Under this basic pattern, Cezanne will realise the remaining deferred revenue (LC2.5 million) only when regulatory approval is probable. Continuing involvement in the compound through complex collaboration or co-promotion arrangements might well cause further deferral over the arrangement terms.

81. Revenue from collaboration arrangements

Background

Pollock Corp. and Vermeer enter into a collaboration arrangement. Pollock receives a non-refundable up-front payment for an anti-infective product it has created and which is currently in development by Pollock Corp. The agreement also allows Pollock to receive non-refundable, success-based milestone payments for further development. In return for these payments, Vermeer will receive the exclusive right to sell the product and will pay Pollock a royalty on future sales. The cost to market the product is borne by Vermeer.

Relevant guidance

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction shall be recognised by reference to the stage of completion of the transaction at the balance sheet date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied [IAS1 8.20]:

a. the amount of revenue can be measured reliably;
b. it is probable that the economic benefits associated with the transaction will flow to the entity;
c. the stage of completion of the transaction at the balance sheet date can be measured reliably; and
d. the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

How should receipts from collaboration arrangements be accounted for?

Solution

Recognition of the collaboration receipts as revenue depends on whether a service has been performed in relation to the amount received. The upfront payment received by Pollock needs to be deferred and recognised over the estimated development period, as no substantive earnings process has occurred between the agreement date and the payment date.

Generally, the other receipts for achievement of milestones for completion of discrete stages should be recognised as revenue when the milestone is achieved. Royalties on the marketed drug should be recognised as royalty revenue as Vermeer makes sales of the product, assuming sufficient information exists to make a reliable estimate of the revenues.

In these arrangements, consideration must also be given as to whether the contractual payments all represent fair value. If Pollock receives significant milestone premiums and a relatively smaller royalty, the fair values should be assessed, as part of the milestone may need to be deferred since it potentially represents part of the royalty income stream. Further, sub-milestones (such as significant payments signing the first participant in a Phase III study) should be evaluated as to whether the payments represent fair value. In most cases, such sub-milestones should be deferred over the expected phases of the respective development stage.

82. 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 based on 'click-through' to its Alzheimer's site. How should the marketing campaign costs incurred be treated in its December 20X4 financial statements?

Relevant guidance

In some cases, expenditure is incurred to provide future economic benefits, but no asset is acquired or created. In these cases, 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 38.69].

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

Solution

Advertising and promotional expenditure should be treated as an expense when incurred. 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 first airs in 20X5. Costs for hits to the company's internet site should be expensed based upon the click-through rate in 20X5.

83. 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. Additionally, Goya runs a special promotion where hospitals get 13 tablets for the price of 12.

Relevant guidance

An entity may classify expenses according to nature or function/cost of sales methods [IAS 1.102 and IAS 1.103]. Functions are defined as cost of sales, distribution activities or administrative activities [IAS 1.103].

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

Solution

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

The cost of the incremental 13th tablet sold under the special promotion should be classified as cost of goods sold rather than marketing expense, as it is related to the overall sales transaction and is not a free sample.

84. 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 that Mondrian pay Matisse 25% of net sales in the US for its marketing efforts. The agreement is material to both parties.

Relevant guidance

When items of income and expense are material, their nature and amount shall be disclosed separately [IAS 1.97]. An entity shall present an analysis of expenses recognised in profit and loss using a classification based on either the nature or function within the entity, whichever provides information that is reliable and more relevant [IAS 1.99].

How should Mondrian classify co-promotion payments and receipts?

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.

Matisse should classify the co-promotion receipts as a separate class of revenues if they are material.

85. Presentation of development supplies

Background

Warhol Inc. is developing a new ingredient for a specific drug. It uses several different raw materials in development which have no alternative future use. These supplies are stored directly in the development facilities and are not recorded in inventories.

Relevant guidance

An asset is recognised by the entity when it is probable that the future economic benefits will flow to the entity and the asset has a cost or value that can be measured reliably [Framework 4.44].

Inventories are assets [IAS 2.6]:

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.

Where should supplies acquired for use in development activities be classified in the balance sheet?

Solution

Supplies acquired for use in development activities do not meet the definition of inventory as they will not be utilised directly to generate revenue and should not be classified as such. Rather, development supplies should be capitalised as a prepaid asset or as another asset (normally current). As the supplies are consumed in development activities, they should be expensed or otherwise capitalised in the development intangible asset, depending upon the status of the project.

86. Business versus asset

Background

Atom Inc is interested in a single compound A of another company Bark Corp. Bark Corp puts compound A, which is currently in Phase II, 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 (e.g. development equipment) put into NewCo. Atom Inc acquires a 75% interest in NewCo, which gives Atom Inc control over NewCo and compound A. Atom Inc will provide the scientists, equipment and financial support to develop compound A through regulatory approval.

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.B7-B12].

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

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

Solution

Any transaction in which an entity obtains control of one or more businesses qualifies as a business combination and is subject to the measurement and recognition requirements of IFRS 3. Processes are included in the acquired group when intellectual property is accompanied by blue prints, plans, protocols or employees, such as a team of scientists, researchers or labour force that will further develop the IP to the next phase or prepare the IP for approval by a regulatory body. It is irrelevant whether or not a legal entity is involved in the 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. The legal form of the transaction does not determine the accounting treatment. Here, the acquisition of an interest in NewCo is an asset acquisition and should be accounted for under IAS 38 because NewCo does not meet the definition of a business.

87. Pay-for-performance arrangements – Benchmarking

Background

The Umbrella Insurance Company and Rembrandt Pharmaceuticals put into place a reimbursement scheme in Territory X for treatment of Alzheimer's with Rembrandts newly developed and approved product. Umbrella Insurance Company will only pay for the treatment in Territory X for those patients in which Rembrandt's product is shown to be effective in Alzheimer's patients under the scheme. Umbrella Insurance has reviewed clinical data to establish the effectiveness of Rembrandts medicine as compared to its competitors. The two parties have agreed to use a benchmarking pricing model for reimbursements based on Umbrellas review.

Relevant guidance

Revenue from the sale of goods shall be recognised when all the following conditions have been satisfied [IAS 18.14]:

a. the entity has transferred to the buyer the significant risks and rewards of ownership of the goods;
b. the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
c. the amount of revenue can be measured reliably;
d. it is probable that the economic benefits associated with the transaction will flow to the entity; and
e. the costs incurred or to be incurred in respect of the transaction can be measured reliably.

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

Solution

Umbrella Insurance and Rembrandt Pharmaceuticals are utilizing a benchmarking pricing model. The reimbursement pricing model has been established up-front based on Umbrella Insurance's review of clinical data with currently available medicines and other treatments. The clinical data review provides a measure of effectiveness and reasonable basis to measure revenue. Rembrandt has no access to the risks and rewards of the medicine and has no further involvement once it has been delivered to the patient. The costs of the medicine are known by Rembrandt. Therefore, assuming the product is shipped in Territory X subject to standard terms and conditions, revenue could be recognised upon delivery to the patient.

88. Pay-for-performance arrangements – Outcome based with floor

Background

The Umbrella Insurance Company and Rembrandt Pharmaceuticals put into place a reimbursement scheme in Territory X for treatment of Alzheimer's with Rembrandts newly developed and approved product. Under the scheme Umbrella Insurance Company will only pay for the product based on a 'floor' price. Umbrella will pay an agreed premium once outcomes data becomes available and proves Rembrandt's product is effectively slowing down the progression of Alzheimer's in patients.

Rembrandts product will be held on consignment in clinics treating Alzheimer's patients.

Relevant guidance

Revenue from the sale of goods shall be recognised when all the following conditions have been satisfied [IAS 18.14]:

a. the entity has transferred to the buyer the significant risks and rewards of ownership of the goods;
b. the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
c. the amount of revenue can be measured reliably;
d. it is probable that the economic benefits associated with the transaction will flow to the entity; and
e. the costs incurred or to be incurred in respect of the transaction can be measured reliably.

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

Solution

Umbrella Insurance and Rembrandt Pharmaceuticals are utilizing an outcome-based performance model. The outcome at the inception of this arrangement is unknown; however the agreement between Rembrandt and Umbrella Insurance includes a floor pricing mechanism which is not refundable. Therefore revenue would be recognised upon sale of the product as the floor mechanism provides a reliable measurement of revenue.

The premium would only be recognised once the sufficient record of outcomes have been achieved and agreed with Umbrella Insurance.

89. Pay-for-performance arrangements – Outcome based

Background

The Umbrella Insurance Company and Rembrandt Pharmaceuticals put into place a reimbursement scheme in Territory X for treatment of Alzheimer's with Rembrandts newly developed and approved product. Umbrella Insurance Company will only pay for the treatment in Territory X for those patients in which Rembrandt's product is shown to effectively slow down the progression of Alzheimer's in patients under the scheme. Rembrandts product will be held on consignment in clinics treating Alzheimer's patients and only paid for once it is shown to have achieved the required outcome.

Relevant guidance

Revenue from the sale of goods shall be recognised when all the following conditions have been satisfied [IAS 18.14]:

a. the entity has transferred to the buyer the significant risks and rewards of ownership of the goods;
b. the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
c. the amount of revenue can be measured reliably;
d. it is probable that the economic benefits associated with the transaction will flow to the entity; and
e. the costs incurred or to be incurred in respect of the transaction can be measured reliably.

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

Solution

Umbrella Insurance and Rembrandt Pharmaceuticals are utilizing an outcome-based performance model. The outcome at the inception of this arrangement is unknown. Rembrandts product has already been subject to clinical trials during the approval process, but the patient population used in the clinical trials is different to the population in Territory X. Revenue would not be recognised because a reliable record of outcomes has not been established and therefore revenue should be deferred.

Over time it is expected that Rembrandt will be able to build a sufficient record of outcomes such that a level of refunds / premiums can be estimated. It would be appropriate to recognise revenue subject to an allowance for refunds once Rembrandt is able to demonstrate that a stable and predictable level of refunds can be reliably estimated and the other criteria for revenue recognition are met,.

90. Revenue recognition to customers with a history of long delays in payment

Background

Tiepolo Pharma sells to a governmental entity in a country in Southern Europe. Tiepolo Pharma have historically experienced long delays in payment for sales to this entity due to slow economic growth and high debt levels in the country. The receivables are non-interest bearing. Tiepolo Pharma currently has outstanding receivables from sales to this entity over the last 3 years and continues to sell product at its normal market price.

Relevant guidance

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

a. the amount of revenue can be measured reliably; and
b. it is probable that the economic benefits associated with the transaction will flow to the entity.

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

Solution

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

Price pressure, discounts, caps and clawbacks that may be demanded by governments should be considered. An estimate of discounts and similar allowances, that will be granted in the future, based on current market conditions and practice, should be deducted from the amount recognised as revenue. Revenue should not be recognised if payment is not expected or the amount of discounts and allowances are expected to be material but cannot be estimated. Revenue is reduced by any discount recorded at initial recognition expected for slow payment and for expected allowances and discounts. Tiepolo's management might immediately factor receivables at a discount from face value. A company using this practice should estimate the discount when sales are made and reduce the amount of revenue recognised. The price received from the factor is likely to be a reasonable proxy for expected discounts, allowances and credit risk when receivables are factored immediately.

Any receivables that are not expected to be collected immediately should be considered for discounting. There is no 'grace period' in the revenue standard for receivables that are collected within one year or any other specific period. Accounts receivable should be discounted at initial recognition, with a consequential reduction in revenue, if the effect of discounting is expected to be material.

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

Estimating the date of collection should use the most recent data available about days sales outstanding for the relevant governmental body although care should be used relying on payment history if conditions are seen to be deteriorating. While history may be an indicator, the current environment history may not be a reliable indicator of the future and all relevant facts will need to be assessed to formulate a judgment of the potential outcome.

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

Tiepolo's management should determine if additional financial statement disclosure is necessary surrounding concentration of risk. This may include: (i) volume of business transacted in a particular market or geographic area; (ii) impact on liquidity; and (iii) discussion of counterpart default risk. Tiepolo's management should consider qualitative factors in deciding whether its exposure to Southern Europe sovereign government is material. The public attention to the Eurozone sovereign crisis is a strong indicator disclosure is material.

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120621-165729-MV-OS