THE APPLICATION OF AC 122 TO RESEARCH AND DEVELOPMENT, IN THE PHARMACEUTICAL INDUSTRY:

CONCEPTUAL ISSUES AND IMPLEMENTATATION CONCERNS

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I certify that this report is my own work and all references used are accurately reported.

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ABSTRACT

Research and development spending has become increasingly important over the last two decades. Despite this, the South African business community has largely ignored the South African accounting standard for research and development costs, AC 122, issued in 1994. A review of the comments received from a number of respondents to the exposure draft to AC 122 and it's international equivalent, IAS 9 (revised), suggests that the implementation difficulties associated with AC 122 are the major reason for the apparent lack of acceptance of AC 122 by the local accounting profession and industry. This research attempts to identify these implementation concerns, specifically in relation to the pharmaceutical industry, so as to provide guidance for implementing AC 122 in this industry.

From an analysis performed of AC 122 and the responses of a number of members of the local and global business community, three main implementation problems associated with AC 122 were identified. These are (a) the appropriate allocation of R & D costs between research costs and development costs, (b) implementing the requirement to capitalise development costs, and (c) determining the most appropriate method and time period for amortising a development asset. The identification of these problems also highlighted that AC 122 is deficient in implementation guidance and requires the exercise of an unusually high level of subjective judgement.

This study illustrates that it is possible to develop guidelines for overcoming the problems identified in the pharmaceutical industry. This research also provides an approach for similar research in other R & D intensive industries. However, the time and cost of performing such an exercise is likely to limit the industry approach to accounting for R & D costs.

The research led to the conclusion that the accounting standard for research and development costs in South Africa is difficult to apply consistently in practice, and requires amendment if it is to obtain the support of the accountancy profession and commerce.

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GLOSSARY

APC	Accounting Practices Committee (SA)
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration (US)
FRS	Financial Reporting Standard
HMO	Health Maintenance Organisation
IASC	International Accounting Standards Committee
IAS	International Accounting Standard
ICAEW	Institute of Chartered Accountants in England and Wales
MCC	Medicines Control Council
PBM	Prescription Benefit Management
R & D	Research and Development
SA	South Africa
SAICA	South African Institute of Chartered Accountants
SFAS	Statement of Financial Accounting Standards
SSAP	Statements of Standard Accounting Practice
UNESCO	United Nations Educational, Scientific, and Cultural Organisation

1. INTRODUCTION

1.1 Increasing importance of Research and Development

Over the last few decades a world wide trend has emerged of rapidly increased investment in research and development activities. An examination of UNESCO's 1990 to 1996 annual statistical yearbooks revealed significant increases in both the magnitude of R & D activity and the number of scientists, engineers and technicians engaged in R & D activities. UNESCO'S definition of research includes fundamental and applied research, the latter being directed toward a specific research aim whereas the former has no immediate practical purpose. Tables 1 and 2 set out the figures for a number of countries, collected from replies to annual statistical questionnaires sent to member states of UNESCO. The survey is not conducted for each member country in every year, and therefore the results for the most recent 3 years were extracted.

Table 1 – Expenditure on R & D by country

COUNTRY - Millions			
Canada $	8 658 (1988)	10 289 (1992)	11 649 (1994)
United States $	88 085 (1983)	139 255 (1988)	171 000 (1995)
Japan (Yen)	9 837 (1987)	10 628 (1988)	13 772 (1991)
U.K. (Pound)	11 532 (1989)	11 906 (1991)	13 829 (1993)
Australia $	3 546 (1987)	4 187 (1988)	5 088 (1990)

The first four countries in the table were selected because of their significance in global markets. Australia was selected to indicate that even the less significant global players have increased their R & D activity significantly. The measure of R & D expenditure is calculated on the basis of intramural[1] expenditure, including current expenditure, overheads and intramural capital expenditure.

[1] Intramural expenditure is defined as expenditure conducted within the borders of the respective countries.

Over the six years ended 1994 Canada's R & D nominal expenditure increased by 35 %. Over the most recently recorded four year period for Japan and the UK, R & D nominal expenditure grew by 40 % & 20 % respectively. Australian R & D activity increased by 44% in the 3 year period ended 1990 and total R & D expenditure in nominal terms in the US increased by 94 % over the 12 year period ended 1995.

Table 2 - Number of personnel involved in R & D activity

COUNTRY				Compound annual increase
Canada	84 190 (1987)	88 210 (1988)	92 870 (1991)	2,5 %
United States	728 600 (1983)	806 200 (1987)	949 200 (1988)	5,5 %
Japan	628 686 (1984)	717 804 (1988)	813 360 (1992)	3,4 %
Australia	36 215 (1981)	51 565 (1987)	57 759 (1990)	5,3 %

The above statistics set out the number of full time equivalent scientists, engineers and technicians engaged in professional work on R & D and is consistent with the increases in R & D expenditure evident from Table 1. The compound annual increase has been calculated over the period spanning the first and last reference years. The US statistics only include scientists and engineers. The data was only made available for the United Kingdom for the 1993 survey and accordingly the increase for the UK could not be examined. The above statistics illustrate the emphasis that major first world countries are currently placing on investment in R & D.

"As world markets metamorphise ever more rapidly, R & D spending is universally recognised as a 'good thing', without which a modern industrial economy cannot hope to keep pace with its international competitors" (Rogerson; 1996).

1.2 The research problem

1.2.1 Lack of global uniformity in accounting for R & D

Despite the increase in importance of research and development spending, the accounting standard bodies around the world have failed to develop an accounting standard that has achieved universal acceptance. Significant differences exist between countries on the matter of accounting for R & D costs. The SAICA, the IASC, the New Zealand Society of Accountants and the Canadian Institute prescribe capitalisation of development costs if certain requirements are met. The Japanese, UK, Australian and French accounting bodies promote optional capitalisation whereas the US and German bodies prohibit the capitalisation of R & D costs (Nix & Nix; 1992). The different approaches that have been adopted by the various countries are indicative of the complexities that flow from accounting for R & D costs.

The central issue in accounting for research and development costs is whether such costs should be recognised as an expense in the year incurred, or recognised as an asset and deferred for amortisation in future periods.

1.2.2 Non-compliance with AC 122

The South African accounting standard for research and development costs, AC 122, was issued in 1994, following the revision by the International Accounting Standards Committee of its accounting standard for R & D costs, IAS 9 (revised). Prior to ED 87, the SA exposure draft to AC 122, no guidance existed in South Africa for accounting for R & D costs. A review of the 1993 annual financial statements of a number of South African companies indicates that they tended to adopt the prudent approach of writing off these costs as incurred. This is the rule for R & D costs in the US as determined by the FASB in SFAS 2 (1974) and reflects the practice of most companies that incur such costs (Cairns; 1997: 61).

A recent survey by Nixon (1997: 271) of the accounting treatment of UK companies for R & D, revealed that 81 % of the 106 respondents write off all R & D expenditure immediately, despite the optional capitalisation of development costs permitted by SSAP 13 (revised). Similarly, a survey conducted of the R & D accounting policy in the 1996 financial statements of thirty[2] listed South African companies indicated that the majority of companies that perform R & D are still writing off R & D costs as and when incurred (De Waal; 1997: 37). The companies surveyed were selected on a random basis from the industrial sector and include one parastatal. Twenty of the thirty companies surveyed adopted an accounting policy for research and development costs of writing off these costs as and when incurred. The remaining 10 companies' policy is to write off both research and development costs in the year in which incurred, unless the development costs are expected to result in future benefits - thus complying with AC 122. If an expectation of future benefits exists, the development costs are capitalised. In spite of their declared policy, not one of the 10 companies appears to have any deferred development costs on their balance sheet. It is conceivable that some of the companies have included the capitalised development costs in the cost of their fixed assets. This is however not apparent from any of the fixed asset reconciliation's in the notes to the financial statements.

It is not clear from the stated accounting policies of the 30 financial statements reviewed if the lack of application of the capitalisation requirement for development costs is because the conditions for capitalisation are not met or if for other reasons.

Nor is it clear why the 10 companies surveyed have adopted a policy in accordance with AC 122, but have failed to implement the requirements of the standard. The following reasons may be offered for this phenomenon:

- The 10 companies may have adopted the policy so as to appear to be complying with GAAP (even though they clearly are not doing so).
- The companies may be encountering significant practical difficulty in implementing AC 122.

[2] Appendix A lists the 30 companies surveyed by the author in July 1997.

- The selection of the capitalisation policy now may be to avoid all the complications of effecting a change in policy if the companies concerned should decide to capitalise development costs in the future.
- The companies do not have development costs that qualify as an asset according to AC 122, and thus are writing off these costs as and when incurred.
- The magnitude of development expenditure is immaterial to the operations of the company.
- The company officials believe that the capitalisation of development costs will attract significant resistance from their auditors, delaying the audit process.

In the comment letters received to E 37 and ED 87, the exposure drafts preceding IAS 9 (revised) and AC 122 respectively, many respondents expressed concern regarding the practical difficulties of implementing the accounting standard for R & D costs. Commonly quoted difficulties included the interpretation and demonstration of the "technical feasibility" criterion, and how to separate research costs from development costs. None of the other reasons suggested above were strongly supported by respondents to E 37 and ED 87, and accordingly the emphasis of this study is on the difficulties associated with the implementation of AC 122. Because of the similarities that exist between IAS 9 (revised) and AC 122, it is probable that the difficulties of implementing IAS 9 (revised) will be common to implementing AC 122. Therefore the comment letters received to E 37 will be evaluated to identify the problems associated with the implementation of AC 122 and IAS 9.

1.3 Statement of the research problem

What are the conceptual and practical issues hindering the implementation of IAS 9 (revised) and AC 122 experienced by preparers of financial statements?

When implementing AC 122 / IAS 9 (revised) three main considerations emerge. Firstly, the costs to be included in the cost category, 'Research and Development

costs", should include only costs directly attributable to R & D activities and those that can be allocated to R & D on a reasonable basis.

The second consideration is the correct accounting treatment for development costs. Development costs should be accounted for either as an expense, or as an asset, or apportioned between an expense and an asset. The method of accounting selected for development costs depends on whether the costs are measurable and will probably result in future economic benefits.

Finally, if the criteria for capitalising development costs are satisfied, an appropriate method and time frame for amortising the development asset must be determined.

As a result of the considerations the research problem is best investigated with reference to the following sub-problems:

- the allocation of R & D costs,
- the capitalisation of development costs, and
- the appropriate amortisation of the development asset.

1.3.1 Objectives of the study

The research consists of a literature review and a case study approach to the problem. The objectives of the research study are to:

Undertake a literature search in order to:

- present a background to the different alternatives that exist for accounting for research and development costs; and
- identify the main reasons for the prevailing lack of application of the capitalisation requirement of AC 122.

Conduct an exploratory case study in order to:

- obtain an understanding of research and development activity in the pharmaceutical industry. The pharmaceutical industry has been selected

(a) because of the magnitude of R & D activity in this industry; and (b) because the complexity of R & D activity in this industry is of such a nature that the study should identify the major difficulties associated with the implementation of AC 122.

- identify the problems associated with the implementation of AC 122 in the pharmaceutical industry; and
- attempt to develop industry specific guidelines to assist with the implementation of the accounting standard for research and development costs in the pharmaceutical industry.

1.3.2 Research questions

In pursuing the research aims, the study will attempt to determine the following:

- What are the conceptual and practical concerns associated with the implementation of AC 122; specifically with reference to the sub-problems identified in section 1.3?
- What are the conceptual and practical concerns associated with the implementation of AC 122 in the pharmaceutical industry, given the nature of R & D activity in that industry?
- What industry specific guidelines can be developed to assist with the consistent implementation of AC 122 in the South African pharmaceutical industry?

1.4 Limitations to the study

The scope of the study is limited by the following constraints:

1.4.1 The requirements of AC 122 have applied in South Africa for all companies with financial periods commencing after 1 January 1994. Since then very few South African based companies have implemented the capitalisation requirements of AC 122. Accordingly most South African companies have not attempted to deal with the accounting implications thereof.

1.4.2 A contractual agreement (Appendix C) with the case study company has indicated their willingness to disclose all confidential information necessary to assist them in complying with the standard, but the sensitive nature of much of the data will restrict its availability for public scrutiny. Notwithstanding , the trends evident from this data are sufficient for a study of the problems in the pharmaceutical industry, and the approach taken should still prove useful to interested parties.

1.5 Thesis organisation

The study will be presented in the following order:

Chapter two: Accounting for R & D costs

The origin, detail and requirements of AC 122 are presented in this chapter to provide a background to the subject matter.

Chapter three: Literature review

In this chapter the literature is reviewed and alternatives to accounting for research and development costs discussed. This sets the background within which the study continues. The attitudes to accounting for research and development of various groups of people are investigated as the basis for identifying the problems associated with the implementation of AC 122 and IAS 9 (revised).

Chapter four: The pharmaceutical industry

This chapter describes the nature and characteristics of the pharmaceutical industry with specific emphasis on research and development activity. It identifies the specific problems that may arise in the implementation of AC 122 in this industry and the context within which these problems should be analysed.

Chapter five: Research Methodology

The chapter describes the methodological approach employed to address the research questions. The design of the methodology is also discussed.

Chapter six: The allocation of R & D costs

Chapter six identifies the cost allocation problems associated with the implementation of AC 122 in the pharmaceutical industry. Current methods used by the case study company are described. Recommendations are made for overcoming the identified problems, so as to comply with AC 122.

Chapter seven: Capitalisation of development costs

This chapter focuses on the difficulties associated with implementing the capitalisation criteria of AC 122 in the pharmaceutical industry. The results of the interviews with employees of the case study firm are presented where applicable to the problem. The typical life cycle of research and development activity in the pharmaceutical industry is presented and analysed. Finally, guidelines are recommended for implementing the capitalisation criteria of AC 122 in the pharmaceutical industry.

Chapter eight: Amortisation of the development asset

In chapter eight the problem of how to amortise development costs in the pharmaceutical industry is presented. The observations made are discussed, analysed and recommendations made for future implementation of this requirement.

Chapter nine: Conclusion

In the final chapter the conclusions are presented. Areas for further research are also suggested.

2. ACCOUNTING FOR RESEARCH AND DEVELOPMENT COSTS

2.1 Introduction

Before attempting to perform the proposed study of the application of AC 122, the statement of accounting for R & D costs, in the pharmaceutical industry, it is necessary to present a discussion of the development and requirements of AC 122. This presentation provides a background of the origins of the major requirements of the standard. It also identifies the problems that may arise when attempting to implement AC 122.

2.2 Origin of AC 122

The South African standard of accounting for R & D costs, AC 122 followed the revised international accounting standard, IAS 9. The original IAS 9 was revised in response to the International Accounting Framework for the Preparation and Presentation of Financial Statements issued by the IASC in July 1988. The SA equivalent of the International Framework is AC 000, which was issued in 1990. The objective of the IASC is to develop a framework that assists in the harmonization of regulations, accounting standards and procedures relating to the preparation and presentation of financial statements (AC 000; para .1(b)). The main purpose of the framework is to assist the Board of the IASC in the development of future international accounting standards and its review of existing international accounting standards.

2.3 The accounting framework

The Framework sets out the objectives and concepts that underlie the preparation and presentation of financial statements. Users depend to a large extent on financial statements for information to assist them in making economic decisions.

In circumstances where conflict arises between the framework and a specific accounting standard, the requirements of the accounting standard should prevail (AC 000; para .03). Conflict arises when an accounting standard recommends treatment for a specific transaction that is different to what it would have been if the principles of the framework had been applied.

2.3.1 Elements of financial statements

The Framework defines the elements directly related to the measurement of the financial position and financial performance of a business enterprise. The elements of financial information are assets, liabilities, income and expenses. The element definitions provide the basis for determining how to account for transactions in the event that no specific accounting statement exists for the type of transaction. The framework goes on further to describe when it is permissible to recognise the element in the financial statements.

Research & development spending can be accounted for either as an expense or an asset, depending on the nature and characteristics of the R & D activity.

2.3.2 Definition of an asset

An asset, in terms of para .49(a) of AC 000, is "a resource controlled by the enterprise as a result of past events, from which future economic benefits are expected to flow to the enterprise." Para .53 describes the future economic benefit embodied in an asset as "the potential to contribute, directly or indirectly, to the flow of cash and cash equivalents." It recognises that the reduction of cash outflows flowing from an improved manufacturing process also constitutes an economic benefit. Para .56 highlights that physical form is not essential to the existence of an asset and that hence patents and copyrights can constitute assets. The requirement that an asset be controlled does not necessarily equate to legal ownership. Control exists if development activity generates knowledge or skill that will, directly or indirectly (by licence for example), result in the flow of future benefits to the company. Para .59 acknowledges a close association between incurring expenditure and generating assets, but accepts that the two do not normally coincide. Incurring R & D expenditure is not conclusive proof that it will result in economic benefit, although that is usually the intention.

2.3.3 Definition of expense

Paragraph .70 of the framework defines the expense element as follows:

> "**Expenses** are decreases in economic benefits during the accounting period in the form of outflows or depletions of assets or incurrences of liabilities that result in decreases in equity, other than those relating to distributions to equity participants."

Expenses should be recognised in the income statement based on a direct association between the cost incurred and the earning of related income.
Sometimes it is expected that economic benefits will arise over several accounting periods and the income association can only be broadly or indirectly determined. In such cases para .96 requires that the expense be recognised in the income statement on the basis of systematic and rational allocation procedures.

An asset holds an expectation of future economic benefit. An expense results in increases or decreases in economic benefits during the current period and has no relevance beyond the current accounting period.

2.3.4 Recognition criteria

Before an asset is included in the balance sheet or before an item of expense is included in the income statement, the recognition criteria must be fulfilled. Para .83 of AC 000 states that recognition should occur if:

a) It is probable that any future economic benefit associated with the item will flow to or from the enterprise; and
b) The item has a cost or value that can be measured with reliability.

a) Probability criterion

Paragraph .85 of AC 000 interprets the concept of "probability" as the degree of uncertainty that exists that the future economic benefits associated with the item of expenditure will flow to or from the enterprise. For this purpose uncertainty depends to a large extent on the economic environment within which the enterprise operates, and the assessment is based on the evidence available when preparing the financial

statements. A company that operates in a regulated industry must not only develop a successful product, but must also satisfy the requirements of the regulating body. Therefore, while developing the product, the company operating in the regulated industry may be less certain of future economic benefits than a company developing an asset in an unregulated industry.

Para .90 of the framework states that an asset should not be recognised in the balance sheet when expenditure has been incurred for which it is considered improbable that economic benefits will flow to the enterprise beyond the current accounting period. Therefore an item of expenditure, failing to meet the probability criterion should be written off as an expense.

b) Measurement criterion

The element must have a cost or value that can be measured with reliability before it can be recognised in the financial statements. Cost usually equates to the amount spent when a payment is made, and no measurability problem exists in such cases. Difficulty arises when attempting to determine the cost of an internally generated asset that should include an allocation of indirect costs, and other costs for which no arms length transaction occurred.

An item that meets the definition of an asset but fails to meet the recognition criteria of measurability may still warrant disclosure in the notes to the financial statements, explanatory material, or a supplementary schedule (AC 000; para .88).

2.4 Fundamental accounting concepts

AC 000 (SAICA: 1990), the accounting framework, identifies two main concepts that underlie the preparation of financial statements. These are the accrual concept and the going concern concept.

2.4.1 The accrual basis of accounting

AC 000, para .22, requires that financial statements be prepared under the accrual basis of accounting. Under this basis the elements of financial statements are

recognised when they occur (and not as cash or its equivalent is received or paid). This will ensure that they are recorded and reported in the financial statements of the periods to which they relate. The accrual basis of accounting results in the matching of expenses in an accounting period with the revenue that was earned in the same period.

When costs are paid or revenue is received, but the related revenue or costs respectively have not been earned or incurred, the income statement element should be deferred and only recognised in the accounting period in which its related revenue or cost occurs.

Application of the matching concept to research and development expenditure, means that if the expenditure is expected to result in future revenue for the benefit of the enterprise, that the R & D expense should, in so far as is possible, be included in the income statement in the same period as the revenue that it earns.

The original IAS for R & D costs, IAS 9, was issued prior to the development and issue of the International Accounting Framework. It required the immediate expensing of research costs and permitted optional capitalisation of development costs if certain criteria were met. In practice very few companies exercised the option to capitalise development costs, and most companies that incur such costs write them off in the year incurred (Cairns; 1997: 61). Prior to the issue of AC 122 the majority of SA companies also followed the US approach of writing off such costs in the year incurred (Everingham & Hopkins; 1997: 101).

Following the issue of the International Accounting Framework, the original IAS 9 was no longer appropriate. The optional treatment of development costs as an asset is inconsistent with the accounting requirements laid down in the accounting framework, whereby an element that satisfies the asset and recognition criteria should be treated as such in the financial statements.

Revised IAS 9 requires that development costs be accounted for as an asset, subject to satisfying specified criteria, and that the asset subsequently be amortised so that the costs are matched to the future revenue that it generates.

The International Accounting Framework requires the exercise of prudence when preparing financial information to ensure that it is reliable. Prudence is the inclusion of a degree of caution in the exercise of judgements needed in making the estimates required under conditions of uncertainty, such that assets or income are not overstated and liabilities or expenses are not understated (AC 000; para .37). Because of the nature of R & D activity, it is probable that the size and timing of future benefits will always have an element of uncertainty, and therefore the company should exercise prudence when accounting for R & D costs.

The practice of writing off R & D costs when incurred is highly prudent and fails to recognise the economic benefits expected to flow from development activity, assuming that an expectation of future benefits does exist. Supporters of the immediate write off of R & D costs oppose the capitalisation of these costs primarily on the grounds that the future revenues from the R & D activity are too uncertain to anticipate.

2.4.2 Going concern

The second fundamental accounting concept of going concern has a lesser impact on R & D accounting than the accrual concept, but deserves mentioning in this section. The going concern concept assumes that the enterprise will continue in operational existence for the foreseeable future and is accounted for on the going concern basis (AC 000; para .23).

2.5 Accounting for Research and Development costs, in terms of AC 122

2.5.1 Introduction

AC 122 is based on IAS 9 (revised), and there are no matters of principle in AC 122 which differ from those contained in IAS 9 (AC 122; 1994: para .37).

The revision of IAS 9 is one of many changes made to fulfil the IASC's objective of harmonising regulations and accounting standards for the preparation and presentation of financial statements. IAS 9 revised, and AC 122 are a specific application to research and development costs of the general accounting principles developed in the framework.

Paragraph 01 of AC 122 states that "the primary issue in accounting for the costs of research and development activities is whether such costs should be recognised as an asset or an expense".

Before proceeding with the overview of AC 122, the effect of the recent issue of ED 120 (SAICA: 1997), 'Intangible Assets' in South Africa, and its International counterpart, E 60 (IASC: 1997), should be mentioned. While ED 120 is intended to replace AC 122 with a more comprehensive standard for intangibles in general, it states the following:

> 'It is believed in practice, it is unlikely that the application of the proposed requirements in ED 120 will result in differences from the application of the requirements in AC 122 (Appendix 7; para .05).

Additionally the comparable status between IAS 9 (revised) and AC 122 is maintained in the new exposure drafts. The technical release to ED 120, para .03, states that

> 'there are no matters of principle in the proposed new SA statement, ED 120, which differ from those contained in E 60.'

Accordingly, the requirements of ED 120 will only be referred to where they are relevant to this study and differ from those contained in IAS 9 (revised) and AC 122.

2.5.2 Definition of Research and Development

The definitions in paragraph .07 of AC 122 are the following:

> **Research** is the original and planned investigation undertaken with the prospect of gaining new scientific or technical knowledge and understanding.

> **Development** is the application of research findings or other knowledge to a plan or design for the production of new or substantially improved material, devices, products, processes, systems or services prior to the commencement of commercial production or use.

The definition of research suggests that the main intention is to be an innovator - the first person to understand an area of science or technology. The main objective of research is to obtain an understanding of a phenomenon that provides impetus to subsequent development.

Development builds on the knowledge or findings obtained in the initial research process to develop a new product or process.

The definitions of research and development are very broad and may be widely interpreted by the preparer of financial statements. Paragraph .08 of AC 122 states that the definitions may not be sufficient to ensure consistent identification R & D activities, as the nature of R & D activities will differ depending on the type of business, how the business is organised and the type of projects undertaken by the business. Paragraphs .09 and .10 includes examples of activities typically included in research and development as practical guidance to preparer's of financial information, namely

- for research:

- activities aimed at obtaining new knowledge,
- the search for applications of research findings or other knowledge,
- the search for product or process alternatives, and
- the formulation and design of possible new or improved product or process alternatives.

- for development:

- the evaluation of product or process alternatives,

- the design, construction and testing of pre-production prototypes and models,
- the design of tools, jigs, moulds and dies involving new technology, and
- the design, construction and operation of a pilot plant that is not of a scale economically feasible for commercial production.

These lists reinforce to some extent the discussion of the definitions above. Research is associated primarily with the search function, whereas development activity is more concerned with subsequent design. The lists do not however assist the preparer of financial statements to distinguish between the "formulation and design of a product or process" included in research activities and the "evaluation of a product or process alternative" included in development activities.

Paragraph .11 lists activities that may be closely associated with research and development but that are neither research nor development activities. These are:

- engineering follow through in an early phase of commercial production,
- quality control during commercial production, including routine testing of products,
- troubleshooting in connection with breakdowns during commercial production,
- routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product,
- adaptation of an existing capability to a particular requirement or customer's need as part of a continuing commercial activity,
- seasonal or other periodic design changes to existing products,
- routine design of tools, jigs, moulds and dies, and
- activities, including design and construction engineering related to the construction, relocation, rearrangement, or start-up of facilities or equipment other than facilities or equipment used solely for a particular research and development project.

This list is an attempt at ensuring that certain activities are consistently excluded from research and development activities. Noticeably, any appearance of R & D activity

during commercial production does not qualify as R & D activity. The exclusion of routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product is open to different interpretations because no definition is provided as to what constitutes routine or non-routine efforts.

The proposed statement of GAAP for intangible assets, ED 120, does not include the examples listed in para's .09 to .11 of AC 122. The APC 'believes that this keeps the proposed standard on Intangible Assets concise without damaging its understandability' (SAICA; ED 120 para .04, Appendix 1).

Chapter 6 investigates this exclusion from R & D activities further in the context of the pharmaceutical industry.

2.5.3 R & D costs

AC 122 states that all costs that are directly attributable to R & D activities or can be allocated on a reasonable basis to such activities should be included in R & D costs (para .12). Paragraph .13 includes the following types of costs in R & D costs:

- the salaries, wages and other employment related costs of personnel engaged in research and development activities.
- the costs of materials and services consumed in research and development activities.
- the depreciation of property, plant and equipment to the extent that these assets are used for research and development activities.
- overhead costs related to research and development activities, which are allocated on bases similar to those used in allocating overhead costs to stock, and
- other costs, such as the amortisation of patents and licenses to the extent that these assets are used for research and development activities.

Because R & D costs are accounted for differently in accordance with AC 122, the distinction between these costs is important. No separation of research costs from development costs was required in the past because both types of costs were written

off as incurred. This was the practice followed by SA companies, despite the option to capitalise development costs in the original IAS 9 (Everingham & Watson: 1998; 101). The mandatory capitalisation of development costs can only be implemented if the costing systems of the company are designed to accurately separate research costs from development costs.

The results of a project score survey conducted in 1973-1974 by the Australian Department of Science revealed that approximately 85 % of total research and development expenditure is incurred on current items[3], of which expenditure on salaries, wages and other employment related costs is the largest and most important component (McGregor; 1980: 22). Lothian (cited in Garbutt: 1989) conducted a survey in 1984 of major UK companies and found that salary costs varied from less that 20 % to more than 80 % of total R & D costs, "with a mean of 40 % to 60 %". An examination of UNESCO's 1995 annual statistical yearbook reveals results consistent with those of Lothian and McGregor's studies. The results of a survey conducted by UNESCO on the cost components of R & D expenditure of four of its member states is set out in Table 3. The countries examined were randomly selected and figures for the most recent two years are included in the table. In some years and for some of the countries the breakdown between labour and other current costs is not available.

[3] Current items of expenditure include direct costs of a non-capital nature.

Table 3 - UNESCO Breakdown of total R & D costs by country

Country	Current costs* as a % of total costs	Labour costs as a % of current costs	Total R & D expenditure - millions
United States (1983)	97,9 %	N/A	88 085
- US $ (1988)	97,1 %	N/A	139 255
Japan -Yen (1987)	82,7 %	54,1 %	9 837
(1991)	84,4 %	51,3 %	13 772
Korea -Won (1983)	64,1 %	53,8 %	622
(1992)	72,0 %	48,6 %	4 989
Australia - $ (1987)	87,6 %	N/A	3 546
(1990)	86,3 %	64 %	5 088

*Current costs include all direct costs, but exclude any allocation of overheads and capital expenditure.

The table indicates that current expenditure makes up approximately 80% of total R & D costs, and that the largest portion of these costs are labour costs. Accordingly a large portion of the work to be performed in allocating costs between research costs and development costs should focus on the allocation of employment costs.

The accounting for the costs described in bullets 3, 4 and 5 of para. 13 of AC 122 challenges the most appropriate means of allocating indirect costs to research costs and development costs. McGregor (1980: 17) states that the allocation of indirect costs, depending on the magnitude of a company's R & D program, could have a significant effect on the asset valuation and pricing structure of a company's products. If an insufficient portion of overhead costs is allocated to the development costs of a successful product, the development asset will be too low. Because the R & D function will not have absorbed a sufficient portion of the overhead costs, the unit cost of the company's other products may be too high. This may result in an inappropriate selling price being determined for both the new product and for the company's existing products.

The lists of research activities and development activities should assist preparers of financial statements to allocate activities on a reasonably consistent basis between research activities, development activities and other activities. However, the failure to lay down a similar distinction between research costs, development costs and other costs provide preparers with the flexibility to allocate costs inconsistently between these activities.

The problems of cost allocation are addressed in chapter 6.

2.5.4 Accounting treatment for research costs and development costs

The characteristics of an asset in AC 000 is that the resource be controlled, that it result from a past event and that future economic benefits are expected to flow to the enterprise. The asset is however only recognized and recorded in the balance sheet if the recognition criteria are satisfied. Accordingly, the following basic rules apply to accounting for research costs and development costs.

- **Accounting for research costs**

Research costs will often meet the definition of an asset, but because of the nature of research, it will be difficult to obtain sufficient certainty of the probability of future economic benefits at the time of undertaking the research activity (AC 122; para .17). At this stage the future economic benefits tend to be a hope rather than a probability. The recognition criteria of AC 000 are not satisfied and prudence dictates that these costs be accounted for as an expense rather than as an asset. Accordingly research costs should be recognised as an expense in the period incurred (AC 122, para .16).

- **Accounting for development costs**

In most cases development costs will also meet the definition of an asset. Secrecy, patent protection or ownership obtains control of the development. The expenditure is the past event and future economic benefits are expected to flow to the enterprise as a result of the development expenditure. Therefore, the remaining issue is whether the development costs fulfil the recognition criteria of probability and measurability. At the time of preparing the financial statements it must be probable with a reasonable

degree of certainty that future economic benefits will flow to the enterprise as a result of the development expenditure. The development asset must also have a cost or value that is reliably measurable.

The problem with the recognition criterion of probability is that the framework provides no explanation as to what constitutes "an acceptable degree of probability".

AC 122 provides 5 criteria for determining whether the development costs should be treated as an asset. These criteria appear to be an attempt to reduce the subjectivity involved in satisfying the recognition requirements of probability and measurability.

Development costs of a project should be recognized as an expense in the period in which they are incurred, unless all 5 criteria of paragraph 18 are met (AC 122: para .18). The intention of this rule is to ensure that measurable development expenditure, from which future economic benefits are expected to flow, is accounted for as an asset.

The five criteria listed in para .18 are:

- The product or process is clearly defined and costs attributable to the product or process can be separately identified and reliably measured.
- The technical feasibility of the product or process can be demonstrated.
- The enterprise intends to produce and market or use the product or process.
- The existence of a market for the product or process or if it is to be used internally rather than sold, its usefulness to the enterprise can be demonstrated.
- Adequate resources exist, or their availability can be demonstrated, to complete the project and market or use the product or process.

2.5.5 The capitalisation requirements

If the allocation of costs between research costs and development costs referred to earlier in the chapter is appropriately performed, the first requirement of para .18 will be satisfied.

The distinction between research activities and costs, and development activities and their costs, is fundamental to ensuring that the net income for an accounting period

and the deferred development asset at the end of the period faithfully represent the research and development activities of the enterprise.

Two categories of development costs emerge as a consequence of the requirements of AC 122 and IAS 9 (revised). Development costs can be separated between those that are capitalised and those that are expensed when incurred. In most cases the demonstration of the "technical feasibility" of the product or process will be the most difficult criterion of paragraph 18 to satisfy. This is because (a) the standard fails to define "technical feasibility", and (b) because the demonstration of technical feasibility requires a degree of subjective judgement. For this reason, the demonstration of technical feasibility, will usually also be the primary determinant of when the capitalisation of development costs should begin.

It is difficult to provide guidance on technical feasibility that will be meaningful to all industries and it may be more appropriate to develop criteria at an industry level. If past research and development experience of various industries can be used to develop guidelines as to when the probability of technical feasibility is sufficiently acceptable for the specific industry, the objective of harmonisation may be more effectively achieved when accounting for research and development costs. One of the major challenges of this study is to determine whether technical feasibility can be further defined in the context of the pharmaceutical industry. For this purpose the study will review historical R & D in the pharmaceutical industry and the typical life cycle of pharmaceutical drug development. The results of this exercise are analysed and interpreted in chapter 7.

Requirements 3 and 4 of para .18 will generally be easy to satisfy and are unlikely to cause significant delay in the capitalisation of development costs if requirements 1 and 2 are satisfied. The intention to market a product or use a process (requirement 3) can be demonstrated more convincingly if a potential benefit from doing so is evident. The fourth requirement to demonstrate the existence of a market for the product or process can be fulfilled by conducting market research studies. These should indicate that a demand for the product or process exists at the price that the enterprise intends

to supply the product. If it is intended to use the product or process internally, this can be demonstrated by the successful testing of the product or process in its intended use. If the product or process is significant to the operations of the business, formal top level approval of its use will usually also exist.

The fifth requirement to be met before the capitalisation of development costs can occur is that sufficient resources for completion of the product or process be demonstrated. Continued investment in a R & D project, if it is significant, will almost always require the approval of top management. When such approval exists the availability of resources will need to be demonstrated by the organisation. Internal investment approval or third party finance approval, depending on the intended source of the finance, is proof that financial resources are available. Accurate budgets of the costs still to be incurred on the project will however be necessary to demonstrate whether the available finance identified is sufficient to complete the product or process.

2.5.6 Limitation on cost capitalisation

> "The cost to be capitalised should not exceed an amount, that, after deducting further development costs, related production costs and selling and administrative costs directly incurred in marketing the product, is probable of recovery from related future economic benefits" (AC 000; para .21).

This requirement has the following two implications.

- Firstly knowledge of the nature and size of all future related costs is required. Based on historic development activity, and with reference to the planned market strategy, it should be possible to obtain a fairly accurate estimate of the direct selling and administrative costs likely to be incurred in marketing the product. The exact amount of costs need not be known, but rather a broad estimate based on a high level of knowledge and experience. In certain industries a novel

development will regularly achieve future economic benefits of such large proportions that the limit of cost capitalisation will not apply.

- The second implication requires a reliable estimation of future economic benefits. Future economic benefits may be the revenue earned on the sale of the product or process or cost savings or other benefits resulting from the use of the new product or process by the enterprise itself (AC 122; para .22). Both the revenue or cost savings resulting from the sale or use of the new product should be possible to measure to some degree. Revenue from sales can be broadly determined based on the results of initial market feasibility studies. Measurement of cost savings will require a comparison of the new product with an existing product or process to determine the benefits that will accrue if replacing the old with the new.

2.5.7 Amortisation of capitalised development costs

AC 122 requires that the costs be amortised and recognized as an expense on a systematic basis so as to reflect the pattern in which the related economic benefits are recognised (para .25). When determining the related economic benefits the enterprise should make reference either to:

- the revenue or other benefits from the sale or use of the product or process,
- or the time period over which the product or process is expected to be sold or used.

The time period of future benefits may be much easier to estimate accurately than the revenue particularly in cases where the useful life is legally limited, for example by patent, licence or contract. Therefore this method is likely to be preferred in the pharmaceutical industry because of its ease of application.
If allocation is to be made on the basis of expected revenue or other benefits, both the time period of future economic benefits and the approximate size of annual future economic benefits in relation to total future economic benefits need to be estimated.

ED 120 (para .69) requires that the depreciable amount of an intangible asset be allocated on a systematic basis over the best estimate of its useful life and provides factors for consideration when assessing the useful life of the product (para .70.) Useful life is defined in para .09 of ED 120 as either:

- the period of time over which an asset is expected to be used by the enterprise, or
- the number of production or similar units expected to be obtained from the asset by the enterprise.

Therefore both AC 122 and ED 120 require that the asset be amortised over the period for which future benefits are derived from the asset. ED 120 (para .75) states that if the pattern of future economic benefits cannot be reliably determined, the straight line method should be adopted for amortisation. In addition to the requirements of AC 122, ED 120 also requires that the amortisation period and method be reviewed at each balance sheet date, and any adjustment be accounted for as a change in accounting estimate in current and future periods (para .81 - .83).

Technological and economic obsolescence create uncertainties because of potential cuts in the number of units sold and the time period originally anticipated for the future economic benefits. These uncertainties make estimation beyond a short time period very difficult and for this reason development costs are normally amortised over a period not exceeding five years (AC 122; para .27). However, the risk of technological and economic obsolescence may not be applicable to all types of development activity. In industries where patent protection creates long protection periods it is probable that technological and economic obsolescence pose a much smaller threat than in cases where there is no patent protection. The same reduction in risk of obsolescence holds in the situation where the product is a necessity as opposed to a luxury. ED 120 (para .69) recognises that a five years amortisation ceiling may be inappropriate and introduces a rebuttable presumption that the life of an intangible asset will not exceed 20 years from the date when the asset is available for use.

If the five years guidance is strictly applied to all industries, the capitalisation and subsequent amortisation of development costs may fail to achieve the matching that it was designed to achieve. The practical and implementation concerns of the amortisation of R & D costs in the pharmaceutical industry are discussed in chapter eight.

2.5.8 Impairment of development costs

At the end of each accounting period, the unamortised development costs should be reviewed. If at such stage the costs to be incurred taken together with the unamortised asset balance exceeds the expected related future economic benefits, an adjustment must be made to the asset balance so that the total does not exceed the expected net future economic benefits. If at any stage any one of the original asset criteria of para .18 cease to be met, the development asset should be written off in full (AC 122; para .29). In the event of this occurrence the R & D expense may be significantly larger in the year that such write off occurs than it would have been if the development costs had been written off as incurred. Para .34 requires separate disclosure of the amount written off in accordance with para .29.

If at any time there is persuasive evidence that the circumstances that led to the write off of the development asset cease to exist, and that the new events and circumstances will persist for the foreseeable future, the costs that were written off may be restated as an asset. This write back should be treated as income and set off against the current year's research and development expenditure in the income statement (AC 122; para .31).

When the write back occurs, the amount to be written back should be reduced for any amortisation that would have occurred between the write off and write back periods had the asset never been written off (AC 122; para .33). Para .26 states that amortisation should only begin once the product or process is available for sale or use. Therefore if both the write off and the write back occur prior to any benefits flowing from the sale or use of the product or process the amount written off and the amount written back will be identical.

The provisions of para .31 appear to be inconsistent with those of para .20. Para .20 states that development costs initially recognised as an expense should not be recognised as an asset in a subsequent period. This means that the write back of development costs is only permitted for development costs that were originally capitalised but not for development costs that were originally expensed. The requirement of para .20 is in conflict with AC 000, because it does not permit the recognition of an asset. On the other hand the reinstatement provision of para .31creates additional scope for profit manipulation and may result in income being abnormally low in one year, and abnormally high in a subsequent year.

At this stage one of the main differences between AC 122 and ED 120 is best clarified. Whereas AC 122 limits the amount of costs to be capitalised as an asset to the amount that is probable of recovery from future economic benefits, ED 120 requires that all costs incurred after the date at which the recognition criteria were first met, be included in the carrying value of the asset. Together with this requirement, ED 120 also requires that an annual impairment test of the asset be performed in accordance with the statement on impairment of assets, ED 112 (1997: para .84). ED 112 (para .07) defines an asset as being impaired if the carrying amount of the asset exceeds its recoverable amount. It also requires that if any of the indications of impairment listed in para .08 to .13 of ED 112 exist that the enterprise is required to make an impairment test. More specifically, in addition to the requirements of ED 112, ED 120 (para .85) requires an impairment test of the following intangible assets at each balance sheet date, even if no indication of an impairment exists:

- Internally generated intangible assets that are not yet available for use.
- Internally generated intangible assets that are amortised over a period exceeding five years from the date when the asset is available for use.
- Other intangible assets that are amortised over a period exceeding twenty years from initial recognition.

Para. 14 of ED 112 states that if either an asset's net selling price or its value in use exceed the carrying value, the asset is not impaired. Net selling amount is defined as

the asset's market price in an active market adjusted for incremental costs directly attributable to its disposal. Value in use involves estimating future cash flows, both in and out, to be derived from use of the asset and its ultimate disposal. The value is then determined by discounting these cash flows by an appropriate discount rate.

The author believes that in practice it is unlikely that the requirements of ED 120, together with the impairment test as determined in accordance with ED 112, will result in a carrying value significantly different to that arrived at if the requirements of AC 122, para .21 and .29 were applied.

2.5.9 Disclosure for research and development

2.5.9.1 Does R & D accounting disclosure matter?

Disclosure of R & D activity and the basis of accounting is useful if it is used by users in making economic decisions. Nixon (1997: 274) concluded from his study on the views of accountants of UK companies, regarding the accounting treatment for R & D expenditure, that the majority of accountants and financial directors do not associate economic consequences with the treatment of R & D expenditure. For them disclosure of information is the key factor determining the value that the capital markets attribute to a company's R & D expenditure, rather than its treatment; therefore R & D disclosure carries great importance. A second conclusion drawn by Nixon was that the annual report of UK companies, the main focus of standard setters, is only one channel of communicating information on R & D activities. Therefore accounting regulators in the UK need to address the gap between total R & D information disclosed and that included in financial statements, so that meaningful information of R & D is disclosed in an equitable way to all shareholders.

Goodacre & McGrath (1997) investigated the behaviour of UK investment analysts to determine if they interpret earnings in the same way regardless of the accounting method used for R & D expenditure. They concluded that the market systematically adjusts earnings for different R & D accounting methods before they are impounded in security prices. Therefore they concluded that since analysts on average seemed able to accommodate different R & D accounting treatments, accounting regulators should focus more on disclosure adequacy that on prescribing accounting practice. If

the magnitude of R & D expenditure and the share price of the firm are positively correlated, the failure to disclose the magnitude and nature of R & D may have a negative impact on the security price of the firm. The results of these two studies support the need for detailed disclosure of the magnitude and nature of R & D expenditure, and the basis on which such expenditure is accounted for.

2.5.9.2 Disclosure requirements of AC 122

Paragraph .34 of AC122 states that the financial statements should include the following disclosures in respect of research and development costs:

- the accounting policies adopted for research and development costs,
- the amount of research and development costs recognised as an expense in the period,
- the amortisation methods used,
- the useful lives or amortisation rates used,
- details of development costs that are being amortised over more than five years,
- the aggregate amounts of development costs and the aggregate amounts provided or written off the assets recognised, and
- a reconciliation of the balance of unamortised development costs at the beginning and end of the period showing all movements during the period.

The disclosure requirements are comprehensive and are intended to provide more information about the extent of R & D costs and the methods used to account for these costs. This enables an informed investor to make comparisons of the R & D activity of different companies by adjusting the financial information of companies that adopt different accounting policies for their R & D activity. In essence, these disclosures should provide sufficient information of R & D activity so that an investor can make a meaningful assessment of the levels of R & D investment by the company in question. Companies are also encouraged to disclose a description of their research and development activities (AC 122; para .35).

2.6 Conclusion

When the accounting standard for research and development costs, AC122, is implemented it is of primary importance that the qualitative characteristics of relevant, reliable, understandable and comparable financial information be upheld (AC 000; para .24). If the application of AC 122 promotes treatment inconsistent with providing information useful for making economic decisions, then the current gap that exists between the accounting theory and practice for research and development costs may be justified (Nixon; 1997: 274).

In the next chapter the literature is reviewed to identify the alternatives for accounting for R & D costs and the benefits and problems of each alternative. The literature is also reviewed to identify the problems associated with the implementation of AC 122 in general.

3. LITERATURE REVIEW

3.1 Introduction

This chapter highlights issues perceived to be of relevance to the study as identified from the literature. It provides a background to the different alternatives that exist for accounting for research and development costs, and in so doing illustrates why accounting for research and development costs has become so important and has prompted the formulation of new and revised accounting standards with respect to these costs across the globe. It focuses on the major problems facing industries engaged in research and development when contemplating implementation of the accounting statement for research and development costs. The identification of these problems provides direction to the study and areas of focus.

3.2 Accounting alternatives for research and development costs

Existing methods for accounting for research and development costs include the following:

- write off research costs and development costs as an expense when incurred,
- write off research costs and development costs as an expense, with an option to capitalise development costs if specified criteria are met, or
- write off research costs and development costs as an expense, except if specified criteria are met, in which case the development costs should be capitalised.

3.2.1 Write off as an expense

The first method requires that both research and development costs be written off as an expense. This approach adopts a prudent attitude to accounting for R & D costs, and is the current accounting rule of the FASB in the US as laid down in SFAS 2. This method of accounting for R & D costs is the easiest to apply as costs accumulated in the cost category, R & D, are simply written off against income in the year incurred. The only concern when using this method is that the cost category, R & D, include all relevant costs. Before issuing SFAS 2 in 1974, the FASB

interviewed a limited number of selected financial analysts and commercial bankers and reviewed a number of published financial statements (SFAS No.2; 1974: para .20). The FASB's interviews were typically concerned with the views of financial analysts on the assumption that, in making economic decisions, investors and creditors are often influenced by the recommendation of financial analysts (McGregor; 1980: 22). The US survey revealed that the immediate expensing of research and development costs was the dominant preference of the financial analysts. They expressed the view that capitalisation would not be particularly useful in assessing the earnings potential of the research and development, as R & D costs represent only a hope for successful new products or services (FASB; SFAS 2: 1974: para .50).

The FASB stated the following reasons for their accounting rule:

- the low probability of success associated with research and development projects. (SFAS 2; 1974; para .39), and
- the failure to demonstrate a direct relationship between research and development expenditure and specific future revenue (SFAS 2; 1974; para .41).

These reasons have been widely criticised. A large number of studies have demonstrated the direct relationship between R & D expenditure and specific future revenue that the FASB were unable to demonstrate. Minasian, Bailey and Angilley (cited in Dukes et al: 1980) demonstrated a relationship between R & D expenditure and future revenue. The probability of success associated with R & D spending is unlikely to be as low as suggested by the FASB. The FASB relied on a study conducted in 1968 on a number of industries that found that an average of less than 2 % of new product ideas and less than 15 % of product development projects were commercially successful (SFAS 2; 1974; para 39). The 1968 study is very old and may no longer be representative of typical R & D projects today. Dukes & Bierman (1975) disagree with the level of uncertainty associated with future benefits from R & D inferred by the FASB. They argue that the FASB definition of risk was made

in terms of probability of failure and ignored the reduction of risk that can be achieved by pursuing a portfolio of research and development projects.

This method of accounting for R & D costs is also criticised for a number of additional reasons including the following:

1. The expense rule results in decreased corporate spending on research and development for small, high technology firms that previously used the deferred methods of measurement. This decreased spending was necessary to maintain profit levels achieved when R & D costs were capitalised (Horwitz & Kolodny; 1980).

2. This accounting practice hinders the financial health of knowledge-based companies, because it promotes an attitude of heavier investment in resource-based industries and ignores the benefits of "invisible capital" such as skilled, knowledgeable employees, technological development or technology licensing rights (Brennan; 1992: 22). Small companies tend to find it more difficult to obtain finance than larger companies with a greater asset base, and the inability to disclose investment in potentially successful development as an asset hinders access to funding for small "technology-intensive" companies still further (Brennan; 1992: 23).

3. This choice of accounting policy may influence a firm's financing costs. If a company has raised a loan subject to a loan covenant, the write off of R & D costs will reduce the net assets and interest earned ratio of the company. The financier often uses the technical violation of the covenant as an opportunity to increase the borrowing rate applicable to the offender (Foster; 1986: 154).

4. The expense rule is theoretically inconsistent with international accounting standards because it precludes possible recognition of the future benefits of development activity as an asset.

5. Research and development costs have similar characteristics to software development costs. Both have uncertainty of future economic benefits and long periods of time between incurring expenditure and future benefits. The expense rule for R & D costs in terms of SFAS 2 is criticised as inconsistent with the more recent thinking embodied in SFAS 86 which permits capitalisation of software development costs (Nix & Nix; 1992).

A vast amount of literature exists that both supports and contradicts the possibility that the expense rule causes a decline in research and development spending. Nix and Nix (1992: 53) support Horwitz and Kolodny's observation in point 1 above at a more general level. They compared US investment in R & D in the 1980's and early 1970's with that of Japan. They suggest that the relative decline in long-term R & D spending in the US as compared with Japan in the two periods indicates that US firms may be reluctant to invest in long term R & D because of the introduction of the "expense when incurred" rule in 1974. Dukes, Dyckman and Elliot (1980) conducted a study to determine whether the expense rule would have adverse effects on the incentive for innovation. They compared the R & D spending of companies that capitalised development costs with those that expensed development costs before the issue of SFAS 2. They made the same comparison after the issue of SFAS 2 to determine whether the rule caused a relative decline in R & D spending for the capitalising firms. They used three models and all three suggest that SFAS 2 had no effect on R & D spending in the US.

The main problem with Horwitz and Kolodny's study and Nix and Nix's observation is that they ignore the complexities of the R & D decision making process. Wolfson (1980) in his discussion of Horwitz and Kolodny's study identifies the main weakness in the experimental design as the failure of the researchers to build in the effect that economic events may have had on R & D spending. Hundley, Jacobson and Ho Park (1996: 1659) compared the effects of profitability on R & D intensity of Japanese and US companies. They observed that US companies tend to reduce spending in R & D when profitability declines whereas Japanese companies respond to declines in profitability by increasing R & D. Whereas Nix & Nix attribute the decline in R & D

spending to the introduction of the expense rule, Hundley, Jacobson & Ho Park support a different theory for this observation. They believe that the reason for the different reactions in the two countries is consistent with the view that shareholders of Japanese firms are usually individuals bound to a long-term relationship with the company (such as employees), and who therefore view an increase in R & D as a positive move to long-term growth of the enterprise. Shareholders of US companies on the other hand are likely to respond more negatively to decreased profits and therefore employees are less likely to make decisions that uphold long-term corporate viability.

It is unlikely that the expense rule alone causes a decline in R & D spending. The stability of research staff, the R & D efforts of competitors, the life cycle of company products, the backlog of research ideas, resource availability and the characteristics of the owners of the company are all factors that may affect the size and timing of R & D spending. Nevertheless, the expensing of R & D costs may be harmful for technology-based companies. It creates a financing advantage for companies that have tangible resources and is excessively prudent. The main advantage of this method of accounting for R & D costs is that it is easy and inexpensive to apply, and achieves greater consistency of R & D accounting treatment both within and between companies.

3.2.2 Option to capitalise

The second method for accounting for research and development costs requires that research costs be expensed. Development costs should be expensed unless specified criteria are met in which case the development costs **may be** capitalised. Therefore, this method permits capitalisation of development costs under certain conditions but does not require it. This approach was adopted in the old International Accounting Standard, IAS 9, and is also the current practice in Australia, Great Britain and Ireland.

This option to capitalise development costs is more consistent with the accounting framework, in that it allows for the recognition of a development asset where future

Table 4 - Reasons for non-capitalisation of development costs

Reason for non-capitalisation	% of respondents who selected the reason for non-capitalisation as most important	% of respondents who considered the reason to be important, but not the main reason for capitalisation
1. Development costs represent part of the cost of doing business	47,4	62,9
2. Uncertainty of future economic benefits of R & D spending	29,3	44,0
3. Write off of costs provides a tax advantage	25,9	43,1
4. Conservatism	15,5	33,6
5. Other	7,0	14,0

One hundred and sixteen companies responded to this part of the survey and some selected more than one reason for their non-capitalisation of development costs. The percentages presented above are based on the number of respondents to the question. The respondents that quoted uncertainty of future economic benefits and conservatism as reasons for non-capitalisation were asked to indicate the percentage of research and development costs they associated with commercially successful products or processes. Research costs were distinguished from development costs for this purpose. The results are set out in Table 5.

Table 5 - Estimation of commercially successful R & D

Proportion that can be associated with commercial successes	Percentage respondents indicating uncertainty of future economic benefit as main reason		Percentage respondents indicating conservatism as the main reason	
	Research	Develop.	Research	Develop.
Large	8,9 %	20,6 %	22,2 %	38,9 %
Moderate	58,8 %	61,8 %	55,6 %	61,1 %
Small or nothing	32,3 %	17,6 %	22,2 %	-
	100 %	100 %	100 %	100 %

McGregor (1980) fails to explain how large, moderate and small are defined for this purpose. Despite this omission, the results of this part of the survey are highly positive. They suggest that R & D spending results in significant commercial benefits. 82,4 % of the respondents that indicated the uncertainty of future economic benefits as the main reason for non-capitalisation of development costs believe that a moderate to large percentage of development costs can be associated with projects resulting in commercially successful products or processes. One hundred percent of respondents indicating conservatism as the main reason held the same view. 67,7 % and 77,8 % of the respondents respectively indicated that a moderate to large percentage of research costs results in commercially successful products or processes.

A more recent survey by Nixon (1997) of 109 UK companies, on their preference for accounting for R & D costs, revealed that the majority prefer to expense all R & D costs immediately, because the ex ante benefits of R & D expenditures are too uncertain. Consistent with the Australian study referred to above, Nixon found that the views of the same UK companies on ex post benefits of R & D expenditures suggested that development projects generate significant future economic benefits.

The positive results of the Australian study were attributed to the nature of R & D in Australian industry. Stubbs (cited in McGregor: 1980) identified a number of

important characteristics of research and innovation in Australian industry. He noted that expenditure tended to be more on development (of new or existing products) rather than research and that most companies held licensing agreements. Similarly, R & D expenditure in the UK is suggested to be relatively low-risk, incremental, development rather than high-risk pioneering research (Nixon; 1997: 268). Stubbs (cited in McGregor; 1980) also noted that because most Australian companies have overseas origin they tend to import technology and adapt it to local conditions. The small size of the Australian industry compared to countries like the US and Canada also lends bias against Australian companies conducting internally generated R & D.[4]

The results of the Australian study may be applicable in the context of South African R & D, given the parallels that exist between current research and development in South Africa and that conducted in Australia at the time that the AARF conducted their study. The current South African pharmaceutical industry in particular has a fundamental similarity with Australian industry in 1976 in that it begins development at a much later stage by buying into the basic research[5]. Therefore, neither conduct large amounts of high risk basic research[6] that produces such a low ratio of success to research effort.

Companies in smaller countries with less financial resources and underdeveloped capital markets will find it more difficult to undertake the type of high risk R & D undertaken by companies that operate in larger, more developed countries. It can be expected that the type of R & D conducted in smaller countries is more likely to be applied research by nature than pure or basic research.[7] Nixon (1997: 272) suggests that it may also be more appropriate for certain industries within a country, such as the manufacturing sector, to capitalise development costs than other industries, like

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[4] The reference to size is based on the geographical area and gross national product of the respective countries.

[5] Interview with Financial Accountant of Pilot company, 26 October 1994.

[6] Basic research is defined by the National Science Foundation (NSF) in the US as the ":original investigation for the advancement of scientific knowledge not having specific objectives.

[7] The NSF use originality and commercial objectives to distinguish basic or pure research from applied research. The former is original with no specific commercial objectives, whereas the latter is more advanced and specific in nature.

healthcare or electronics. Whereas R & D in the manufacturing sector tends to be primarily operational in nature, R & D in industries like health care and electronics assumes a more strategic role. Accordingly the probability of future economic benefits resulting from R & D activity in the manufacturing industry is greater than the probability of future economic benefits arising from R & D in an industry like healthcare or electronics. Brennan (1992: 23) suggests that the risk of failure is higher in situations when small scale feasibility has not been established, and that the decision to capitalise costs should depend on the level of risk associated with the development. The lower the risk of the R & D, the greater the probability of future economic benefits.

The effect of the mandatory capitalisation of development costs is to overcome the weakness identified in the second method, i.e. the reduced comparability that results from the optional capitalisation of development costs. This approach to accounting for research and development costs has been adopted by the IASC, New Zealand and Canada and is required of South African companies in accordance with AC 122.

3.2.4 The need for harmonisation of R & D accounting

Evidently, much disagreement exists as to the best method for accounting for R & D costs. The differences in accounting treatment between countries makes a meaningful comparison of companies in different countries difficult. Additionally, the optional capitalisation method has the effect of reducing the comparability of companies within countries.

The need for harmonisation of accounting practice between countries makes it necessary for global Accounting Standard Setting Bodies to achieve consistency of accounting treatment for R & D. The FASB have acknowledged to some extent the inappropriateness of their current accounting standard for research and development costs, SFAS 2, in the following statement:

> "In summary, while US GAAP currently does not permit capitalisation of development costs and a general statement for costs similar to development costs has not been issued, in some instances the FASB and AICPA have been able to establish criteria for capitalising costs that are associated with uncertain future

> benefits. However, because US practice has not developed a well-defined model for capitalisation of such costs, the outcome of a reconsideration of Statement 2 in the US is unpredictable" (Comment Letters on Exposure Draft E 37; 1992: 59).

3.3 Responses to E 37

When the Board of the IASC identifies an accounting topic to be considered, a steering committee is appointed to develop a statement of principles, an exposure draft and, ultimately, an International Accounting Standard. The statement of principles and the exposure draft are submitted to the public for their comments. These comments are evaluated and considered before the new accounting standard is finalised. Very few changes were made to E 37 when IAS 9 (revised) was finalised[8]. Accordingly, the majority of comments received from the public on exposure draft E 37 remain applicable to IAS 9 (revised). In the remainder of this chapter these comments are reviewed to identify the implementation concerns of AC 122 and IAS 9 (revised) of both preparers and users of financial statements.

Comment letters on Exposure Draft E 37, research and development activities, include fifty three comments from Member Bodies of the IASC, National Standard Setting Bodies, other representative groups, accounting firms and individual companies within industry and commerce. These comments were generally positive toward the changes made to the original IAS 9. Of the 53 responses, 14 opposed the major change proposed to the original IAS 9, which sanctioned the optional capitalisation of qualifying development costs (whereas IAS 9 (revised) mandates the capitalisation of development costs, provided the capitalisation criteria are met).

3.3.1 Mandatory capitalisation of development costs

Because auditors are responsible for the final approval of the financial statements of a company, the responses of accounting firms to this requirement were reviewed. The accounting firms that submitted comments on E 37 included Moore Stephens (Bermuda), Price Waterhouse Meyernel (Johannesburg), Arthur Andersen & Co.

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[8] Established by performing a comparative review of E 37 with IAS 9 (revised).

(Chicago), Coopers & Lybrand (New York), DRT International and Ernst & Young International (Comment Letters on Exposure Draft E37; 1992: 98-114).

Ernst & Young was the only accounting firm that did not support the changes recommended in E 37, for the following reasons:

- Because various national standard setting bodies have reached supportable, different positions on accounting for R & D the agreement between countries on the fundamental accounting treatment prescribed by the IASC in certain important areas is not attainable in the near term. Ernst & Young suggest that allowed alternatives be retained if comparability can be achieved through supplementary disclosure. They believe that this will result in greater recognition and acceptance of international accounting standards without compromising the IASC's overall objective of enhanced comparability.

- Consistency will not be achieved for accounting for R & D because the asset criteria are highly subjective and will permit various interpretations.

- The requirements of E37 are such that the development asset will not depend on the proportion of valuable costs, but on the pace of development, the forseeability of technical and commercial success, and the relatively arbitrary timing of when periodic accounts are drawn up (Comment Letters on Exposure Draft, E37; 1992: 114).

Comments made by the Swiss Institute of Certified Accountants and Audit firms concur with those made by Ernst & Young. They believe that accounting standards have to recognise the differences in attitude and practices in accounting, finance and taxes between countries (Comment Letters on Exposure Draft, E 37: 1992: 35). They indicate that the Swiss capital market has an unfavourable attitude to development costs as an asset because of past bad experiences with irrecoverable capitalised development costs. Therefore the Swiss Institute do not accept the requirement to capitalise development costs in E 37. They also believe that the subjectivity of the asset criteria will promote profit manipulation. The Swiss Institute

perceive that companies seeking to reduce profits will not acknowledge the capitalisation criteria, while companies with poor profits will want to defer costs even when it would be inappropriate to do so (Comment Letter on Exposure Draft, E 37; 1992: 36). Therefore, it is unlikely that consistency will be achieved.

The observed acceptance of the mandatory capitalisation requirement by accounting firms, with the exception of Ernst & Young, is inconsistent with the view that auditors have an incentive to support the immediate write off of research and development expenditures to avoid unnecessary audit risk. Much of the support for the US rule for expensing R & D costs as incurred came from auditors prior to the issue of SFAS 2 (Nix and Nix; 1992: 60). Auditors may be uncomfortable with signing off a set of accounts that includes a material development asset because of the difficulty of measuring future benefits. This should not discourage companies from capitalising a supportable development asset. Scicluna (1994: 101) states that difficulty of measurement does not equate to unreliable measurement and that the exercise of professional judgements is the nature of the auditor's job.

It can not however be assumed that auditors are generally technically qualified to verify the technical feasibility of the development asset. They will need to rely to a large extent on the opinion of experts and written representations by management to obtain assurance of the validity of the development asset.

Despite the positive response to the changes to the original IAS 9, many respondents did express reservations concerning the implementation of the requirements of E 37. These reservations are discussed in the following section and provide guidance to the implementation problems to be addressed in chapters 6-8.

3.3.2 Implementation concerns

The problem expressed by so many of the respondents is summarised in the following statement made by Ernst & Young International:

> "We believe that the guidance provided should not be so complex or subjective that it cannot be applied effectively on a world wide basis. Comparability of financial information can only be achieved if international accounting standards

> set forth requirements that can be interpreted clearly and applied consistently throughout the world" (Comment Letters on Exposure Draft, E 37; 1992: 113).

The Institute of State Authorised Public Accountants in Denmark notes that the optional capitalisation of development costs permitted in the original IAS 9 is difficult to apply in practice, and that if capitalisation is to be made mandatory, that the statement be formulated in order to make it possible to implement the capitalisation requirement (Comment Letters on Exposure Draft, E 37; 1992: 11).

The conceptual and practical issues identified from the examination of the commentary to E 37 is the subject of the remainder of this chapter.

3.4 Conceptual issues and practical concerns of E 37

3.4.1 The allocation of R & D costs

The FASB indicates that experience in the US has shown that the application of the definition of research and development activity is one of the most judgemental areas in accounting for these activities (Comment letters on E 37; 1992: 54). Studies and publications issued in the 1970's on accounting for R & D costs tended to focus mostly on how to separate R & D from other cost categories.[9] This was important for ensuring that the R & D expense disclosed by a company faithfully represented the actual R & D activity undertaken.

The requirement to capitalise development costs imposes the additional burden on accountants to distinguish development costs from research costs. This distinction was previously not necessary because both types of costs were accounted for on the same basis and disclosed as one cost category in practice. When research and development activity occurs simultaneously on a number of projects, the overhead expense must be allocated to the various projects. Once these costs have been allocated to the various projects, they need to be separated further into research costs and development costs. Even then, not all of the development costs are automatically

[9] Studies were performed by Gridley (1974), McGregor (1980) and Gellein & Newman (1973), among others.

capitalised. Only costs that meet the five specified criteria may be deferred to future periods.

It is clear that the successful implementation of IAS 9 (revised) and AC 122 depends to a large extent on the correct allocation of costs to the research activity and development activity. This will be best achieved if clear definitions of research and development exist, and guidance on the allocation of costs is provided.

The Japanese Institute of Certified Public Accountants (JICPA) believe that the cost involved in distinguishing research costs from development costs far outweighs the benefits of doing so, and that the desired comparability of financial statements can be achieved by footnote disclosure of the R & D activity (Comment letters on E37; 1992: 24).

It is often argued that R & D costs are a stable ongoing expense that must be incurred to maintain and / or develop a business. As such the future economic benefits arising from such expenditure are likewise relatively stable and considered to be ongoing, and therefore cannot be readily identified to a particular period. In such a case the cost of implementing a capitalisation policy in respect of development costs far outweigh the benefit of doing so. To illustrate,

Assume a company spends R1 million per annum on general development activity and capitalises the development costs and amortises the asset over a three year period (the estimated period of future benefits arising from the expenditure.)

In year three, a 'stable state' will be achieved with annual amortisation of R1 million (3 X R1m X 1/3), equal to the amount which would be charged to profits. Only for years one and two will the development charge in the income statement (if the development costs are capitalised), be lower than if the expense rule is adopted. Therefore, if the R & D lifecycle of a company is relatively constant from year to year, both accounting methods will result in the same charge in the income statement once the 'stable state' is reached. The effect on the balance sheet of applying the expense rule to the development costs is that the assets and retained income will be lower by the amount of development costs incurred in a year, viz. R1 million, once the 'stable state' is reached. Clearly, the cost of creating systems to ensure that research costs and development costs are accurately allocated is not warranted. Development costs should simply be written off in the year incurred with other research costs.

3.4.2 The asset criteria

It was stated in section 3.3.1 that Ernst & Young, the Swiss Institute and the American Institute of Certified Public Accountants all oppose mandatory capitalisation of development costs because of the subjectivity of the criteria listed in para .16 of E 37. The equivalent criteria are stated in para .18 of AC 122.

The FASB also oppose this because they believe that too much judgement is involved in determining whether a product is 'clearly defined', 'technologically feasible', 'marketable' or 'useful' (Comment letters on Exposure Draft, E 37; 1992: 59). No guidance exists in E 37 or AC 122 to assist preparers of financial statements in interpreting what constitutes technical feasibility and this is likely to result in a number of diverse interpretations of this requirement. The US Society of Investment Analysts (Comment letters on Exposure Draft, E37; 1992: 83) is concerned that neither the user nor the auditor of the financial statements can be assumed to be technically qualified to verify the validity and valuation of the asset. This means that the user is effectively left with a director's valuation of the development asset. The New York State Society of Certified Public Accountants (NYSSCPA) also criticises the subjectivity of the decision because of the lack of guidance as to what constitutes reasonable assurance of technical feasibility. It recommends that the IASC provide detailed guidelines as to how to satisfy these criteria, and that these guidelines be industry specific. The NYSSCPA believes that this will promote consistency of accounting treatment for R & D costs within different industries (Comment letters on Exposure Draft, E37; 1992: 94).

The problem with the NYSSCPA approach is that the development of industry guidelines is likely to be both time consuming and costly. However, broad guidelines such as those provided by the FASB in SFAS 86, Accounting for the costs of computer software to be sold, leased, or otherwise marketed, may be a useful starting point for developing industry specific guidelines for accounting for R & D costs. Software activity is very similar in nature to research and development activity for the following reasons:

- the probability and magnitude of future benefits that may result are difficult to assess because of the risk and uncertainties inherent in both activities, and
- both activities have a long development lead time.

SFAS 86, para .3, states that all costs incurred to establish the technological feasibility of a computer software product are research and development costs and should be accounted for in accordance with SFAS 2. Para .5 requires that all costs incurred subsequent to establishing technological feasibility should be capitalised. Therefore "technological feasibility" is used in both SFAS 86 and IAS 9 as a factor that determines when software development and other development costs respectively should be accounted for as an asset. SFAS 86, in para .4, sets out the minimum activities that must be performed as evidence that technological feasibility has been established. In summary, it requires that if the product includes a detailed program design, that the design must be completed and the availability of resources established. Additionally, the consistency of the program design with the product design must be confirmed and all high risk development issues resolved. If no detailed program design is required a product design and working model must be complete and the consistency of the working model with product design confirmed. This guidance is significantly more than that provided in E 37 that simply requires that technological feasibility of the product be demonstrated.

The Institute of Management Accountants (New Jersey) suggests that the criteria in para .16 should include the need to consider regulatory approval, if applicable (Comment letters on Exposure Draft, E 37; 1992: 40). In cases where regulatory approval is required, a sixth criterion may be appropriate, to the effect that capitalisation may not occur before regulatory approval is assured beyond reasonable doubt.

The Pharmaceutical Manufacturers Association (Comment letters on Exposure Draft, E 37; 1992: 96) , Moore Stephens (Comment letters on Exposure Draft, E 37; 1992: 99) , Ernst & Young (Comment letters on Exposure Draft, E 37; 1992: 113) , Abbott Laboratories (Comment letters on Exposure Draft, E 37; 1992: 130) and the Royal

Dutch Shell Group (Comment letters on Exposure Draft, E 37; 1992: 119) expressed concerns similar to those documented above.

The exclusion from development of "routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product" in para .9 of IAS 9 also requires the exercise of subjective judgement. JICPA highlights the difficulty inherent in distinguishing improvement costs for existing products (due to routine and minor modifications) from substantive development costs (Comment letters on Exposure Draft, E 37: 1992: 25).

The New Zealand Society of Accountants (NZSA) perceive that this exclusion may create uncertainty as to what constitutes R & D and result in inconsistency of accounting treatment. However, FRS 13, the New Zealand Financial Reporting Standard for Research and Development costs, also excludes routine costs or costs incurred on minor modifications from R & D (para .4.10). FRS 13 provides practical guidance for assistance in implementing the exclusion of these costs. It distinguishes research and development activity from non-research based activity by "the presence or absence of an appreciable element of innovation. If the activity departs from routine and breaks new ground it should normally be included; if it follows an established pattern it should normally be excluded" (FRS 13; 1996: para .4.4).

The IASC's approach in E 37 is to exclude from research and development activity most of the activity performed on an existing product. In contrast, FRS 13 focuses on the newness of the activity when determining whether it is research and development or not.

The dissatisfaction of many of the respondents with the amount and quality of implementation guidance provided in E 37, particularly with respect to interpretation of the asset criteria of para .16, is evident. Chapter 7 addresses the identified problem by attempting to implement the recommendation of the NYSSCPA of developing specific implementation guidance for capitalising development costs in the pharmaceutical industry.

3.4.3 Amortisation of development costs

The third main concern identified with the implementation of E 37 relates to the amortisation requirements of para's .22 through .24. The equivalent requirements of AC 122 are stated in para .25-.28. These state that:

> "Capitalised development costs should be allocated on a systematic and rational basis to current and future accounting periods by reference either to the sale or use of the product or process or the time period over which the product or process is expected to be sold or used." (E 37: para .22), and
>
> ".....development costs are normally amortised over a period that does not exceed five years. Amortisation commences when the product or process is available for sale or use." (E 37: para .24)

One of the main objectives of capitalising development costs must certainly be to achieve better matching of the expenses and the benefits that result from the development activity. The deferral of development costs only achieves matching if the subsequent amortisation is appropriately performed.

The main concern that the respondents to E 37 have with the amortisation requirements is that the five year amortisation guidance is arbitrary and contradicts the requirements of para .22.

The Pharmaceutical Manufacturers Association (PMA) criticises the five year rule and does not believe that it will achieve better matching of revenue and expenses related to development activity. It states that the future economic benefits of pharmaceutical products are generally measurable, and the amortisation periods and methods adopted should conform to the related earnings streams (Comment letters to E 37; 1992: 97). Price Waterhouse Meyernel (Comment letters to E 37; 1992: 102) and the Institute of Management Accountants, New Jersey (Comment letters to E 37; 1992: 39) agree that some guidance should exist to ensure that unreasonable time frames are not used

for write off, but that the statement should include examples of circumstances or industries when the amortisation period may exceed five years. The Consultative Committee of Accountancy Bodies (Comment letters to E 37; 1992: 38), Johnson & Johnson (Comment letters to E 37; 1992: 127) and the Institute of Certified Public Accountants (Comment letters to E 37; 1992: 29) also criticise the five year rule as arbitrary and inappropriate. The latter argues that the existence of the five year limitation will result in enterprises using five years even if a shorter or longer period would be more appropriate. They submit that the duration for amortisation be left open, but that the asset be reviewed annually to allow for the recognition of technical and economic obsolescence. This is more consistent with the requirement of ED 120, that envisages a 20 year amortisation ceiling together with an annual asset impairment test.

The Financial Manager of Comalco Aluminium Limited also prefers to conduct an annual review of capitalised research and development when determining the write off required. He argues that products covered by patent have a minimum life of 17 years in the US before competition may freely use developed technology. In these circumstances the benefits of R & D expenditure may be derived over the patent lifetime, and the five year guidance would be highly inappropriate (Comment letters on E 37; 1992: 141).

Arthur Andersen and Co. (Comment letters on E 37; 1992: 108) and the Norwegian Institute of State Authorised Public Accountants (NSRF) (Comment letters on E 37; 1992: 32) agree with the five year limit for the amortisation of development costs as stated by IAS 9 and AC 122. The former agree because of the prudence of this approach and the latter because it concurs with the standard issued by the NSRF.

A second issue requiring clarification is the requirement to commence amortisation when the product or process is available for sale or use. The French Institute of Accountants are unclear as to whether amortisation should begin once commercialisation has started or once it is capable of commercialisation, but such has been deferred (Comment letters of E 37; 1992: 15). Johnson and Johnson anticipate

problems in implementing this particular requirement because their products are frequently accepted abroad before they have been approved by the Food and Drug Administration (FDA) in the US (Comment letters of E 37; 1992: 127). This means that their products are ready for sale abroad, but no such sales may be made until FDA approval is achieved. The author believes that if the main objective of capitalising development costs is to achieve matching, then amortisation should begin concurrently with commercialisation; that is when the product is sold.

3.5 Conclusion

This chapter described the three main areas of concern likely to arise when implementing IAS 9 (revised) as identified from the examination of comment letters to E 37. Because of the similarities between IAS 9 (revised) and AC 122, the same areas of concern are likely to arise when implementing AC 122.

Before addressing the identified conceptual and practical issues in the context of the South African Pharmaceutical Industry, it is necessary to present a discussion of the pharmaceutical industry of South Africa. This follows in chapter four.

4. THE PHARMACEUTICAL INDUSTRY

4.1 Introduction

Before embarking on an attempt to implement E 37 in the pharmaceutical industry, it is necessary to examine the industry and the implementation issues specific to that industry. This chapter presents a discussion of the nature of the pharmaceutical industry, the factors that influence the industry, and the constraints within which it operates.

4.2 Types of drug developments

The types of drug developments undertaken by the pharmaceutical case study company are defined at this stage of the chapter, because of the numerous references made to the different types of drugs developments in the remainder of this chapter. The case study company develops a number of different types of drugs and each have different R & D life cycles and pose different accounting challenges. The case study company undertakes the following types of drug development:

Generic drug - This is a copy of the novel new chemical entity (NCE) once the patent life of the NCE has expired. The cost and the development lifecycle of the generic drug is significantly less than for the ethical drug, although the development lead time to market is still lengthy. The generic typically does not require clinical trials because the efficacy will have been demonstrated by the trials required for the chemical entity when it was new. Instead, generic approval usually requires a dissolution test, to prove that the drug is correctly absorbed into the blood stream. Generic dissolution tests that are successful will progress to a bio-study. Generic drugs that progress to the bio-study stage have an 80 % likelihood of obtaining registration approval from the MCC.

Me too - This drug is developed from a New Chemical Entity and offers very little difference in medical therapeutic value to the original (ethical) drug.

Ethical Drug - This drug is developed from a novel new chemical entity, is patented, and is the first in its therapeutic class. It is seldom developed in South Africa by the case study company, although the company does currently have two such developments in progress. Bio-technology companies are primarily involved in the initial screening and handling of the molecule or New Chemical Entity. The case study company prefers to purchase a right to develop the molecule once significant synthesis has been performed, thereby avoiding the cost of a multitude of failures. The ethical drug is very costly to develop and takes a long time to get to the market. If successful registration is achieved, the majority of the costs are recovered in the first two to three years of commercialisation of the product[10]. Amgene Inc.'s Neupogen and Epogen, both ethical drugs, each generate more than $500 million a year in turnover. Thus it can be seen that the high risk developments yield high returns if successful.

The Combination - The combination drug consists of two or more non-novel chemical entities and is usually branded by the manufacturer. The development period is also of considerable length as clinical trials to prove safety and efficacy are required. These drugs have experienced enormous success in the South African market and have in most cases recovered all development costs. An example of this in the case study company is a product that was launched in 1988, that recovered its development costs by 1991 and continues to generate profits to date.

The different characteristics of the drugs described above, suggest that in the context of the South African market, it would be inadequate to focus only on the development of the ethical drug. The South African pharmaceutical industry is following the world wide trend of generic substitution[11], and 'me too' and 'combination drugs' also constitute a major part of the research and development activities of the local industry. South African Druggists issued 23 products during its 1996 financial year, and the majority of these were generic medicines (SAD Annual Report; 1996: 30). Therefore all of the above type of drugs should be considered in this study.

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[10] Interview with Financial Director of the case study company, 15 November 1995.

[11] Generic substitution means that the doctor prescribes a generic drug with the same therapeutic characteristics of the ethical drug.

4.3 Historical performance of the pharmaceutical industry

The pharmaceutical industry has historically experienced significant growth in turnover and earnings in the 1970's and 1980's both locally and on a global basis. This was attributed primarily to the introduction of new products, strong patent protection and the pricing flexibility afforded to the industry during this period. The world's largest market in the pharmaceutical industry, namely that of the U.S, achieved an annual growth rate of 18 % from 1982 to 1992 (Pisano and Wheelwright; 1995: 100). Many analysts agree that the prescription-pharmaceutical industry has been one of the most profitable in U.S. manufacturing in the 1970's and 1980's (McGahan: 1994: 116). The South African pharmaceutical industry has also performed well and recorded turnover growth in 1994 of 14 % over 1993 turnover (Kahonovitz: 1995: 8).

Investment in R & D by pharmaceutical companies is significant and tends to be targeted as a percentage of turnover. F. Hoffmann-La Roche AG (US) spent approximately 15 % of turnover on R & D in 1990 (Comment letters to E 37; 1992; 121), and Eli Lilly and Company (U.S.) spent about 13,5 % of turnover on R & D in the same period (Comment letters to E 37; 1992: 135). Additionally, the investment of public funds in health services has also increased significantly over the last decade. Table 6 details the investment of public funds on research in health services as determined by surveys conducted by UNESCO between 1982 and 1992.

Tables 6 - Public Funds invested on R & D in Health Services

COUNTRY	First reference year 000	Latest reference year 000	% of total public funds invested in R & D in the latest reference year
Canada ($)	194 000 (1986)	337 000 (1992)	9,5 %
U.S ($)	4 455 000 (1982)	7 936 000 (1988)	12,8 %
Japan (Yen)	38 335 (1986)	44 068 (1988)	4,7 %
France (Franc)	1 377 000 (1980)	3 546 000 (1991)	*4,4 %
U.K. (Pound)	190 000 (1986)	292 000 (1991)	5,8 %
Australia ($)	237 852 (1986)	346 700 (1990)	*12,3 %

* This represents the percentage of total public funds invested in health sciences in the 1st reference year, as this information was not available for these countries in the most recent year of reference.

It is evident from the above table that the government of the major countries invest a significant amount of their resources on R & D in health services

Pharmaceutical companies are dependent on available resources, especially cash, to conduct research and development. Therefore the growth of the industry is driven to a large degree by the availability of cash of manufacturing pharmaceutical companies. Historically the multinational pharmaceutical companies have been highly cash flush, because of the significant profit margins they were able to achieve. The price pressure now being placed on the industry by state and HMO's is likely to have negative effects on cash flow in the future, thereby reducing the resources available for high quality health care research and development.

Judy Lewent, CFO of Merck & Co., in an interview with Nichols (1994: 90) identifies the paradox of the pharmaceutical industry as the following:

"The route to success is to put more money at risk."

4.4 Current accounting practice in the industry

The research conducted to date has failed to identify any pharmaceutical company in South Africa or elsewhere that has capitalised development costs. South African Druggists Limited and The Premier Pharmaceutical Company Limited are the two major players in the South African pharmaceutical market. Pharmaceutical sales to the private market in 1994 was approximately 73 % of total pharmaceutical sales and South African Druggists and Premier held approximately 9 % and 10,2 % of the private sale market share in July 1995 respectively (Kahanovitz: 1995: 6). Adcock Ingram and Roche are the only two other local pharmaceutical companies that hold more than a 5 % share of the market and the rest of the market is highly fragmented (Kahanovitz: 1995: 6).

A review of the 1996 annual financial statements of South African Druggists, Premier Pharmaceuticals and Adcock Ingram revealed that only the latter acknowledges the capitalisation requirement of AC 122. The first two companies have both adopted an accounting policy of writing off research and development costs as incurred. Adcock Ingram has the following accounting policy for research, development and related expenditure in its 1996 annual financial statements:

> "Expenditure on research is charged to operating income in the year in which it is incurred. Development expenditure is also charged as operating expenditure in the year in which it is incurred unless the viability of the future product is assured in which case it is capitalised. Capitalised development costs are amortised over the expected future life of the related products."

Further investigation of the 1996 balance sheet of Adcock Ingram revealed that no capitalised development costs exist. This supports the suggestion by Rogerson (1996: 6) that companies are not capitalising development costs because of the difficulty associated with doing so. Comment letters received to Exposure Draft E 37 from pharmaceutical companies include F.Hoffman-La Roche AG (Swiss), Johnson & Johnson, Abbott Laboratories and Eli Lilly and Company (all U.S). All are opposed to the capitalisation of development costs and currently do not do so.

The strong profits achieved by pharmaceutical companies in the past have made it unattractive to capitalise R & D costs. They prefer to absorb research and development expenditure when profits are high, rather than to defer these costs to future periods, when the amortisation of the asset may have a cumulative impact on poor profits. The capitalisation of development costs may become a more attractive alternative to the industry if the future decline in profits, predicted for the industry by McGahan (1994: 117), materialises.

Furthermore, very few South African pharmaceutical companies have complied with the disclosure requirements of AC 122. Neither South African Druggists Limited nor Premier Pharmaceuticals Company Limited disclosed total expenditure on research and development in their 1996 audited annual financial statements and both were issued unqualified audit reports. This requirement is the easiest to comply with and the most important of the new disclosure requirements, as it informs investors of the efforts made by the company to ensure success in the long term through continued investment in R & D.

4.5 Factors influencing the pharmaceutical industry

4.5.1 Health care reform

The pharmaceutical industry world wide has undergone major changes since 1993. The emergence of Health Maintenance Organisations and proposed health care reform in the U.S. and locally are placing increasing price pressure on the pharmaceutical industry. Since 1993 President Clinton has called for health care reform in the United States. His proposals address the need for controlling health care costs and ensuring health care is available to all U.S. citizens (Holmes; 1993: 40). One of Clinton's major proposals involves the creation of a National Health Board that is expected to impose price restrictions on the industry and discourage the use of drugs that it believes to be excessively priced. Judy Lewent, Chief Financial Officer of Merck & Co.[12], (Nichols; 1994: 99) believes that this will act as a disincentive to

[12] Merck & Co. is one of the largest pharmaceutical manufacturing companies in the US and worldwide.

pharmaceutical companies to take on the high risk, high cost research that results in medical breakthroughs, and that the quality of health care will stagnate.

In South Africa, proposed health reform includes the mandatory prescription of generic drugs by doctors and the imposition of limitations on the dispensing of medicines (Financial Mail; 1996: 69). Both provisions are an attempt to reduce the costs of health care to recipients, thereby making health care affordable to the entire South African population. The effect of making generic name prescription mandatory is to ignore the intellectual property rights, including patents and trademarks acquired by companies. The second provision prevents a doctor from administering any prescription pharmaceutical product to the patient. More recently the South African Minister of Health, Dr Zuma, has permitted duty free importing (parallel importing) of medicines from other countries and this has resulted in "dumping" in the South African market. An example of this is South African Druggists (SAD) loss of the State's penicillin tender to an Indian manufacturer in 1996. 'The intended benefits to be derived from parallel imports of cheaper medicines are questionable unless these products are subject to the same rigorous controls as locally manufactured products. Failure to do so could see the influx of counterfeit and sub-standard medicines, as has happened in Africa' (Adcock Ingram Annual Report;1997: 6).

The main concern with the proposed health care reform both in the U.S. and locally is that novel ethical drug research is discouraged. The main incentive to performing high risk, novel research is the enormous benefits that result from this type of product, if it is successful. If the amendments described above are adopted they will have the effect of diluting the future revenue of ethical drug developments, thereby discouraging continued investment in ethical drug research and development.

4.5.2 The generic trend

In the United States the Waxman Hatch Act of 1984 simplified the requirements for the FDA's approval of generics (McGahan: 1994: 115).

A generic has already been defined as a copy of the therapeutic active ingredient of a novel drug once the patent on the original has expired (Adcock Ingram; 1993: 18).

The generic will contain the chemical entity of the original product, but may use different non-active ingredients and different production techniques.

The Health Maintenance Organisations strongly favour the use of generics as a method for containing health care costs. Additionally, McGahan (1994: 117) notes that the patents on many major drugs are scheduled to expire between 1994 and the year 2000. Pisano and Wheelwright (1995: 100) estimate that patents on branded drugs in the US with annual sales of approximately $20 billion will expire in the 1993 to 1999 period and that generic substitutes are expected to capture a significant share of these sales thereafter. This means that leading companies will have to integrate increasingly into the generic market in order to maintain historic levels of revenue. The generic drug is typically priced at 30 % to 60 % below the novel "ethical" drug and offers health care at affordable rates to a much broader spectrum of the population (Pisano and Wheelwright; 1995: 100). By 1993, roughly half of all prescriptions in the United States were filled with generics, as measured by the Standard and Poor's industry survey, up from approximately 2 % in 1980 (Pisano and Wheelwright; 1995: 100). In the decade ending 1992, generics sales grew from 21 % to 43 % of all United Kingdom based written prescriptions and are expected to grow to 50 % by 1995 (South African Druggists; 'Druggists Digest'; 1994: 16).

A study conducted by Kahanovitz (1995) on the pharmaceutical industry in South Africa revealed that in 1994 strong sales growth occurred in the public sector. Simultaneously the private sector experienced increased membership of medical aid schemes. Medical schemes, HMO's and government, with their emphasis on cheaper healthcare, have concentrated their bargaining power, and are largely responsible for the new sustainable levels achieved for generic sales in South Africa.

Table 7 - Sales breakdown of the South African pharmaceutical industry

	1994 - Actual	1994 - % of private market sales	1999 - Estimated	1999 - % of private market sales
PRIVATE MARKET SALES	72,9 %	100 %	71 %	100 %
Ethical drugs	34,4 %	47,18 %	26,1 %	36,76 %
Generic drugs	8,3 %	11,38 %	13,0 %	18,31 %
Self-medication drugs*	30,2 %	41,43%	31,9 %	44,93 %
PUBLIC MARKET SALES	27,1 %		29,0 %	

SOURCE (Kahonovitz; 1995: p.8)

* Self-medication drugs can be obtained without a prescription, whereas ethical and generic drugs can only be purchased with a valid prescription.

Table 7 breaks down market sales in the South African pharmaceutical industry between sales made to the private sector and the public sector. From this it is evident that the mix of total drug sales is expected to change significantly over the five year period ended 1999. The percentage of total sales to the private market is expected to decline in favour of sales to the public market. Additionally, generic drug sales are expected to obtain an increasing share of the private market at the expense of ethical drug sales.

In 1994 total sales revenue of pharmaceuticals in the South African market grew by 14 % over 1993, of which 72,9 % of sales were made to the private market. Public sector sales grew by 20 % over the same period and comprised 27,1 % of the total market (Kahanovitz; 1995: 8). Public sector sales are made primarily to public, provincial and local authorities and to Health Management Organisations. No breakdown of the sales to this market were available, but the low cost emphasis of these organisations makes it probable that the majority of these sales comprise generic drugs.

In 1994 generic drug sales in South Africa represented 11,38 % of total sales to the private market and 19,44 % [8,3 \ (34,4 + 8,3)] of prescription drugs sold to the private market. Total generic sales achieved a 36 % rand growth in sales on 1993 sales as compared to a 5 % rand growth in ethical drug sales over the same period (Kahanovitz; 1995: 8). Kahonovitz (1995) predicts that 1999 private sales will be represented 18,31 % by generic drugs and 36,76 % by ethical drugs, compared to 11,38 % and 47,18 % respectively in 1994. This means that generic drug sales are expected to constitute approximately 33 % [13,0 / (26,1+13,0)] of total prescription sales made to the private market by 1999. Actual sales of generic drugs increased by 9 % in the 8 months to August 1995 and represented 25 % of total prescription drug sales (SAD Annual Report; 1996: 14). South African Druggists believe that generics will ultimately represent 50 % of the total pharmaceutical prescription market, thereby bringing South Africa in line with pharmaceutical markets in the major first world countries.

The generic drug cost structure is significantly less than that of the ethical drug, mainly because the efficacy and safety of the chemical ingredient has already been demonstrated. The high risk and costs associated with researching an ethical drug is avoided when a generic drug is developed. The regulatory requirements before a generic drug can be approved are less stringent than those for ethical drugs, thereby resulting in a shortened development life cycle. These differences mean that, when accounting for research and development expenditures, the concerns may be different and have different emphases depending on whether the drug being developed is a generic or an ethical drug.

The rapid growth of generics in the South African market makes it imperative that this study also focus on the research and development aspects of the generic product, and in so doing, highlight its differences from the ethical drug.

A further observation is that the industry has experienced a shift from product on product competition to therapeutic on therapeutic differentiation. Historically,

pharmacy benefits business that provides management to managed healthcare companies and medical scheme administrators. Its functions include performing on-line drug utilisation reviews, formulary management, and the compilation, interpretation and dissemination of outcomes information for assisting in the development of disease management and treatment protocols (South African Druggists Annual Report; 1996: 31).

SAD has also established 44 Medicross centres across the country, used by approximately 140 000 medical and dental patients monthly, and dispensaries have been established in 28 of the centres. These dispensaries create an outlet for promoting the use of products manufactured by SAD and its related companies. The objective of these clinics is to provide overall health care at a cheaper cost to the individual, medical aid fund or the employer. In the future members will be permitted to buy health care at a fixed monthly amount known as a capitation program. In return the member may only use a Medicross clinic or a doctor with whom the company holds a preferred provider agreement. The clinic and the PBM companies create limited formularies or lists of drugs that the physicians are encouraged to prescribe, and generic substitution is encouraged where appropriate.

Chief Executive Officer, Roy Vagelos, of Merck & Co., argues that vertical integration into PBM companies provides pharmaceutical manufacturers with the ability to improve the quality of health care at lower costs and to increase market share (Nichols; 1994: 110). Greater market share is obtained by sacrificing margins in return for increased turnover volumes by offering overall health care to the patient. Vertical integration is likely to have a number of implications for pharmaceutical R & D. These acquisitions are expected to assist the manufacturer to develop more effective drugs, utilising the large databases of the management company, and to achieve maximum usage of their drugs. Vagelos (Nichols; 1994: 110) also recognises that the marketing strategy of pharmaceutical companies needs to be reconsidered. Traditionally, pharmaceutical companies marketed their products by sending medical representatives to doctors' offices. The emergence of managed care and PBM's, and their ability to prescribe and dispense medicines, means that

It is unknown how much information is needed before a patent can be secured, and how the Patent and Trademark office in the U.S. will grant patent protection to gene developments. Because gene fragments are currently in public databases, the possibility exists that the patent application may be rejected as prior art, making the full gene unpatentable. If the benefits of patent protection are lost, R & D spending may decrease, thus affecting the quality of new drug developments. It would be reasonable if the Patent and Trade office were to allow exclusive rights to a company provided that it has read the full gene's code and understands how it works in the body (Carey, Hamilton, Flynn & Smith; 1995: 42).

Gene sequencing is anticipated to revolutionise the pharmaceutical industry. If the patent protection that currently exists is applied to gene developments, increased R & D activity, with shorter development life cycles and higher success rates is likely to result. It is however unlikely that the gene sequencing trend will have any significant impact on the current South African market because SA pharmaceutical manufacturers do not currently undertake any major form of drug research. Accordingly, the consequences of this type of development activity are not considered in the remainder of this research.

4.6 Factors affecting R & D in the pharmaceutical industry

A number of factors directly affect the risks and returns relating to R & D activity in the pharmaceutical industry. These are discussed in the remainder of this chapter.

4.6.1 Patent law in the pharmaceutical industry

Patent protection exists for a period of 17 years in the U.S (Holmes; 1993: 42) and 20 years in South Africa[14] from registration of the patent. Patent protection takes two forms. The first type of patent is where the company patents a new chemical entity in its expected use, e.g. in the cure of cancer. The second type of patent is that whereby

[14] Interview with Regulatory Affairs Manager of the case study company, 15 November 1994

a company patents the delivery system[15] of the product.[16] The manufacturing process of the product is adjusted so that the traditional delivery is replaced with a sustained release delivery system.[17] The research and development life cycle reduces the commercial patented life of the product, making speed to market critical if the company hopes to recover its investment before the patent life expires. Assuming that a company registers a patent in South Africa 4 years into the R & D process and it takes a further 6 years to complete, the product will have 14 remaining years of patent protection. It is possible for a company to obtain an extension of a patent, but in such a case the timing of the extension application is critical to successfully extending the income stream of the patented product. If a company with a patented product expects generic competition when the patent expires, good timing may extend the patent life of the drug to the company. Using the same fundamental inputs of the product, but developing a new delivery system would do this. The company can then patent the product in the new delivery process, and provided that it is the first to do so, will benefit for many more years from the sale of the drug. Timing is critical, because to patent the new delivery system too early would cut short the market life of the original patent.[18]

4.6.2 Regulatory influence on the industry

The presence of regulatory control significantly affects the timing and extent of future economic benefits to be derived from R & D activity. The Thalidomide disaster[19] of the 1960's resulted in increased regulation of the South African pharmaceutical industry in the form of the Medicines Control Council (MCC), established in 1965.

The regulatory authority in South Africa, the MCC, must approve any medical product for registration before it can be sold. The Medical Control Council Act 101 of 1965 specifies that the MCC shall consider the safety, quality and efficacy of a

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[15] Delivery system refers to the method by which the drug is administered to the patient.
[16] Interview with the Financial Director of the case study company, 16 November 1994
[17] This method of delivery results in the drug being released into the body over a longer time period.
[18] Interview with Business Development Analyst, case study company, 13 November 1995.
[19] The thalidomide disaster resulted in a number of deformed babies, because of the medication taken by pregnant mothers to overcome nausea.

medicine before granting registration approval. Efficacy refers to the determination of the most qualified dosage, and requires that the drug, in its recommended dosage, performs sufficiently well to warrant the approval of its registration application. To prove efficacy, clinical trials test the drug against a placebo which is identical to the drug in appearance, but which has no active ingredient. All clinical trials compare the drug in question to a placebo, unless another approved drug is available against which the new drug can be tested. The stringent requirements governing clinical evidence prolong the development process and increase development lead time to market. Even once all the statistical data from the clinical trials is available, the registration process can take approximately eighteen months to two years. This time period assumes that no major complications will arise during the approval process and the average period for the development of an ethical drug before it gets to market approximates twelve years (McGahan; 1994: 117). The MCC also has no firm rule regarding unacceptable patient quotas for clinical trials, but decides on each case on its merits. When proving efficacy of a drug it is necessary to disclose the number of patients treated in each claimed indication, the period for which they were treated and the dosage administered. The MCC will sometimes approve and permit the registration of a new drug, but will use the safety period demonstrated in the clinical trials to limit the time period that the drug may be registered. Therefore, if safety of the drug has been proved over a two year administration period, registration may be limited to a two year period.[20]

The MCC in South Africa has enormous powers to regulate issues pertaining to the manufacture, testing, storage, sale and advertising of medicines.[21] These powers mean that excessive demands by the MCC can significantly influence the ultimate cost structure of a product, eliminating margins and rendering the product commercially non feasible.

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[20] Interview with R & D Business Development Analyst, Case study Company, 15 November 1995.

[21] Interview with Regulatory Affairs Manager of case study company, 13 November 1995.

No changes may be made to the product once application has been made without the prior approval of the MCC. This includes a change in the source of active or inactive raw materials, packing materials, manufacturer or packer. It also applies if the testing laboratories are changed or if any change occurs in the manufacturing process or control procedures. Any change requires stability data and any additional claims made of the medicine must be proved.

The registration application is made in two stages. The purpose of the first stage is to eliminate obviously unacceptable submissions before the full application is compiled. The MCC usually takes 9 to 12 months to respond, following which the replies of the applicants to queries are assessed. The assessment of clinical trials usually lasts an additional 9 to 12 months. Therefore the minimum average period for registration is two years, except in the case of generics where 15 months is the average time period. Non-approval can occur if the MCC takes such a resolution. In such cases additional data is usually required to support the safety or efficacy aspects of the drug, and a distinction must be drawn between the original submission and the new data submitted. This information is evaluated by the MCC taking a further 9 to 12 months before completion. Therefore in cases of initial non-approval the period between final development and commercialisation can be as long as 3 years. When time to market is of the essence, this prolonged registration period may eliminate the viability of commercialising the product. It is not unusual in the pharmaceutical industry for a product that is technically feasible to never be marketed commercially.[22]

Two methods of speeding up the registration application process have evolved over recent years and are being used more frequently.
The first is the Pharmaceutical Evaluation Report (PER) scheme. This method applies to applications for products registered within the last 3 years in a country that is a signatory to the PER scheme. The procedure involves an exchange of PER reports between the regulatory authorities of the two countries. If the second country accepts the PER report of the first country, approval for registration will usually take 6 to 8 months. This scheme is only applicable to applications for new chemical entities.

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[22] Interview with R & D business analyst, Case study company, 15 November 1995.

The second method is the Abbreviated Medicine Review Procedure (AMRP). This method applies to medicines registered in selected countries within the last 2 years, provided that good quality comprehensive expert records are available from the UK, US, Australia, EEC, Sweden or Canada. Obtaining and providing the expert report can take between 4 to 6 months and in addition to this the MBR1[23] application must still be submitted even though only the expert report is evaluated. If the expert report is considered to be inadequate a request will be made to submit a full MBR1 report which will take a further 9 to 12 months to evaluate.

It is clear that the registration process described above may cause significant delays in marketing the new product once development of the product is complete. Additionally, if the period between final development and registration approval is too long it may no longer be financially feasibly to market the product. The costs of setting up full scale production facilities may not be recovered if the remaining patent life is too short. Therefore the impact of registration application on the future marketability of the drug should be considered when predicting the probability of future economic benefits. Most of the local drug manufacturers have had sufficient experience with the MCC to predict fairly accurately the expected response to their application for registration.[24]

4.6.3 Joint venture & other licencing partnerships

The South African drug manufacturers tend to get involved in joint venture projects with overseas partners. The commonly quoted price of developing a drug, inclusive of failures is $359 million in the United States (Nichols: 1994: 89), whereas in South Africa the cost is significantly lower at approximately R50 million for a novel drug[25]. The lower cost structure of the drug developments of South African companies is because they seldom get involved in the biotechnology stage of the development process. They prefer to buy a right to the new chemical entity, once the

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[23] The MBR1 application includes comprehensive sections covering pharmaceutical, clinical and pharmacological trials.
[24] Interview with R & D business analyst, case study company, 15 November 1995.
[25] Interview with Financial Director of case study company, 15 November 1995

initial testing on animals has been performed. An alternative to buying the rights of the new chemical entity is for South African companies to assist an overseas partner by performing certain clinical trials in lieu of an access payment (Adcock Ingram; 1993: 9). When registration application is made, the two countries each produce dossiers of the clinical trials that they have performed and these are used to support the local application of both companies. Usually this type of agreement results in the South African company obtaining territorial rights to certain areas, and a royalty stream for sales made to non-territorial areas. In South Africa, S.A. Druggists, Adcock Ingram and Premier Pharmaceuticals together hold approximately 25 % of the South African private sector market share and all undertake a significant amount of local drug formulation. The former two companies are both involved in joint ventures with overseas partners, the agreements taking one of the forms described above[26].

These joint venture projects significantly reduce the overall risk and cost to the South African based company when compared with the average costs incurred by the multinational pharmaceutical manufacturer. Accordingly, the probability of future economic benefits flowing from development activity is likely to be higher for SA pharmaceutical manufacturers than the pharmaceutical companies that perform research from the biotechnology stage.

4.6.4 Marketing intention

A further factor that affects the magnitude and time span of future economic benefits arising from R & D in the pharmaceutical industry is that the South African pharmaceutical manufacturer may develop a generic drug with no intention of ever marketing it. This may be done for strategic reasons, to be used as a bargaining tool to prevent a competitor from entering a therapeutic market of the developer.[27] Alternatively, the drug may be developed with every intention of marketing it, but time between the development and commercialisation of the drug may be significantly longer than usual. The registration process described in the previous section may cause significant delay, which renders commercialisation non-feasible. This may also

[26] Adcock Ingram perform collaborative development with Baxter, Kabi-Pharmacia, Astra, Leo Laboratories, Jeyes, Mundipharma and Helene Curtis (Adcock Ingram; 1993: 9).

[27] Interview with Clinical Scientist of the pilot company, 26 October 1994.

occur in the situation where a joint venture contract is due to expire and the company intends to market a locally developed substitute. In this case the company cannot register the product because approval thereof prior to the expiry date of the joint venture contract would constitute a breach of contract. Therefore the lead-time to market is still further extended, and the risk of capitalising the development costs incurred in this scenario is heightened still further.

A further reason for developing a product with no marketing intent may be because of the existence of the MCC since 1965. The problem arose as to how to deal with old medicines that existed in the market prior to the 1965 Medicines Control Act. The MCC ruled that they would be entitled to call up all old medicines by class, whereupon the manufacturing company would need to demonstrate the safety and efficacy of the old drug. Shortly after the ruling it was rumoured that medicines containing tartrazine would be banned from the market. A manufacturing company developed and registered a large range of substitutes for their existing tartrazine affected products[28]. The Medicines Control Council approved all the substitute drugs, but to date none of the substitutes have ever been marketed. In such a case it would clearly be misleading to capitalise development costs in expectation of future economic benefits.

4.7 Conclusion

The pharmaceutical industry has and continues to undergo major change. As the environment in which it operates continues to become more competitive each participant in the industry will rely increasingly on new drugs for continued success.

The challenges facing the industry together with the intensity of research and development required, makes it the ideal target for a study of the application of the statement for accounting for research and development costs, AC122.

The following chapter describes the methodological approach and design employed to address the research questions.

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[28] Interview with Research and Business Development Analyst of the case study company, 15 November 1995.

5. RESEARCH METHODOLOGY

5.1 Introduction

This chapter briefly describes the case study approach to research and the conditions under which this is considered to be the most appropriate research strategy. This is followed by a discussion of the research design. Finally, the way in which the data will be analysed and reported is described.

> "The case study is but one of several ways of doing social science research. Other ways include experiments, surveys, histories, and the analysis of archival information. Each strategy has peculiar advantages and disadvantages, depending upon three conditions:(a) the type of research question; (b) the control an investigator has over actual behavioural events, and (c) the focus on contemporary as opposed to historical phenomena" (Yin: 1994).

5.2 Research methodology

The case study technique for accounting research incorporates descriptive, illustrative, experimental, exploratory, and explanatory research (Ryan, et al: 1992). This study is primarily exploratory in nature, and represents an investigation into the practical difficulties associated with the implementation of AC 122 generally, and specifically in the pharmaceutical industry.

The case study research strategy has often been criticised as a weak method of performing research, lacking in precision, objectivity and rigour. A case study, like all other methods of research, has advantages and disadvantages. Yin (1994) states that case studies are generally the preferred strategy when "how" or "why" question are posed, when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real-life context. The unique strength of

the case study approach is its ability to deal with a full variety of evidence beyond what might be available in the conventional historical study. Because of the contemporary nature of events, direct observation and interviewing can be additional sources of evidence.

5.3 Research design

Case study research literature including Yin (1994) and Ryan, Scapens and Theobald (1992) provided guidance to the design of the research methodology. The main issues considered were:

- the propositions of the study;
- the unit of analysis;
- data collection, and
- analysing and reporting the evidence.

5.3.1 Propositions of the study

Yin (1994) describes the proposition as the component of the research design that directs attention to something that should be examined within the scope of the study. The research problem identified is the lack of implementation of the requirements of AC 122 and IAS 9 by preparers of financial statements. The result of an in depth study of IAS 9 (revised), AC 122 and the literature lends support for the following proposition of the study:

> The reason for the lack of implementation of IAS 9 and AC 122 is because of the conceptual and practical concerns associated with such implementation. The conceptual and practical concerns are best investigated within the following three areas:
>
> - the allocation of R & D costs;
> - the capitalisation of development costs; and
> - the amortisation of the development asset.

5.3.2 Unit of analysis

Case study research will adopt either a single case design or a multiple case design to address the research question. The specific design for this case study is a single-case design. Yin (1994) identifies the single case design as appropriate if it represents a critical case, a unique case or a revelatory case[29]. The single case as an exploratory device or as a pilot case in the conduct of a multiple-case study may also be appropriate. It differs from the multiple case design to the extent that the latter adopts a replication logic. This replication logic is analogous to a few critical experiments that provides more compelling evidence and is therefore regarded as being more robust. Each case should serve a specific purpose within the overall scope of inquiry. Therefore multiple case studies are usually used to compare the results of a number of single case studies to see if all of the studies (a) support similar results, or (b) produces different results for predictable reasons.

The stated objectives of this case study are to identify problems associated with the implementation of AC 122 in the pharmaceutical industry, and attempt to develop industry specific guidelines to assist with the implementation of AC 122. Therefore, the research is primarily exploratory in nature and does not attempt to provide support for a developed theory. Accordingly, replication will serve no purpose in this study and the multiple case study design is not considered to be appropriate. Two additional reasons favour the use of the single case study approach. Firstly, the nature of R & D activity in the pharmaceutical industry is of such a sensitive nature, that strict confidentiality is imperative. Secondly, the pharmaceutical manufacturing companies in South Africa all undertake similar R & D activity, and the multiple case study approach is unlikely to reveal any significant problems not identified in the single case study approach.

Because of the sensitive nature of the data relating to R & D activities in a R & D intensive industry like the pharmaceutical industry, the question of case anonymity

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[29] critical case: used to test a well formulated theory.
extreme / unique case: very rare in occurrence.
revelatory case: investigator has an opportunity to observe and analyze a phenomenon previously inaccessible to investigation.

needs to be considered. At the request of the case study company, its identity is to remain anonymous. Similarly, interviewees of the case study are also to remain anonymous, unless the information is already in the public domain and therefore of no threat to the R & D activity of the case study company.

5.3.3 Data Collection

A pilot study was conducted prior to performing the case study. The objective of the pilot study was to identify the practical difficulties of implementing AC 122 in the pharmaceutical industry in broad terms. Interviews were held with the Financial Accountant, Clinical Scientist, and Drug Developer of the pilot company. This assisted in the preparation of the detailed questions to be posed to the case study company. Both the pilot study company and the case study company were selected because of their willingness to disclose sensitive information (subject to confidentiality and anonymity), and the nature of their R & D activities. Additionally, geographic proximity and the benefit of previous personal contact made the conduct of the pilot case study possible. The main criterion used to select the case study company, but not necessary in the selection of the pilot study company, was its willingness to apply the requirements of AC 122 fully. This was necessary (a) to confirm the continued viability of the research problem, and (b) to maximise the commitment of the case study company to the research effort. If the company does not wish to apply the requirements of AC 122 fully, then the lack of application may not be because of the practical difficulties of doing so, but because implementation is not desired.

Three sources of evidence were used in this study, namely (1) interviews, (2) direct observation, and (3) documentation in the form of newspaper clippings and articles appearing in professional magazines. The nature of R & D activity in the pharmaceutical industry is currently a popular topic of the media and this source was used primarily to corroborate and augment the evidence obtained from the interviews.

the initial objective is to address the application issues at a more general academic level, the proposed application of the standard will be specific to the pharmaceutical industry and will identify problems that are specific to that industry alone.

The general implementation problems identified in chapter three may be of interest to other R & D intensive industries, but it is unlikely that the guidelines developed to assist with the implementation of AC 122 in the pharmaceutical industry can be generalised. It will however provide an example for developing such guidelines on an industry specific basis in the future.

The reliability of a research study is its ability to provide consistent results. Therefore the objective should be to minimise the errors and biases in a study. In order to enhance the ability of replicating this case study, all documentation used to corroborate the results obtained from the interviews has been organised in a systematic way. Additionally, the procedures taken to establish contact with the case and pilot study companies, and the method used to establish feasibility of the study have also been documented together with the results of the interviews conducted. A copy of the original letter sent to potential case study candidates is included in appendix B.

5.4 Analysing and reporting the evidence

The proposition of the study is stated above as:

> The reason for the lack of implementation of IAS 9 and AC 122 is because of the conceptual and practical concerns associated with such implementation. The conceptual and practical concerns are best investigated within the following three areas:
>
> - the allocation of R & D costs;
> - the capitalisation of development costs; and
> - the amortisation of the development asset..

Therefore, in analysing the data collected during the study, the evidence is considered in relation to this proposition. The implementation problems identified are separated into three main categories and each is reported in a separate chapter, viz., chapters six through eight. The evidence is presented in each chapter by describing the problems identified within each main category from the case study company. Where applicable, this is followed by a description of current practice or methods used by the case study company, thereby putting the problem into context. Finally, recommendations are made in the form of industry guidelines for overcoming the problems. These guidelines are developed after careful consideration of the environment within which the pharmaceutical industry conducts R & D, and are therefore specific to the industry.

5.5 Conclusion

This case study research is exploratory in nature. No known previous work has been conducted in this area of research and accordingly the main contribution of this study is found in its exploratory findings. It also raises the question as to the adequacy of accounting standards, specifically AC 122, in South Africa.

The following three chapters address the implementation concerns associated with the implementation of AC 122 in the pharmaceutical industry.

6. THE ALLOCATION OF R & D COSTS

6.1 Introduction

The focus of this chapter is on the major problems of cost allocation associated with implementing AC 122 in the pharmaceutical industry. The problems identified are discussed, and where applicable, current methods used for allocating R & D related costs by the case study company presented. Finally, recommendations are suggested to assist preparers of financial information to overcome these cost allocation problems.

6.2 The cost allocation problem

In the United States, the accounting standard for R & D costs does not permit the capitalisation of development costs. Both research and development costs are written off in the same year as incurred. Therefore, very little guidance exists in the U.S. literature as to how to allocate the costs incurred on R & D activity between research and development. However, the requirement of SFAS 2 and the original IAS 9, to separately disclose R & D expenditure, has resulted in much literature concerning the best accounting and costing methods to use to achieve accurate disclosure of the amount of R & D expended in the accounting period (McGregor: 1980; Gridley: 1974; Gellein & Newman: 1973). Gridley focused on obtaining understandable definitions of R & D and the activities and costs to be reported as R & D. A corollary to ensuring that all R & D expenditures are included in the R & D cost category, is ensuring that no non- R & D costs, such as production costs, are included in these costs.

The requirement of IAS 9 (revised) and AC 122 to capitalise development costs, subject to satisfying the specified criteria, now means that research costs and development costs will not always be accounted for on the same basis. Whereas previously no allocation of costs between research and development was required, now this is a necessary if compliance with AC 122 is intended.

Research costs should be expensed, and development costs of a project or product should be capitalised if the five criteria of para .18 of AC 122 are satisfied. The first criteria of para .18 require that "the product or process is clearly defined and the costs attributable to the product or process can be separately identified and reliably measured." ED 120, the proposed new statement for intangible assets, states in para .19 that an intangible asset (including internally generated development assets) should only be recognised as an asset if:

a) it is probable that future economic benefits specifically attributable to the asset will flow to the enterprise; and
b) the cost of the asset can be measured reliably.

Therefore, irrespective of whether AC 122 will continue to apply in SA or whether ED 120 is eventually adopted by SAICA, the costs of the development assets should be separately identifiable and reliable measured. Therefore if a company seeks to capitalise its development costs, its costing system should support the following objectives:

1. the allocation of R & D costs between research costs and development costs; and
2. the accurate accumulation of these costs at a product or process level.

6.2.1 The allocation between research costs and development costs

The employees of the case study company interviewed, expressed concern regarding the practical difficulties of separating research costs from development costs on a product basis. The financial director indicated that the company makes no effort to separate research costs from development costs, even though the capitalisation of development costs is desirable.

The case study company is not the only company that fails to separate research costs from development costs. During the conduct of this study, the author reviewed the 1996 annual financial statements of 30 companies from a wide range of industries (the companies are listed in Appendix A). The following observations support the

view held by the author that very few companies in South Africa distinguish research expenditure from development expenditure:

- All of the companies that disclosed R & D disclosed the two costs as one cost category.

- The accounting policy for research and development costs for the majority of the companies' stated that "research and development costs are written off in the year incurred." Where this is the selected accounting policy, no need exists to separate research costs from development costs.

- All of the companies with an accounting policy of capitalising qualifying development costs have written off all such costs. Therefore, no development asset exists on the balance sheet of these companies.

Davies (cited in Garbutt: 1989) made a similar observation from a survey conducted of R & D establishments in the UK. His survey showed that only one third of the companies were able to distinguish in their control systems between the costs of research and those of development. He noted that this is in any event only required for outside reporting purposes if the company intends to capitalise development costs. If research costs and development costs are both expensed as incurred, the failure to separate these costs has no effect on either the income statement or balance sheet.

6.2.2 Recommendation

AC 122 requires the separation of research costs from development costs based on the type of activities that lead to these costs. The lists in paragraphs .09 and .10 are relatively easy to apply to R & D activity in the South African pharmaceutical industry. Because South African pharmaceutical companies do not perform the basic research performed by the biotechnology companies abroad, they will seldom carry out research activities as defined in para .09 of AC 122 (this list was reproduced in chapter two). The current trend of South African pharmaceutical companies, whereby they enter into joint venture agreements, and obtain a licence to develop a compound

products simultaneously, between research activity and development activity, at an individual project level.

A second problem identified is the difficulty of allocating patent and overhead costs between R & D projects.

2. **How to distinguish development activities from non-development activities**
   Another problem identified is the lack of consensus that exists between the case study company and some of South Africa's other major pharmaceutical manufacturers as to whether a generic drug developments constitutes a "routine effort to refine, enrich or otherwise improve on the qualities of an existing product", and therefore not development as defined.

3. **How to account for marketing costs incurred in the pharmaceutical industry**
   Marketing costs are incurred at various stages during the development process. The issue to be resolved is how to account for the market research costs incurred prior to development of the product as compared with those marketing costs incurred prior to the launch of the product. IAS 9 (revised) and AC 122 offer no guidance for accounting for marketing costs incurred during the development process. ED 120, provides some guidance for accounting for advertising and related costs. The recommended accounting treatment for marketing costs is discussed in the final section of this chapter.

6.3.1 The allocation of R & D costs between individual R & D projects

"Research and development costs should comprise all costs that are directly attributable to research and development activities or can be allocated on a reasonable basis to such activities" (AC 122: para . 12). Para.13 accordingly requires that R & D costs include:

- salaries, wages and related costs of personnel engaged in R & D activities,
- the cost of materials and services consumed in R & D activities,

- the depreciation of property, plant and equipment to the extent that these assets are used for R & D activities,
- overhead costs related to R & D activities, and
- other costs, such as the amortisation of patents and licences, to the extent used for R & D activities.

The case study company has indicated that it does not allocate R & D costs between individual projects. The difficulty of this requirement is the focus of the following section. Here the actual methods used by the case study company for allocating costs to R & D are examined as a basis for subsequent recommendations. This exercise also identifies the costs that are not included in R & D, but that in accordance with AC 122, should be included.

6.3.1.1 Employment costs

Para .13(a) includes in R & D costs, where applicable, "the salaries, wages and other employment related costs of personnel engaged in research and development activities". Employees, including scientists, engineers and technicians, employed in the R & D function are seldom involved in only one research and development project and are usually involved in multiple developments at a point in time. The direct employment costs of such employees include salaries, retirement benefits, medical aid, sick and leave pay, payroll taxes and any other costs that are traceable to the employee through the payroll system. The indirect costs include expenses incurred when attending seminars, conferences or performing background research related to specific R & D activity, or R & D activity in general. The size of local pharmaceutical companies and the nature of their developments in relation to multinational pharmaceutical companies does not permit the allocation of R & D employees to one project only. The R & D division of the case study company is treated as a separate profit centre from the rest of the company. This enables the company to easily allocate all employment related costs to the R & D activity as a whole, but does not facilitate the accurate allocation of these costs between research activities and development activities on an individual project basis. Therefore the challenge of this study involves determining a method of accurately allocating the

employee costs of employees working on multiple projects, between the research costs and development costs of the various projects

6.3.1.2 Depreciation costs

Para .13(c) of AC 122 requires that R & D costs should include the depreciation of property, plant and equipment to the extent that these assets are used for R & D activities. Historically, the case study company has not allocated depreciation of the machinery to R & D as both the asset depreciation and R & D costs incurred were written off in the year. Now in order to comply with para .13(c), the company allocates any machinery used by the R & D division to an appropriate cost code. Therefore any related depreciation is charged to the division as "R & D: depreciation." However, no attempt is made to allocate this depreciation between the different R & D projects. Nor is any attempt made to separate the depreciation of the asset between research activities and development activities. This would be an onerous task because machinery used on R & D projects in the pharmaceutical industry is frequently used for a large number of product developments and seldom used in isolation on a single product. Therefore a basis for allocating the depreciation charge further between research activities and development activities at an individual project level is required.

6.3.1.3 Overhead costs

Overhead costs are those costs that can not be directly attributed to the product. These would include costs like rent for the factory, electricity, information technology costs, time spent by research employees on research of a general nature, general administrative, registration and other similar costs. Prior to the issue of AC 122, no local accounting standard required that these costs be allocated to R & D. The only reason that the company would have absorbed such costs into the R & D function in the past was if management required a full cost for the project development. Now para .13 (d) of AC 122 states that research and development costs should include "overhead costs related to research and development activities, which are allocated on bases similar to those used in allocating overhead costs to stock." The case study company charges the R & D division with a fixed charge for rent, electricity and

information technology costs incurred by the company. No attempt is however made to allocate any of the overhead costs to projects at either an individual level, or between research activities and development activities. Therefore, the requirement to separately identify and reliably measure the costs attributable to the project is not met. The survey performed by the author (referred to in chapter 1) of the financial statements of 30 listed South African companies, revealed that only one of the companies examined included a description of the bases used to allocate overheads to the R & D function. While this phenomenon does not necessarily imply that companies are not allocating overhead costs to R & D activities, the author believes that it indicates that overhead cost allocation is not in accordance with the requirement of para .13(d) of AC 122.

6.3.1.4 Patent and licencing costs

Para .13(e) includes in R & D costs, "the amortisation of patents and licences, to the extent that these are used for R & D activities" . These costs, particularly licencing costs, are significant in the local pharmaceutical industry, as most of the local manufacturing companies prefer an active in-licencing programme as an alternative to research into new chemical entities. The case study company discloses royalty, licence fees and other similar costs separately from R & D costs and charges these costs to income. This observed failure to include licencing costs in R & D is consistent with the results of a survey conducted by Fisher & Lothian (cited in Garbutt: 1989) on a number of UK companies, in which they found that only 26 % of the companies surveyed included the amortisation of intangible assets in their R & D costs. If compliance with AC 122 is intended, then these costs should be allocated to the R & D costs of individual projects. Patent and licencing costs are usually only incurred once research as defined in para .07 of AC 122 is substantially complete. Therefore, it is unlikely that any of these costs will qualify as research costs, and they should all be accounted for as development costs.

6.3.1.5 Conclusion

The concerns expressed by the interviewees as described above, together with the observations made of current methods used for allocating costs to R & D, indicate

that the allocation of costs in the case study company requires improvement before the correct implementation of AC 122 can be achieved.

6.3.2 Recommendations

The historical and current failure in SA to distinguish research costs from development costs on an individual project basis means that very little practical experience exists for addressing the concerns raised above. Therefore, the recommendations that follow are theoretically based, having given consideration to attempts being made by the case study company.

6.3.2.1 Employment costs

In Table three a breakdown of the R & D costs of four member states of UNESCO revealed that employee related costs make up a significant portion of total R & D costs. The results of an examination of the approximate cost breakdown of four drugs developed by the case study company between 1989 and 1992 are detailed in table eight.

Table 8 - Cost breakdown of pharmaceutical drugs in case study company 1989-1992

Product	Raw material cost	Labour, overhead, machinery, etc
A	0,5 %	99,5 %
B	19,6 %	80,4 %
C	0,7%	99,3 %
D	15,5%	84,5 %

The costs in the table are expressed as a percentage of the total cost for the drug, and because of the sensitive nature of this information, the names of the drugs are not disclosed. The above details were extracted by an authorised employee of the case study company and the researcher was not permitted access to the raw data. This and the fact that the data was prepared based on the current allocation methods employed by the case study, as explained in section 6.3, limits its usefulness for the purpose of

this study. Nevertheless, from discussion with the Financial Director and the analysis performed by UNESCO (depicted in Table three), it would appear that employee costs constitute a major portion of total R & D costs. Accordingly the accurate allocation of employee costs to individual projects, should improve the accuracy of the individual project costs significantly.

The case study company does allocate total labour costs of R & D employees to the R & D division but does not allocate labour costs at an individual product or project level. Because most of the scientists, technicians and other specialist research staff are seldom used on one project, each should keep a record of the projects on which they spend their time. These records can be used to allocate the employees' costs across the projects on which they have worked. Therefore all staff that perform R & D activities should be held responsible for maintaining accurate time control for a specified period. A unique project costing code should be allocated to each project. At the end of each specified time period, the employees performing R & D activities submit their time sheets, indicating the proportion of their time spent on various projects. The total time spent by employees on the respective projects can then be accumulated under the project code. The system design should allow R & D employees to allocate time to general R & D activity, such as attending seminars, conferences or any other activity that does not relate to a specific project. The exact labour costs of the employee can then be charged to individual projects. The charge is calculated by determining the percentage of total labour hours that the employee has spent on the individual projects during the specified time period. All direct employee related costs of the employee should be taken into account when determining the charge to the respective projects. However the indirect employment costs of personnel engaged in R & D activities, such as attending seminars and conferences that relate to R & D activities in general, should not be allocated to individual projects. This is inappropriate (a) because AC 122 does not appear to require it, and (b) because it is unlikely that any specific benefit will be derived from R & D activity. of such a general nature. Additionally, the author does not believe that the benefits derived from allocating these costs to individual projects will outweigh the cost of doing so.

6.3.2.2 Raw material costs

Raw material costs generally make up a small portion of the total development costs incurred on a project in the pharmaceutical industry. The costing analysis of the four drugs developed locally by the case study company, revealed that in all four cases, raw material costs made up less than 20 % of the total R & D costs. For two of these products the raw material content was less that 1 % of the total R & D costs. For product B, with a raw material content of 19,6 %, the rand value of the expenditure was very low and immaterial to the company. Raw material costs spent on development projects are generally easy to manage. The case study company accumulates these costs in a designated project cost code during the routine transaction capture of purchase requisitions and internal store requisitions.

6.3.2.3 Depreciation costs

Another cost not allocated to individual projects by the case study company, is the depreciation of assets used in the R & D process. The main reason for this is that the plant is seldom used on a single project. Rather, any item of plant of equipment is used on a number of generic product developments simultaneously. If the plant or equipment is to be used exclusively on a project, and has no known future alternative use , the allocation of depreciation to the project should be routine. The asset should be identified with the project by allocating it an appropriate costing number. All related depreciation costs can then be included with the other R & D costs of the specific project. The asset should either be depreciated over the life of the asset or the estimated R & D time span of the project, whichever is the shortest.

If the plant and equipment are general purpose, and used on a number of R & D projects, these should be depreciated over the estimated useful lives of the plant and equipment. The depreciation can be allocated to the various projects in a number of ways, including but not limited to the following:

1. The simplest method is to allocate the total depreciation charge for the year equally across all the development projects for which the plant and equipment has been used in that year. Because of the general purpose nature of the plant and

equipment, its life span is not restricted to that of the projects for which it is used. Therefore the depreciation rate used is determined with reference to the useful life of the asset. This method of charging each project equally with depreciation would not be appropriate if a single project makes significantly greater use of the plant and equipment than any other.

2. If the plant and equipment are used disproportionately on the various projects, the depreciation should be allocated to the projects on a usage basis. One way of doing this is to estimate the total usage hours of the plant and equipment over its useful life, and to allocate the depreciation on this basis. Again, time records of total machine hours utilised, and the breakdown of the individual project utilisation of these hours, is required.

Both of the above mentioned methods will ensure that each project that uses plant and equipment is at least charged on a reasonable basis for its usage of the asset on its R & D activities.

6.3.2.4 Overhead costs

The fourth important category of costs to be included in R & D costs is overheads. AC 122 requires that these costs be allocated to R & D costs on bases similar to those used in allocating overhead costs to stock. Therefore these costs can be allocated to individual R & D projects using the traditional methods used for allocating costs to stock.

The case study company does include overhead costs in R & D costs on a predetermined basis. A fixed portion of electricity, information technology and rental costs are charged to the R & D department, but are not allocated between the individual projects of the R & D function.

A number of methods would be suitable for allocating these overhead costs to individual R & D projects. Machine hours spent on an R & D project may be used as the basis for allocating electricity costs to R & D. Allocating rental costs on the basis of floor space required for the project development would also be appropriate.

Therefore, the extent to which each type of overhead cost is included in R & D costs globally and at a project level depends on the bases selected for such allocation. One method currently used by the case study company for allocating registration costs to individual projects is Activity Based Costing. This method identifies the activities that drive the registration costs, and recognises that registration costs are unrelated to normal cost bases such as labour hours and machine hours spent on the project. The identified activities are referred to as cost drivers. Cost pools are identified for each cost driver, and divided by the recurrent activity to determine a cost per activity. The case study company has performed this exercise to enable it to formulate an estimated registration cost per drug development project.

Evidently a number of different absorption bases would be appropriate for allocating overhead costs to individual projects. No method is stated in AC 122 as being better than any other. The author believes that the fact that a company is allocating overhead costs to R & D,. if so, and the basis on which this is done should be disclosed. This will enhance comparability and enable users of the financial statements to fully understand the nature of the costs included in the R & D expense or development asset in the financial statement.

6.3.2.5 Patent and licencing costs

Finally, AC 122 requires that the amortisation of patents and licences also be included in R & D costs to the extent that these are used for R & D activities. The case study company accounts for these costs separately from R & D costs, and does not allocate them to individual R & D projects.

The basis on which these costs should be allocated to R & D costs depend on the projects to which they relate. The costs of patents and licences are seldom general in nature and usually relate to a specific project. Therefore it should be easy to allocate these costs to the specific projects to which they relate. The patent or licence expenses should be amortised to the individual development projects in the same way suggested above for the depreciation of plant and machinery used on specific projects. If the patent relates to an ethical drug, the owner secures sole rights to the product for

the duration of the patent. Historically, successfully developed, patented ethical drugs have earned profits for the entire duration of the patent life. Accordingly, the amortisation period should coincide with the life of the patent, which could last as long as 20 years. Therefore, while the development is still in progress, the amortised patent costs will be included with other development costs for the project, and accounted for in accordance with AC 122. If development is ceased due to unsuccessful activities, the patent costs should be expensed in full immediately. If the development is successfully completed, the patent costs will no longer be included with development costs when amortised, but simply included with other costs in the income statement.

If the company has acquired the right to licence a product, ethical or generic, the amortisation period should be the shorter of the period of the licence agreement or the estimated future economic life of the product.

6.3.2.6 Conclusion

The above recommendations are not an attempt to prescribe the way in which costs should be allocated to individual R & D projects in the pharmaceutical industry. The author has simply attempted to illustrate that allocating costs of R & D to individual projects is possible, and that the costs of a project can be separately identified and reliably measured. It is recognised that the different bases for allocating overheads may affect the total amount of R & D costs disclosed, thereby reducing comparability between companies. However, the limitation on comparability can be overcome provided that each company uses a consistent basis from year to year, and discloses the methods and bases used.

6.4 Development activity or non-development activity

During the initial stages of this research it was noted that some of SA's major pharmaceutical manufactures disagree concerning the type of development projects that constitute "routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product". Bullet 4 of para .11 of AC 122 specifically excludes the "routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product" from research and development activities.

This disagreement could cause significant inconsistency of accounting treatment in the pharmaceutical industry when attempting to capitalise development costs

6.4.1 The generic problem

The specific exclusion of the "routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product" from development activity has resulted in conflicting views in the pharmaceutical industry concerning generic drug developments. South African Druggists (SAD) claim that AC 122 has no impact on its accounting for R & D activities[31], because its development activity does not meet the definition of development costs. They divide their R & D costs into two main categories, viz.:

- "costs incurred in gaining new knowledge - being research as defined in para .07; and
- costs incurred in refining and improving existing products - clearly not development as per examples in para .11."

The specific reference to para .11 above relates to the exclusion of "routine efforts to refine, enrich or otherwise improve on the qualities of an existing product". At the time that Jonathon Henderson of SAD made the above statement, a significant portion of SAD's business was generic in nature. Therefore, at the time that AC 122 was issued, SAD held the view that AC 122 did not apply to its drug developments because generic drug development constitutes a refinement and improvement of existing products.

The Financial Director of Adcock Ingram and the Financial Accountant of Warner Lambert disagree with the view taken by SAD. They believe that generic drug developments do constitute development as defined, and should therefore be capitalised if the requirements of para .18, for doing so, are met.

Three problems of definition arise from the exclusion from development activity of the "routine efforts to refine, enrich or otherwise improve upon the qualities of an

[31] Written response by Jonathon Henderson, Management Accountant, SAD dated 31 October1994, to letter addressed to Mr Lou Morris, Managing Director of South African Druggists dated 06 September 1994.

existing product." Firstly, no guidance exists as to what constitutes a routine and non-routine effort. Secondly, it is uncertain whether activity that refines or makes improvement upon the qualities of an existing product, to be used in a new product, should be included in development activities or not. Finally, it is unclear whether the reference to an existing product refers to an existing product of the company, or to the market at large.

6.4.2 Recommended classification of generic drugs

In chapter five a generic drug was described as a copy of the novel new chemical entity (NCE), once the NCE comes off patent protection. Therefore the generic drug comprises a known active ingredient. In the assessment of whether the generic drug development is part of development activity or not, the following factors are relevant:

- Because the patent life of the NCE has expired, competition in the form of generic drugs emerges. Therefore the company that holds the patent to the original drug should consider whether or not to develop a generic drug in the face of expected competition. The seemingly obvious approach of this company should be to simply reduce the price of its ethical drug, thereby eliminating the huge price differential between the ethical drug and emerging generic competition. However, this approach is not always followed, (a) because the company wishes to maximize the commercial life of the ethical drug at its premium price, and (b) because the company believes that it can introduce a generic that can successfully compete in the lower cost market. Therefore two categories of generics emerge, namely,

    a) a generic of the company's own ethical drug; or
    b) a generic of another company's ethical drug.

- If the pharmaceutical manufacturer develops a generic drug that is a generic of another company's ethical drug, the generic drug will be new to the company developing it, although not novel in therapeutic value to the industry. Provided that the reference to 'existing product' in bullet 4 of para .11 relates only to

existing products of the company itself, the generic development should not be excluded from development activity, because it is new to the company in question.

- If the company develops a generic of its own existing ethical drug, it will still need to invest significant labour time and other resources in developing an effective substitute to the original drug using different (usually less costly) non-active ingredients and production techniques. These modifications may improve the absorption of the drug to a slow release method or make consumption or application thereof more pleasant. Therefore, even though the active ingredient is not novel to the company, the suggested modifications to the final product are more likely to be of a non-routine than routine nature. Therefore, development of a generic drug includes a known active ingredient in a non-routine way to develop a new product, and therefore should not be excluded from development activity for the reason stated by SAD.

It may be interesting to note that ED 120, drops the list of exclusions in para .11 of AC 122. It makes no reference to the exclusion of the "routine effort to refine, enrich or otherwise improve on the qualities of an existing product" required by bullet 4 of AC 122. The Accounting Practices Board omitted the examples of para .09 to .11 of AC 122:

> "In order to keep ED 120 concise without damaging its understandability. The Board believes that, in practice, it is unlikely that the application of the proposed requirement in ED 120 will result in differences from the application of the requirements in AC 122" (ED 120, SAICA: Appendix 1,para .02).

The proposed exclusion of paragraphs .09 through .11 of AC 122 by the IASC suggests that the lists in IAS 9 (revised) and AC 122 have never been very useful to preparers of financial statements.

6.5 Marketing costs in the development lifecycle

Industry sources estimate that pharmaceutical companies in the US spent about $1 billion more on promotion than research in 1991 (McGahan; 1994: 116). The

case study company has also identified marketing costs as a major portion of expenditure incurred during the R & D lifecycle. The company incurs a form of marketing costs at two major stages during the drug R & D process.

AC 122 and IAS 9 (revised) are silent on how to account for marketing costs incurred during the R & D process. The Australian Accounting Research Foundation (AARF) and the NZSA both commented on the specific exclusion of selling costs and general administrative costs from research and development activities in E 37 and the lack of accounting guidance regarding these, and marketing costs, incurred during the research and development process. FRS 13 (para 4.12), on marketing costs, states the following:

> "Costs incurred to maintain production or to promote sales of existing products are excluded from the costs of research and development activities. So too are the costs of carrying out market research that is of a routine or promotional nature. However, market research activities undertaken prior to the commencement of commercial production to establish the usefulness of a product or the existence of a potential market may be similar to development activities. Thus the related costs may be treated in the same way as development costs and expensed or deferred based on the same considerations."

The requirements of FRS 13 regarding marketing costs clearly states that such costs are not to be allocated to development activity, despite their similarity to development costs in some cases. This guidance may be appropriate in the SA context.

6.5.1 Stages of marketing activity

The stage at which the first marketing activity occurs depends on the historic development of the product. A "local product development" refers to a product that has never been developed elsewhere in the world. If the proposed development is a "local product development" the case study company subcontracts the market research function to a medical field research company. The case study company briefs the research company on the product and its potential therapeutic value. The research company in turn conducts interviews of doctors to determine the potential size of the

market, at a cost of approximately R60 000 to R100 000. This marketing research is conducted early in the R & D lifecycle, often before any major development has begun, and is performed to ensure that a market exists for the product before commencing any major development activities.

Alternatively, the case study company conducts the research in-house if the product is already sold locally and/or internationally. The business development department use DSI to assess the status of the market. DSI, the Decision Survey International audit manual, details the market for the product elsewhere by value, growth and company market share for the most recent three to five year period. If a local market for the product exists, information also includes a market share analysis of the product between available delivery systems. When the public sector distributes a drug, no record of drug distribution exists. Therefore, the case study company analyses and extrapolates clinic information for the best indicator of the public sector market. This research need not be performed as early as is the case when the product is a "local product development". The intention of the research is not to determine that a market exists, but rather to determine whether the market strategy originally identified remains feasible.

Therefore, the main focus of the first stage of marketing activity is to establish or confirm that a market exists for the proposed development.

The second marketing activity performed during the development life cycle, is incurred prior to commercialisation, usually while awaiting registration approval. This marketing effort entails exposing doctors and other opinion leaders to the drug and informing them of usage specifications and benefits. The costs incurred are significant, and are likely to be greater for novel drug developments than for generic drug developments. The case study company recently spent approximately R5 million on marketing a product that it had acquired a licence to market from a foreign company. At the time of performing this marketing activity, some form of development activity usually continues to take place. The development activities at

this stage usually involve an attempt to determine different indications for the drug, thereby maximising its therapeutic value.

The Medical Director of the case study company raised the issue of how these marketing costs should be accounted for, and whether they form part of R & D costs.

6.5.2 Recommended Accounting for marketing activities

In considering whether marketing costs should be included with R & D costs, the two stages of marketing activity need to separately analysed.

The first stage conducted prior to development of a new product may possibly be classified as research activity. The main issue is whether the research is "undertaken with the prospect of gaining new scientific or technical knowledge and understanding". If so, then the market research activity should be accounted for as R & D costs in accordance with AC 122. It is however unlikely that obtaining knowledge about a potential market has any scientific or technical component. Therefore the market research costs should not be included with other R & D costs. Because these costs are usually incurred very early in the R & D process, it may not be possible to obtain sufficient assurance of the probability of future benefits. Therefore, expensing these costs appears to be the most conceptually correct treatment.

The marketing costs performed prior to commercialisation are clearly not R & D costs as defined. The fact that these activities are performed intermittently with development activities does not mean that they should be accounted for as such. If future economic benefits from the development project are assured, these marketing costs should be deferred and amortised against the revenue earned when the developed drug is sold. This will be the case if the registration approval is merely a formality. If registration approval is not a formality, usually more so in the case of an ethical drug development, then future economic benefits may not be sufficiently probable. In this case the marketing costs should be expensed in the year incurred.

The accounting for marketing costs suggested above was based on the accounting principles laid down in AC 122 and AC 000. ED 120 has corrected the lack of guidance for marketing costs in AC 122 and IAS 9 (revised), stating in para .50 that

> "as a consequence of the definition of, and recognition criteria for, an intangible asset , examples of costs that are recognised as an expense when they are incurred include: (c) advertising and related costs."

Therefore, ED 120 provides clarity on the nature of marketing costs and how these should be accounted for.

6.6 Conclusion

This chapter described the cost allocation problems associated with implementing AC 122 in the pharmaceutical industry.

Chapter seven addresses the practical concerns related to implementing the capitalisation criteria in the pharmaceutical industry.

7. THE CAPITALISATION CRITERIA

7.1 Introduction

In chapter 3 the concerns of a number of respondents to E 37 were presented. Their main criticism was aimed at the mandatory capitalisation of development costs because of the subjectivity of the criteria of para .16 of E 37 or its equivalent, para .18 of AC 122. The New York State Society of Certified Public Accountants (NYSSCPA) suggested that the IASC provide detailed guidelines as to how to satisfy the capitalisation criteria listed in para .18 of AC 122, and that these guidelines be industry specific (Comment letters on Exposure Draft, E 37; 1992: 94).

This chapter investigates the difficulties associated with implementing the capitalisation criteria of AC 122 in the pharmaceutical industry. This is followed by an attempt to implement the recommendation of the NYSSCPA, to provide industry specific guidelines to assist with the implementation of the capitalisation of development costs in the pharmaceutical industry. If this attempt is successful, it may provide guidance to other industries of the approach to take in developing their own guidelines.

In the next section the accounting capitalisation criteria are discussed and specific discussions with interviewees of the case study company presented. These provide insight into the appropriateness of capitalising development costs in the pharmaceutical industry. This is followed by an investigation of the typical life cycle of pharmaceutical drug developments as the basis for reducing the subjectivity of the para .18 criterion to demonstrate technical feasibility. Finally conclusions are drawn as to the practicability of the NYSSCPA's suggestion in the pharmaceutical industry.

7.2 The capitalisation criteria

In order to facilitate easy reference, the five criteria to be satisfied for capitalisation to occur are listed below. They are:

- that the product or process is clearly defined and the costs attributable to the product or process can be separately identified and reliably measured.
- the technical feasibility of the product or process can be demonstrated.
- the enterprise intends to produce and market or use the product or process.
- the existence of a market for the product or process or, if it is to be used internally rather than sold, its usefulness to the enterprise can be demonstrated.
- adequate resources exist, or their availability can be demonstrated, to complete the project and market or use the product or process.

Not all of the capitalisation criteria are discussed in this chapter. Methods for satisfying the criteria required by bullets 3, 4, and 5 of para .18 were discussed in chapter two. The requirement of bullet 1 to separately identify and reliably measure the costs of the project was addressed in the previous chapter. Therefore, this chapter only addresses the implementation challenges of bullet 2, whereby the 'technical feasibility' of the product must be demonstrated.

The criteria of para .18 are an attempt to provide guidance for determining the probability of the future economic benefits of the product. They are sufficiently stringent that not all development costs will satisfy the capitalisation criteria. Therefore, some of the costs incurred on a development project that continues for a long time period, such as the average twelve year period of an ethical drug, will have been charged to income. Once the capitalisation criteria are satisfied all additional costs should be deferred to future periods. It is frequently argued that this basis of selective capitalisation only partially achieves the matching of costs that capitalisation was intended to achieve.

Another view held is that large companies that operate a central research department, which works primarily on ideas for new products, should defer all R & D costs. The thinking behind this is that a research department of this nature is a permanent operation to provide the company continually with ideas for alternative new products. It is expected that the departments efforts will not affect current production, but increase future profitability, and that therefore the related costs should be matched to the future profitability. The main problem with this argument is that it ignores the concept of probability of future economic benefits. While all R & D activity is undertaken with an expectation of future economic benefits, such future economic benefits do not always result. Therefore the probability of the future economic benefits needs to be assessed.

The mandatory capitalisation of development costs, if the specified criteria are met, appears to be the most theoretically correct accounting treatment, but raises many implementation difficulties in practice.

7.3 Implementation concerns

The main difficulty associated with the capitalisation of development costs is the practical application of the five criteria to be satisfied before capitalisation may begin. Additionally the extent to which these development costs may be capitalised in accordance with the limitations of net future recoverability should also be addressed.

An investigation of the comments to E37, which formed the basis for the revised IAS 9, revealed that the two most quoted concerns with the capitalisation requirements of the new standard are:

1. the criteria for determining when capitalisation should begin are extremely difficult to satisfy, as no guidance exists for determining what renders a product or process "technically feasible", and
2. the difficulty of predicting the probability of future economic benefits to be derived from R & D activities.

7.4 Technical feasibility

The second bullet of para .18 of AC122, requires that the "technical feasibility of the product be demonstrated before any of the costs may be capitalised.

For the purpose of this chapter the author assumes that technical feasibility means that the product achieves what it was designed to achieve. In the context of the pharmaceutical industry, this means that the developed drug will have the desired therapeutic effect on the patient, without any adverse side effects.

7.4.1 The interpretation problem

The comments received to E 37 were highly critical of the requirement to demonstrate the technical feasibility of the product. The main reason for this criticism is the lack of guidance as to what constitutes 'technical feasibility' and the consequent potential inconsistency of accounting treatment. Scope exists for numerous interpretations of the term 'technical feasibility", and the subjectivity of this decision may also be largely influenced by the personality traits of the decision maker.

In order to confirm the validity of the respondents concerns, two employees of the pilot company and three employees of the case study company were asked for their interpretation of the meaning of 'technical feasibility'. In both cases enquiry was made of the financial accountant / director because of their influence on the accounting for R & D. The other employees were selected because of their in-depth knowledge and understanding of the R & D process. Their responses revealed a complete lack of consensus, and in some cases, lack of understanding, as to what "technical feasibility" means. Their interpretations are summarised below:

Pilot company

- A clinical scientist held the opinion that technical feasibility is achieved at the point at which it is established that a drug has a legitimate therapeutic value.[32]

[32] The drug has a therapeutic value when it can be demonstrated that is can be used effectively in a defined disease indication.

- The financial accountant of the same company believes that technical feasibility is established only once all costs are covered and it is known that the product will generate profits.

Case study company

- The financial director believes that no defined basis for establishing technical feasibility exists, and is therefore unwilling to attempt to interpret its meaning.
- The registration manager suggested that the term "medically feasible" would be more appropriate and that his understanding of this term is 'the satisfactory demonstration of superior efficacy in a specific disease indication.'
- The medical director holds the opinion that technical feasibility means that 'the product could be technically possible for the company or an affiliated party to develop at a market related price.'

The above interpretations suggest that accountants and scientists hold a vastly different understanding of technical feasibility. Scientists associate technical feasibility with the point at which the analytics and testing indicate that a valid therapeutic value exists for the product. Accountants, on the other hand, reflect a tendency to link commercial viability to technical feasibility and therefore to confuse bullets 2 and 4 of para .18 of AC 122. This type of confusion is expected from an accountant as it is ultimately the commercialisation of the product that generates economic benefits. Because accountants report historic information in monetary terms, it is reasonable for them to favour corporate action that improves monetary performance.

The para .18 requirements of AC 122 do not require that commercial feasibility be proven, but only that a market or use for the product be demonstrated. It is possible that at some stage during the development process, that a clear market or use exists for the product, but that the product will never be marketed. This eventuality is more likely in the pharmaceutical and software industries, than in other less complex R & D active industries, because of the long time period between completion of the development and the marketing thereof. The complexities of the regulation process

and its impact on the marketability of the final product are discussed later in this chapter. Therefore, it would have been more useful if AC 122 had included a requirement to prove commercial viability within the scope of para .18. ED 120 states in para .41 that "before an intangible asset is recognised, it is particularly important to demonstrate the technical feasibility of a development project and the probability of its commercial success by evidence that can be verified objectively." Therefore ED 120 expands on the AC 122 requirement to demonstrate technical feasibility in that it requires that commercial success also be evident. This inclusion addresses the concerns of accountants and will ensure that development costs are not capitalised unless future economic benefits are sufficiently probable, irrespective of the satisfactory demonstration of technical feasibility.

The difference in interpretation of the scientists and accountants presented above confirms that the personalities and responsibilities of various individuals will influence their interpretation of technical feasibility. The varied interpretations described above also indicates the need to express the capitalisation requirements, particularly that of technical feasibility, in practical terms, thereby promoting consistent implementation of AC 122.

7.4.2 The drug development life cycle

In the previous section technical feasibility was defined for the purpose of this study as meaning that the product achieves what it was designed to achieve. In the context of the pharmaceutical industry, this means that the developed drug will have the desired therapeutic effect on the patient, without any adverse side effects.

This section evaluates the product development life cycle of drugs developed in the pharmaceutical industry, as a basis for determining whether it is practically possible to define the achievement of technical feasibility in the industry. The life cycle of an ethical drug is evaluated, as the other type of drug developments include some or all of the stages of an ethical drug to a lesser degree. The development life cycle includes certain main phases, and each phase is associated with an average time period and probability rate of success. The life cycle developed below is based on a US

interpretation of ethical drug development, but has been modified to reflect the life cycle of development projects of the case study companies. The process is as follows:

7.4.2.1 Phase I

This phase of the research and development life cycle includes basic research and the discovery of active substances. The active substance is the ingredient that influences the therapeutic value of the final product.

Phase I includes synthesis of the active substance on a laboratory scale and the determination of animal models. This process lasts between 1 to 2 years and costs between R500 000 and R1 000 000.

In the US, Canada and other large countries that perform biotech research, this process is significantly more expensive. This is because traditionally 8 000 to 10 000 compounds are screened for every one drug that is successfully marketed (Bains; 1991: 83). This differs from South Africa, where pharmaceutical manufacturers prefer to purchase rights to a compound once significant synthesis has already been performed.

7.4.2.2 Phase II

Stage one

In phase II of the development process the majority of work performed is in the field of pre-clinical trials. In stage one of phase II, basic pharmacological- and biochemical screening is performed. Patent application is also usually made during this stage.

The first pre-clinical trials are performed primarily on animals. These include toxicology tests whereby the substance is administered to two animal species. The purpose of these tests is to determine whether there is an effective presence of any poisonous substances. It also provides information regarding any main or side effects of the substance administered and the duration of any identified effect.

At this point the active substance is analysed and the stability thereof is tested. These trials usually last for about one year and cost approximate R2 million.

Stage two

During this stage, pharmacokinetics is performed. This involves the science of testing further active responses including the absorption, distribution, metabolism and excretion effects of the substance.

Animal toxicity tests are repeated to determine medium term effects and reproduction toxicology studies are conducted. This is followed by the synthesis of active substances on a technical scale followed by the development, analytical evaluation and stability testing of final dosage form. Clinical samples are then developed.

These trials take between 1-2 years to complete and cost between R1 million and R2 million.

7.4.2.3 Phase III

Clinical trials I

Three stages of clinical trials are performed. The differences between the clinical trials in the three stages include varied subjects, objectives and the types of tests performed. The nature of the various clinical trials is set out in table 9.

Table 9 - Phase III Clinical trials

	Stage I trials	Stage II trials	Stage III trials
Subject	Volunteer healthy humans (small scale)	Sick patients (small scale)	Sick patients (large scale)
Objective	Dose finding studies (1)	Establish efficacy of the drug. Controlled trials are performed.	Establish final therapeutic profile of the drug.(2)
Tests performed	• Pharmacokinetics tests in stage 2 of phase II are duplicated in humans. • Additional test on animal species to incorporate long term effects	• Additional toxicity tests to determine long run effects of repeated administration. • Tests for cancerous effects performed.	• Proof of efficacy & safety in the long term administration of the drug. • Demonstration of therapeutic advantage
Duration	+- 2 years	2 - 3 years	2-3 years
Cost	R 2 million	R 10 million (3)	R 35 million (3)

(1) These studies are used to determine the highest tolerated, smallest effective and other dose / effect relationships.

(2) Large scale clinical trials are conducted at a number of medical centres. Aspects of the drug profile to be finalised include indications, dosage and types of administration, contraindications, side effects and precautionary measures. Final clarification of interaction with concomitant medications should also be achieved.

(3) These costs are made up primarily of the employment and other related costs of the clinical scientists responsible for administering the patients and monitoring the results of the clinical trials. The remaining costs are those incurred in preparing the clinical packages.

7.4.2.4 Registration

Registration is the final step in the drug development process and can take up to two years before approval is obtained. Preparation for registration involves the documentation of all relevant data required for the registration application. The data includes expert opinions on the results of the clinical, pharmacological, toxicological and analytical trials. The costs incurred during this stage are not material to the total development process.

7.4.2.5 S.A. development lifecycle compared

The allocation of costs to stages of development above is based on the typical costs of South African pharmaceutical manufacturing companies for developing a non-generic drug. These costs tend to fall significantly below the US$ cost of developing an ethical drug. The main reasons for the lower development costs in S.A. are:

1. the US Food and Drug Administration is more stringent in its approval of new drugs than the local MCC, thus requiring additional procedures to be performed.;
2. S.A pharmaceutical manufacturers tend to get involved in the development process with international principals, thereby sharing major development costs; and
3. S.A. companies usually develop products, of which the active substance has already been approved elsewhere. Therefore, the extent of clinical trials required by SA's MCC is significantly less, because the dossiers of the foreign company may be used when applying for registration.

Adcock Ingram acknowledge that collaborative development of in licenced projects is a major part of their business (Financial Mail Supplement: A corporate report; 1993: 9) The foreign principals with whom they operate include Baxter, Kabi-Pharmaa, Astra, Leo Laboratories, Jeyes, Mundipharma and Helene Curtis. Adcock Ingram get involved in development at the phase 3 clinical trial stage, and in return gain access to marketing rights in certain territories.

In 1994 South African Druggists decided to extend its access to technology by merging with Inmed (Pty) Ltd, thereby acquiring world wide marketing rights to the

new Autostar production technology. The agreement also gave South African Druggists first-refusal rights to future development in the medical field of Inmed (Druggists Digest; September 1994: 9).

Warner Lambert, a pharmaceutical manufacturer based in Cape Town, begins its research and development process at a later stage than multinational pharmaceutical companies. Warner Lambert (S.A) purchase compounds from Warner Lambert International or some other foreign principal and then develops the compound into a potential therapeutic drug. Warner Lambert (S.A) also enters into agreements with its foreign head office whereby it purchases the rights to a developed drug, following which it performs development adjustments to suit local production facilities and standards.

Historically, the above mentioned SA's pharmaceutical manufacturers have preferred not to perform basic research into new chemical entities, but to get involved at a later stage of the development process by entering into joint venture or licencing agreements with foreign manufacturers, and making adaptations to meet the needs of the domestic market. The following two statements indicate that this continues to be the preference for two of SA's largest pharmaceutical manufacturers, although some are entering into the arena of ethical product development.

> "We have taken the decision to discontinue our own research into new chemical entities. This form of research, in addition to being costly and high risk, also requires an appropriate infrastructure in main international markets so that the required return on investment can be achieved during the patent life of a new chemical entity. This decision also enables the Group to concentrate its resources on local development and an active in-licencing programme" (CEO Review: Adcock Ingram Annual Report; 1996: p.9).

> "In line with SAD's export drive a decision has also been taken to move out of basic generic research into novel product development..... . We will, however, continue with the conventional generic product development..... . I anticipate a steady growth in the group's research and development budget and in the number of people involved in the actual research. It is important that SAD is recognised as a research orientated company" (R&D director: SAD Druggists Digest; 1994).

Adcock Ingram and SAD are clearly aware of the increasingly critical nature of research and development. The latter, the largest local pharmaceutical manufacturer, has expressed its intention to perform R & D in the area of ethical drugs. Therefore, the accounting for research and development costs should consider a broad scope of product developments ranging from generic drugs to novel drug developments.

7.4.3 Guidance for practical implementation

The evaluation of the development life cycle was undertaken in an attempt to provide insight as to when a drug is technically feasible. It appears reasonable to assume once phase 2, pre-clinical trials and the first two stages of phase III clinical trials have been successfully completed, it is possible to predict the success of a drug with a high degree of certainty in a particular therapeutic class. By the time that stage II of phase III clinical trials are completed, animal toxicity tests have been performed to determine the short, medium, and long term effects of administering the drug. Extensive pharmacokinetics is complete and clinical trials will have been performed on both healthy and ill patients. Efficacy and safety should also have been significantly demonstrated. Although the last stage of phase III clinical trials involves the establishment of final therapeutic profile through large scale trials, historic experience suggests that a drug reaching this stage has a high probability of achieving technical feasibility[33]. The extensive nature of testing performed up to this stage should ensure that any technically unacceptable features of the drug have been detected. Therefore at this stage it would seem reasonable to assume the successful demonstration of technical feasibility.

7.4.3.1 Industry experience

In order to gain support for the above assumption, historical experience of drug developments in the pharmaceutical industry were examined. Over the last few years numerous biotechnology companies have experienced problems with drug developments at a very late stage of the development cycle. In 1994 Procyte Corporation's lamin gel product did not show the same statistical differences between the drug and the placebo in stage III, phase III clinical trials as it did during the

[33] Interview with the Clinical Scientist of the pilot company, 26 October 1994.

stage II clinical trials (PR Newswire; October 17, 1994). The phase III studies involved thirty medical centers and 511 people with diabetes and chronic ulcers on the plantar region of the foot. Dosage was administered at 0,5 % of drug, 2 %, or placebo and the patients showed little difference in achievement of the primary endpoints. The primary endpoints of the study were reduction in wound size and full closure of the wound. At the stage that this failure was identified, the company had been preparing the product to enter the priority review program at the US Food and Drug Administration due to the apparent success of treatment up to the stage II clinical trials. In stage II the lamin gel showed a high success of closure rate of wound, reduced healing time and the reduction in incidence of infections. When the poor results of the phase III clinical trials were announced the company's share price plunged by 68 % (Reuter Financial Report (USA); December 2, 1994). This is indicative of the huge importance that investors attribute to drug development performed by pharmaceutical manufacturers.

The Chief executive officer of Procyte Corporation, Joseph Ashley, indicated that the company has no intention to reinstitute the study and felt that biotechnology companies need to perform collaborative research and development to achieve a higher percentage of success with research and development expenditures (Reuter Financial Report (USA); December 2, 1994).

Another biotechnology company, Gensia Inc of San Diego, California, lost more than half its share price value when its lead development product, Protara, failed to achieve its endpoints during human clinical trials. Gensia abandoned the product and had to downsize its labour force. Procyte had to take similar measures with its labour force reducing by 35 %. Gensia had been spending approximately $18 million a quarter on R & D and this was expected to be reduced by $ 6 million per quarter with the abandonment of Protara (Financial Times Business Information, Ltd.; October 24, 1994).

"The woes of biotech companies continue" by Marketletter Publications Ltd (November 7, 1994), described a number of additional cases of late stage failures in pharmaceutical R & D.

In October 1994 Telios Pharmaceuticals had a product that indicated in late stage trials that its healing rates were no better than those of untreated patients. In November of 1995, Biogen's thrombin inhibitor, Hirulog, failed to achieve its primary efficacy endpoints, although it did demonstrate efficacy by way of its reduction in the incidence of major bleeding complications. The trials were conducted in 113 hospitals in the USA and Europe and 4 675 patients took part in the trial. The failure of the trials to demonstrate a statistically significant effect on the primary endpoints in the overall patient population led to Biogen's decision to halt development of the drug. Their decision did not have a major impact on the value of the share price of the company, probably because of the stage III clinical trial success of its multiple sclerosis drug, and the significant income that its reaps from licensed-out products.

Celtrix Pharmaceuticals was also disappointed in the failure of its BetaKine drug to produce a statistically better outcome than that of patients treated with a placebo. Again the results of earlier studies did not carry through to stage III, phase III clinical trials. Celtrix have decided to continue researching the drug.
Cortech, Synergen Inc, Medimmune, Chiron, Glycomed and Magainin Pharmaceuticals all halted development in 1994 because of poor results achieved during stage III, phase III clinical trials. The main reasons were because of failure to demonstrate efficacy or because of unacceptable side effects that resulted from use of the drugs.

The specific cases described above reflect the high risk of developments undertaken by biotechnology companies and indicates that success at stage I and stage II of phase III clinical trials in reality provides little assurance of the success of the drug in stage III, phase III clinical trials. The predicament facing biotech companies undertaking such high risk R & D projects is evident from the following statement:

> It should be noted that less than one third of drugs that successfully navigate stage I, phase III clinical trials actually reach the market, and while each progress step for biotechnology products receives considerable attention, sometimes little effort is made to point out that success at these early stages in reality means very little. This may be in no small part because biotechnology

> companies often rely on "feel-good" news about their drugs to support their efforts to raise cash from investors, and they may continue development of equivocally -effective agents which a larger company would have dropped" (Marketletter Publications Ltd; November 7, 1994).

Despite the high failure rate of developments in stage III, phase III clinical trials in the U.S., interviewees of both the pilot and case study companies believe it appropriate to accept that technical feasibility has been achieved once large scale phase III clinical trials begin. One of the reasons why S.A. companies are more positive of final results of the project at stage III, may be because of the nature of their research. Their tendency to perform local product development of products already proven abroad increases their probability of success. If capitalisation begins at the beginning of stage III, phase III clinical trials, approximately R35 million plus registration costs would qualify for capitalisation. This represents the size of costs usually incurred over the last three to five years of the development process.

It is appropriate at this point to consider the second problem raised by the respondents to E 37. The fact that the start of stage III, phase III clinical trials may be deemed as an appropriate bases for demonstrating that technical feasibility has been achieved does not provide assurance of future economic benefits. However, because stage I and stage II clinical trials have been successful, the probability of future economic benefits at stage III increases. The results of the cases described above does however show that early prediction of future benefits may be premature. Therefore, the problem of reliably predicting the probability of future economic benefits is considered in the following section.

7.5 Difficulty of predicting probability of future economic benefits

This concern was particularly prevalent in the responses of representatives of the pharmaceutical industry. The Pharmaceutical Manufacturers Association that represents over 100 research-based US Manufacturers, F. Hoffmann-La Roche AG (Switzerland), Johnson and Johnson (New Jersey) and Eli Lilly & Co. all believe that the probability of future economic benefits cannot be reliably predicted in the pharmaceutical industry. All of these companies invest a large percentage of annual

turnover in research and development and are highly regarded drug manufacturers. Their concern is that future economic benefits may never be realised because of the regulatory approval and registration required before a drug can be sold in the market for commercial gain. In the United States the Federal Drug Administration can at any time reject a new drug application and, in the past has frequently refused to register more than one or two drugs for any single indication (Comment letters on E 37, 1992: 96). Therefore it is conceivable that a drug which is technically feasible may never become a commercially feasible product. Additionally, the accurate estimation of future economic benefits is likely to become increasingly more difficult because of the huge impact that health reform, HMO's and other regulatory bodies are having on initial selling price targets.

Despite the reservations held by the above respondents, the case study company believe that future economic benefits can be estimated with a large degree of accuracy. Historically, their market surveys performed to determine future market size and potential have produced accurate results. Additionally, because their main area of development is in generic and combination drugs, the likelihood of not achieving registration approval is significantly lower than is the case when registration approval of an ethical drug is required. Therefore, the representatives of the case study company are confident that they can estimate future economic benefits with a reasonable degree of probability.

7.6 Recommendations for capitalising the costs of development projects

South African companies should capitalise the development costs they incur to the extent that their activities meet the definition of development as defined in AC122 and satisfy the capitalisation criteria of para .18. The fact that South African companies tend to get involved in the development process at a much later stage does not reduce the importance of the development work they perform, but does reduce the level of risk associated with their development projects. Accordingly, South African companies can probably predict future economic benefits with more certainty, and will in most cases be able to capitalise a far greater proportion of the total

development costs incurred by themselves than international pharmaceutical manufacturers.

7.6.1 Purchased developments projects

When the development rights to a patented compound are acquired, it might be argued that this is no different to what would constitute research had it been performed by the acquiree in its own right. At the time that the compound is acquired a very low probability exists that any future economic benefits will result from the compound. The fact that the compound has been patented does not necessarily imply that future economic benefits are highly probable. Rather it ensures that the company that holds the patent or rights thereto secures any potential future benefit. Statistically, for every 8 000 to 10 000 compounds screened, only between 10 and 20 make it to phase III clinical trials, and from these only one is successfully marketed (Bains; 1991). Therefore the costs of acquiring the right to develop a screened compound should be expensed because the probability that future economic benefits will flow to the enterprise as a result of the compound is very low.[34] The compound does not meet the definition of an asset.

In contrast to this, the acquisition of the right to licence a fully approved drug holds an expectation of potential future economic benefits with a high degree of certainty.[35] Both South African and International Accounting standards require that expenditure, that is probable to result in future economic benefits, should be accounted for as an asset to the extent of its future recoverability. Therefore the costs of acquiring the right to licence the drug should be accounted for as an asset in the financial statements of the acquiror and amortised against expected future revenue on an appropriate basis. Any additional development costs incurred to adapt the drug for the local market can then be recognised as deferred development costs without any doubt existing as to the technical feasibility of the product. The only accounting concern would be the extent to which future economic benefits to be derived can be reasonably measured.

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[34] Interview with financial director of case study company, 15 November 1995.
[35] Interview with financial director of case study company, 15 November 1995.

7.6.2 Ethical drug developments

When accounting for the research and development costs of an ethical drug development it is unlikely that that any general rule can be established for determining when capitalisation should occur that will result in a consistent basis for accounting for R & D costs. This chapter has attempted to define an industry guideline for determining when technical feasibility has been demonstrated.

The financial director and clinical researcher of the case study company believe that the beginning of stage III, phase III clinical trials is an appropriate point to begin the capitalisation of ethical drug development costs in SA. However, the author believes that because of the high failure rates recently experienced during the conduct of large scale, stage III clinical trials by pharmaceutical companies developing ethical drugs, that the capitalisation of ethical drug development costs at any time before the start of the registration process could be premature. The reason for this is not only the questionability of technical feasibility, but also the high risk of failure that still exists at this stage of the development process.

If the decision is taken to capitalise the development costs of an ethical drug when the registration application is lodged, the amount of costs available to be capitalised will be very small, as the major costs are all incurred prior to the registration phase in the development life cycle. The amount to be capitalised should be limited to the future recovery, after further costs, in accordance with para .21. Because of patent protection, the unique qualities of an ethical drug, and the fact that the remaining costs will be immaterial, it is unlikely that the limit on cost capitalisation will apply. Accordingly, the only real consideration of the probability of future economic benefits is whether the drug will be approved for registration.

The "Me Too" drug life cycle is identical to that of the ethical drug because it comprises a new chemical entity. Therefore, all of the safety and efficacy requirements that relate to an ethical drug are also relevant to the "Me Too". The case study company develops very few of this type of drug. "Me Too" drugs generally result because the company has just been beaten by a competitor to the market, by a

drug with the same therapeutic value as the "Me Too" drug. In such cases, the case study company will no longer wish to incur significant costs on the development and will usually only continue with the development, if it is substantially complete. A problem may arise if the future economic benefits of a drug are estimated for capitalisation purposes, prior to the release of the competitor's drug which renders the development a "Me Too". The future economic benefits will usually be significantly less than originally estimated because of the presence of the competitor's drug with the same therapeutic value. However, the fact that pharmaceutical companies like to use successful drug development stages as "good news" means that any pharmaceutical manufacturer should be aware of the risk of its "ethical" development being rendered a "Me Too".

Because of the similarities between the ethical and "me too" drug developments the guidelines developed above for the ethical developments apply equally to "me too" drug developments.

A further investigation of other type of drug developments will be undertaken to determine whether similar guidelines can be developed.

7.6.3 Generic drug developments

The profile of a generic drug is very different to that of an ethical drug. The generic has been described as a copy of a NCE used together with different non-active ingredients and production techniques to develop a new product. The development life cycle of a generic drug is significantly shorter than that of an ethical drug, primarily because efficacy need not be demonstrated, as it would already have been demonstrated when the NCE was used in the novel drug. Generic drugs usually require a dissolution test to prove correct absorption of the drug into the bloodstream. If the outcome of the dissolution test is successful, a bio-study is undertaken with a high probability of success.[36] The bio-studies are performed on small groups of humans to prove its successful flow into the bloodstream.

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[36] Interview with Medical director and financial director of the case study company, 21 February 1996.

The case study company revealed that enormous investment in generic products is the current trend in South Africa today. The risk of generic product failure is also considered to be relatively lower than with all other type of drugs developments.[37] The main threat to the success of generic products is the time that it takes to get the drug to market once the ethical product patent expires. If the time period between patent expiry and generic launch is too long it is most likely that the generic will be beaten to the market. The window of opportunity is recognised by the industry as being very small and it is usually only the first and second generics to market that are assured of success in the form of total cost recovery.[38]

The second issue to be considered is the probability of future economic benefits arising from generic drug developments. The regulatory approval for generic drug developments also takes a relatively long time period, but the likelihood of initial acceptance is much higher than is the case for an ethical drug development. Very few generic products fail to generate sufficient revenues to cover its development costs, provided that it is one of the first to enter the market. The cost of developing a generic drug in South Africa is in the region of R200 000 to R300 000 and reaches as high as R800 000 if a bio-availability study is required.[39] Because these costs are so low development costs are normally always recovered, and no need exists to estimate the exact size of future economic benefits.

Therefore, provided that the company is reasonably assured that it will be one of the first generic products to enter the market, the generic development costs should be capitalised once the dissolution tests have been successfully completed. The shorter the period of time between estimated market entry of the generic and the patent expiry date of the original drug, the greater the likelihood that the generic will be the first to reach the market. Therefore the company will need to assess its likelihood of early entrance into the market.

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[37] Interview with financial director, case study company, 21 February 1996.
[38] Interview with financial director, case study company, 15 November 1995.
[39] Interview with financial director of case study company; 15 November 1995.

7.6.4 The combination drug

The case study company has enjoyed a large degree of success with its combination drug developments. Recall, that this type of drug consists of two or more known NCE's. The development period of this type of drug is longer than that of the generic drug because safety and efficacy of the new combination must be demonstrated by conducting clinical trials. The total life cycle of this type of development is very similar to that of the ethical drug, but the probability of phase III clinical trial failure is reduced because the starting point consists of two or more already successful chemical entities. Additionally, the duration of the life cycle will be shorter as the original clinical results of the individual drugs can be used to support and confirm the clinical results of the combined drug.

Therefore, the author believes that once the development of the combination drug reaches the start of stage III, phase III clinical trials, that it may be appropriate for all remaining development costs to be capitalised. It is unlikely that the development will fail at this stage because of the prior success of the independent compounds. The final decision on capitalisation should however take into account the approval required by the MCC and the impact that any known competition may have on the future benefits of the product.

7.7 Conclusion

Because of the nature of development activity performed in the pharmaceutical industry, fair presentation is best achieved by adopting a prudent approach to the capitalisation of development costs. However, the exercise of prudence should not be used as an excuse for unchallenged non-compliance with AC 122. The evaluation of the development life cycle of pharmaceutical drug developments provided the framework within which the basic rules, regarding the earliest stage of development at which capitalisation should be considered, were developed. The guidelines that have been developed should be used together with predictions for future economic benefits, if an accounting policy of capitalising development costs is adopted.

Similar guidelines may be developed for other research intensive industries, to reduce the subjectivity inherent in capitalising development costs. However this study shows

that the exercise of developing industry specific guidelines is time consuming and requires an in depth understanding on the R & D activity of the relevant industry.

Chapter eight addresses the most appropriate method and time period for amortising the development asset.

8. AMORTISATION OF THE DEVELOPMENT ASSET

8.1 Introduction

In chapter seven the research focused on the criteria of para .18 that need to be satisfied before development costs should be accounted for as an asset. This attempted to determine whether accounting for development costs as an asset is practically possible in the pharmaceutical industry, and concluded that this was so, but only for certain types of drug development.

If development costs are deferred to future periods, they should be amortised as an expense over such future periods. One of the primary objectives of capitalising development costs is to match such costs with the future benefits that the costs are expected to generate. The objective of this chapter is to determine the method and the time period over which the development asset should be amortised if best matching is to be achieved.

AC122, the South African accounting standard for research and development costs, deals with the amortisation of development costs in paragraphs .25 through .28. In summary, it requires that the costs be recognised as an expense on a systematic basis so as to reflect the pattern in which the related economic benefits are recognised. A maximum amortisation period of five years is recommended.

8.2 The amortisation problem

A number of issues flow from the requirements of para .25 to .28 of AC 122. These have been discussed in chapters two and three of this research. The following two main questions were raised by the interviewees of the case study company:

1. What method of depreciation should be used for amortising development costs? Alternatives include the straight line, reducing balance and units of production methods.

2. Over what time period should the deferred development costs be amortised? The financial and medical director both consider the five years amortisation ceiling guidance to be inappropriate to a number of their drug developments.

The appropriateness of the five years rule to development projects in the pharmaceutical industry is considered in the following section.

8.3 The five year rule

Para . 27 of AC 122 states the following reasons why development costs should not be amortised over a period exceeding five years:

> "Technological and economic obsolescence creates uncertainties that restrict the number of units and the time period over which the development costs are to be amortised. Furthermore, it is usually difficult to estimate the further costs and related future revenues of a new product or process beyond a short period."

Whereas para .27 may be true of the majority of R & D projects, AC 122 fails to recognise that there may be exceptions that are less prone to technological and economic obsolescence. This may specifically be true of the pharmaceutical industry where patent protection, for as long as 20 years in some cases, reduces the threat of obsolescence considerably.

Additionally, the nature of pharmaceutical drugs means that in some cases it may be relatively easy to estimate further costs and related future revenues beyond a short period. Products under patent protection may be assured of continued revenue streams for the remaining life of the patent[40], thereby negating the need to estimate the duration of future revenues. The future revenues of successful patented drugs are usually of sufficient magnitude that they will far exceed any further costs to be incurred. Therefore it may no longer be necessary to estimate further costs beyond a short period. It is however possible that a competitor may develop a competitive drug to the patented product, and achieve registration first. The competitor's drug would have to at least achieve the same therapeutic benefits as the patented drug, but by

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[40] As per written confirmation by the financial director of the case study company dated 21 February 1996.

using a completely different new chemical entity (NCE). If this were to happen, the continued future revenues of the patented product beyond a short time period could be threatened. However, because of the tendency of the international pharmaceutical industry to 'talk' of the success of its current developments (The woes of biotech companies continue; November 7, 1994), it is reasonable to believe that the company developing its product would become aware of therapeutic competition at a relatively early stage. This 'talk' is regarded as being 'good information' and is usually included in the annual report of the developing company and other media sources. Therefore, the company would be able to use this information when making its estimation of future economic benefits.

The appropriateness of the five years ceiling to the pharmaceutical industry may depend on the nature of the drug development. Therefore, the differences between the types of drug developments in the pharmaceutical industry are considered.

8.4 Drug turnover trends

In order to determine the appropriateness of the five years rule to drug developments in the pharmaceutical industry, the total turnover and turnover volumes for four drugs owned by the case study company were examined for a four to seven year period. This information together with industry turnover volume trends was used to determine whether any clear pattern existed for the revenue generated.

The details of drugs provided by the case study company include one ethical drug (still under patent protection), one ethical drug (no longer under patent protection), one branded generic drug, and one licensed-in drug. These were selected by the financial director of the case study company, so as to provide details of a spread of different drug types. The turnover trends of a fifth drug, a combination drug, were discussed, but no statistics thereof provided.

Despite the confidentiality agreement entered into between the author and the case study company, the company was reluctant to divulge this type of information because of its sensitivity. The author was not permitted to extract the information

independently and had to rely solely on the information provided for the five drug types. No reason exists to believe that the information provided by the case study is not true and accurate in its entirety. Because of the limited data, and in order to obtain a better understanding of the volume trends of the various drug types, additional discussions were held with the financial director and financial accountant of the case study and pilot study company respectively.

These discussions confirmed that the volume and turnover trends observed of the five drugs examined are representative of the types of drug development undertaken by the case study company. The results of the discussions held and observations made are described in the following section.

8.4.1 Ethical drug (still under patent protection)

In the second year of this product's commercial life, revenue in rand terms increased by 25 % over that of the first year. For the next three year, revenue in rand terms increased by between 30 % and 40 % per annum. Years five and six also showed increases, but at a lower rate of approximately 25 %. This product was also successfully registered in South Korea, one of the world's largest pharmaceutical markets at the end of year six. Forecast turnover values and volumes for year seven and eight indicates that a continued upward trend is expected. Total revenue for the drug currently makes up approximately 2 % of the company's total revenue. The turnover values each year as a percentage of the first year (or base year) are tabulated in Table 10. From this it can be seen that turnover value for the drug in year five was 2,89 times that of year one. Additionally, the sum of actual turnover for year six and forecast turnover for years seven and eight, significantly exceeds actual turnover earned for the first five years of the product's commercial life.

TABLE 10 - Actual and forecast turnover of ethical drug

Year	2	3	4	5	6	7	8
Percentage of base year (i.e. year 1) 100%	124%	175%	227%	289%	312%	358%	412%

Ethical drugs under patent protection tend to earn significant revenues for the duration of the patented life of the product. This appears to be true for the ethical drug reviewed. These revenues increase at a significant rate over the first few years due to increases in volume as doctors become more aware of the benefits of the drug. Thereafter, until patent protection expires, the volumes tend to flatten out, and revenue increases are largely attributable to inflationary price increases.

8.4.2 Ethical drug (off patent)

A previously patented ethical drug, once off patent, effectively becomes a generic drug. The period both before and after the expiry of the patent was examined. In the four years since expiry of the patent, the turnover generated fell considerably in relation to the period prior to expiry of the patent. The decline in turnover value was not accompanied by a corresponding decline in turnover volumes. Volumes only fell marginally, mainly because of a massive reduction in the price in order to remain competitive[41]. Provided that the ethical drug (now off patent) remains price competitive, it usually maintains its market share. This is because doctors in S.A. generally still prefer to prescribe the ethical drug over its generic substitute.

Therefore, it appears that the revenue from ethical drugs does not dry up altogether once it comes off patent, although it is significantly reduced.

8.4.3 The licenced ethical drug

The right to market this drug was acquired through a joint venture partnership. The turnover trend for this drug indicates that both turnover volumes and prices have remained very stable over a six year period. Any increase in turnover value is the result of inflationary price increases. The actual and forecast turnover suggests that the revenue stream of this drug is totally dependent on the duration of the licensing agreement. This fact was confirmed by discussion with the financial director of the case study company. Revenue from this drug currently makes up approximately 2 % of the total revenue of the company.

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[41] Written confirmations from Financial Director dated 21 February 1996 and 1 March 1996.

8.4.4 The generic, branded drug

Revenue earned from this drug made up less than 0.1 % of the case study company's total revenue in the years 1993 through 1996. Forecast revenues for 1997 indicate that an increase in real terms is unlikely beyond year four. Although the turnover generated was insignificant to the company, all of the development costs were recovered in the first year of marketing the product.

The size of revenue for a generic type drug is highly dependent on how quickly it gets to market. The first or second generic to market captures increasing market share over the first two years and can usually maintain its revenue stream in real terms for a total of three to five years. Thereafter, revenues decline as a market price is reached. This price is normally about a third or less of the price of the original drug and only the low cost competitors can actually remain active in this market[42]. Therefore, it is highly unlikely that a generic drug generates a notable revenue stream beyond a five year period.

8.4.5 The combination drug

The results of this drug were obtained by discussion with the Financial Director of the case study company. The product, developed in 1989 recovered all of its development costs in the first two years of its commercial life. Over this period the market for this product was established. Since then, the product has continued to dominate the market share and increases in revenue are largely attributable to inflationary price increases.

The financial director revealed in 1996 that these revenues were expected for at least an additional three years. If this expectation is met, the branded combination will have generated significant revenues for at least ten years.

The observations made of this particular combination drug may not be generalisable to all such drugs. Because the case study company leads other South African pharmaceutical manufacturers in its manufacture of this type of drug, the commercial life usually extends beyond the typical three to five year life of the generic drug.

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[42] Written interview with Financial Director of case study company, 21 February 1996.

8.5 Recommendations

The interviewees sought clarity on two issues concerning the amortisation of the development asset. Their questions were presented in section 8.2.

The volume trends and revenue trends described in section 8.4 provide the base from which to answer these questions.

8.5.1 Depreciation method

Para .26 of AC 122 states that

> "deferred development costs be recognised as an expense on a systematic basis so as to reflect the pattern in which the related economic benefits are recognised. When the enterprise is giving consideration to the systematic basis to be used the pattern of benefits should be based on either the:
>
> - revenue or other benefits from the sale or use of the product or process, or
> - time period over which the product or process is expected to be sold or used."

Therefore the method selected should either simulate expected revenue patterns of the drug or the expected time period of future revenues.

The size of future revenues may be difficult to estimate in the pharmaceutical industry over a long period of time. This is not impossible though, as the DSI market survey information enables the company to identify potential market size before completion of the development. This information together with the expected launch price and generally observed volume trends for the drug type can be used to estimate total projected revenues.

If revenues tend to be stable for the commercial life of the drug, the straight line method may be most appropriate. This would therefore be the preferred method for the costs of an in-licensed drug, combination drug or for a patented drug, with a long remaining patented life.

The reducing balance method may be most appropriate for drugs that derive high initial revenues that are replaced by significantly lower sustainable revenues. This is likely to be the case for a generic market leader or for an ethical drug with only a short commercial patented life once development is complete.

8.5.2 Time period for amortisation

The second question raised by the interviewees is the time period over which the development asset should be amortised.

The five years ceiling provided for in para .27 of AC 122 is inappropriate for the pharmaceutical industry. It is apparent from the volume and revenue observations made above that the five years ceiling is generally only appropriate to generic type drug developments. The prudence of the five years ceiling impedes the achievement of best matching in the pharmaceutical industry.

It is possible that the five years ceiling may also be appropriate to combination type drug developments, although not in all cases. Therefore, unless information is available that clearly supports a longer future benefit time period, the five year rule should be applied to these type of drug developments.

Patented drugs should at a minimum be amortised over the total commercial patented life of the drug. Depending on the duration of the development life cycle, the remaining patented life could range from 0 to 15 years. This assumes that the development life cycle lasts for at least five years. It may even be appropriate to amortise the patented, ethical drug asset over an even longer period, since patented drugs, once off patent usually continue to earn revenue for at least a three year period.

The main costs incurred for in-licensed drugs are licensing fees. If the initial cost is a once off fee, this amount should be capitalised and amortised over the period to which the licence applies. Any additional fees paid as a percentage of turnover should be expensed in the year in which the related turnover is generated.

Irrespective of the amortisation method and period selected, both should be reviewed at each balance sheet date. If the pattern of economic benefits is different to what was originally expected, the method or period should be adjusted to reflect the new circumstances. This change should be accounted for as a change in accounting estimate (ED 120 1997: para. 81). This will ensure that the asset on the balance sheet best reflects the expected future economic benefits of the development.

8.6 Conclusion

In this chapter two main questions raised by the case study company concerning the amortisation of the development asset were addressed.

The observations made in this chapter are reinforced by the requirements of ED 120, the proposed new accounting standard for intangible assets. ED 120 strongly favours the straight-line amortisation method, and states that this method should be adopted if the pattern of future economic benefits cannot be reliable determined (para .75).

Additionally, ED 120 drops the five years ceiling amortisation guidance of IAS 9 (revised) and AC 122. Instead, para .69 of ED 120 states that there is a rebuttable presumption that the useful life of an intangible asset will not exceed 20 years from the date when the asset is available for use.

In conclusion, while the amortisation requirements of AC 122 can be implemented with relative ease, the amortisation requirements of ED 120 are more appropriate to drug development assets in the pharmaceutical industry than those of AC 122.

9. CONCLUSION

9.1 Conclusions

The world-wide trend of rapidly increased investment in R & D activities has resulted in a need for a consistent standard of accounting for R & D costs. A number of standards for accounting for R & D costs have been issued or revised over the last few years, and the research has identified that these vary between countries. South Africa has followed the approach taken by the International Accounting Standards Committee in its own accounting standard for R & D costs, AC 122.

The problem identified for investigation in this study was the lack of application of AC 122 in SA. The objectives of the study were to identify the reasons for this lack of implementation and the conceptual and practical difficulties associated with the implementation of AC 122 in the South African pharmaceutical industry. The conceptual and practical difficulties were investigated under three main areas, these being (a) the allocation of R & D costs, (b) the capitalisation of R & D costs, and (c) the amortisation of the development asset.

The pharmaceutical industry proved to be a more than satisfactory subject for the purposes of this study. A large number of conceptual and practical implementation issues, specific to the pharmaceutical industry, were identified through the case study approach. These are described within the three main areas of concerns alluded to above.

The allocation of R & D costs in accordance with AC 122 is deficient in the pharmaceutical industry for two reasons. These are (a) the failure to separately identify research costs from development cost, and (b) the failure to allocate research costs and development costs to individual R & D projects. A possible reason for these deficiencies is that existing costing systems of a number of manufacturing companies are not able to cope with R & D cost allocation at this level. This research described

practical methods for improving current allocation methods for all types of R & D costs, as identified by AC 122.

An second cost allocation problem identified was the confusion in the pharmaceutical industry as to whether generic drugs development projects satisfy the definition of development or not. The reason for the confusion is the exclusion of 'routine efforts to refine, enrich or otherwise improve upon the qualities of an existing product' from development costs in terms of AC 122. The author believes that such development projects do satisfy the definition of development costs, provided that the product is new to the company developing the generic substitute. ED 120 has excluded the list of exclusions contained in AC 122, thus eliminating the confusion created from this exclusion in AC 122.

The results of the investigation of the conceptual and practical difficulties associated with implementing the capitalisation criteria of AC 122 support criticism of AC 122 on the grounds that the requirement to demonstrate technical feasibility of the product requires a level of subjectivity not conducive to consistent accounting treatment. In both the pilot company and the case study company, technical feasibility was found to be subject to widely divergent interpretation by different persons. This suggests a need to amend AC 122, which could be either in the form of blanket guidance, such as that provided in SFAS 2 on software development costs, or through the development of industry guidelines.

Additionally AC 122 has not placed sufficient emphases on commercial feasibility. Development costs should not be accounted for as an asset if the product is technically feasible but commercial feasibility is not assured.

In cases where regulatory approval is required before a product may be marketed, regulatory approval should be assured before the development costs are capitalised.

This research evaluated the development life cycle of drugs in the pharmaceutical industry as the basis from which to develop industry guidelines for demonstrating technical feasibility. In so doing this research demonstrated that it is possible to capitalise and amortise development costs in the pharmaceutical industry.

Finally the amortisation requirements of AC 122 are not appropriate to the pharmaceutical industry. Pharmaceutical drugs have vastly different turnover volume and revenue trends depending on the type of pharmaceutical drug under consideration. Most pharmaceutical drugs generate revenues – significant in magnitude – for a period beyond five years, the recommended amortisation ceiling of AC 122. The systematic amortisation of the development asset over five years will not result in the matching of development costs with the 'pattern of future economic benefits that it generates.' More appropriate to the pharmaceutical industry, ED 120 introduces a 20 years ceiling to replace the five years of AC 122, and simply suggests the straight-line method of amortisation where no clear pattern of future economic benefits can be determined.

The author therefore concludes that AC 122 and IAS 9 (revised), and therefore also the accounting standards for R & D costs as prescribed by other global standard setting bodies, do not promote the capitalisation of development costs in practice. Although this study has demonstrated that the development of industry specific guidelines is possible, and provided an example of attempting such an exercise, the effort and cost of doing so is unlikely to encourage similar efforts on an industry wide basis in South Africa or elsewhere. Therefore, unless national accounting standard setting bodies provide more specific guidance in the future, practical implementation of R & D accounting is unlikely to improve beyond what is currently witnessed as generally accepted accounting practice. ED 120 is an improvement on AC 122 in certain identified areas, specifically the introduction of the 20 years ceiling and the requirement to demonstrate commercial feasibility before capitalising development costs. It does not however provide any additional guidance on how to demonstrate technical feasibility or achieve satisfactory cost allocation.

9.2 Areas for further research

This research has adopted a case study approach and has identified problems associated with implementing AC 122 at both a general level, and specifically in the

pharmaceutical industry. It was noted above that an exercise of this nature is unlikely to be performed on an industry wide basis because of the cost and effort of doing so. However, the methods employed in this study may encourage similar studies in other research intensive industries, that support or reject the conclusions reached in this study.

This study focused on the implementation concerns associated with AC 122 as the main reason for the non-compliance with the requirements of AC 122. Scope exists for further research into any other reasons that may exist, to provide further insight into the seemingly unquestioned acceptance by the accounting profession of this non-compliance with AC 122.

In the literature review to this study a number of studies performed in the US and the UK were quoted. Similar studies on the SA market may provide greater insight into whether the market adopts a mechanistic or myopic approach to R & D spending. This in turn may provide an explanation for the preferred accounting method for R & D costs currently exhibited by South African companies.

10. APPENDICES

Appendix A: List of 30 companies' 1996 financial statements reviewed in July 1997.

Companies that write off R & D costs as incurred

1. Dorbyl
2. Eskom
3. Coates Brothers
4. Consol
5. Consolidated Metallurgical Industries
6. Control Instruments Group
7. Cadbury Schweppes
8. Polifin
9. Powertech
10. PPC
11. Q data
12. Reunert
13. Malbak Group
14. Master Fridge
15. Langeberg Holdings
16. SA Druggists
17. Premier Pharmaceuticals Company
18. Rembrandt Group
19. Sentrachem
20. Spanjaard

Company policy is to capitalise development costs if specified criteria are met

1. Tiger Oats
2. Teljoy
3. Omnia Holdings
4. Sasol
5. Nampak
6. Adcock Ingram
7. Minorco
8. Illovo sugar
9. Cullinan
10. ICS Holdings

APPENDIX B : LETTER SENT TO POTENTIAL CASE STUDY CANDIDATES

UNIVERSITY OF CAPE TOWN

Department of Accounting

Leslie Commerce Building
Engineering Mall · Upper Campus
OR Private Bag · Rondebosch 7700
Tel: 650-2269
Telex: 57-21439
Tel. Add.: ALUMNI. Cape Town
Fax No: (021) 650-4085

6 September, 1994

Mr L R Morris
Managing Director
South African Druggists Ltd
P O Box 5644
JOHANNESBURG
2000

Dear Sir

APPLICATION OF THE NEW ACCOUNTING STANDARD FOR RESEARCH AND DEVELOPMENT COSTS IN THE PHARMACEUTICAL INDUSTRY OF SOUTH AFRICA

I am a postgraduate student at the University of Cape Town currently undertaking a study for my Masters degree in Accounting.

The intended focus of my research is the Pharmaceutical Industry of South Africa with a view to determining the type of problems that may be encountered in applying the new accounting standard on research and development costs, AC122, and thereby assist in promoting an acceptable solution to such problems.

This standard is effective from 1 January 1994 and requires that development costs be capitalised as an asset and amortised on a systematic basis when certain specified criteria are met.

It is thus necessary for me to ascertain whether or not research and development activities are performed by your organisation. I envisage that some difficulty may be encountered in applying this new accounting standard, and would be interested in how it is being interpreted by the person/s in your organisation that have the responsibility for performing the accounting function.

I will make telephonic contact with you in the near future and would be most grateful if you would assist me in making contact with the relevant person/s.

Thanking you and looking forward to further contact.

Yours sincerely

SUZANNE BAIRD (MISS)
ACCOUNTING DEPARTMENT

PH: W +2721 650 2279
CR H +2721 53 4100

EAGERLY AWAITING YOUR RESPONSE

secrecy
020994

SECRECY AGREEMENT

between

and

M. S. BAIRD

"the recipient"

1. INTRODUCTION

1.1 The parties record that in the process of negotiations being conducted between them and/or its directors or employees will disclose to the recipient certain confidential information.

1.2 The recipient wishes to receive the confidential information solely to evaluate its interest in entering into contractual relationships with w.r.t research for masters degree for the benefit of both parties involved

1.3 is willing to disclose the confidential information solely in accordance with the terms and conditions herein set out in this agreement.

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2. DEFINITIONS

As and when used in this agreement, the following terms shall have the following meanings:

2.1	'the recipient"	shall mean and any associated or subsidiary company in whatever country organised.
2.2		shall mean and any associated or subsidiary company in whatever country organised.
2.3	"confidential information"	shall include, but not be limited to, any information relating to business arrangements, products, contracts, financial arrangements which may be disclosed by either directly or indirectly and whether in writing or by any other means.

3. CONFIDENTIALITY

3.1 will disclose confidential information to recipient upon signature of this agreement. considers the confidential information proprietary and valuable and releases same to recipient solely for the purpose stated herein. The confidential information so released shall at all times remain the sole and exclusive property of

secrecy
020994

3.2 Recipient undertakes:

3.2.1 to treat as confidential and not to release the confidential information to any third party. - (except to the reviewer of the dissertation who is also bound to by confidentiality ethics) MBaard

3.2.2 not to duplicate or use for any purpose other than as provided for in this agreement the confidential information. (FOR MASTERS DEGREE) MBaard

3.2.3 to exercise due care and to limit the release of the confidential information to those employees who reasonably require same for the purpose herein provided and recipient undertakes to ensure that all employees receiving the confidential information shall likewise be bound by the undertaking of confidentiality.

3.2.4 to take all reasonable steps to prevent unauthorised use of duplication of the confidential information and to use the same level of care to prevent any unauthorised use, disclosure or duplication thereof as it exercises in protecting its own most secret information.

[UCT exercises an Embargo on all dissertations + does not allow it into the public domain for a determined period] MBaard

3.2.5 to return promptly all copies of the confidential information at the request of and at the conclusion of the objects set out in this agreement.

3.2.6 not to use such information whether directly or indirectly in competition with

3.2.7 to treat as strictly confidential its discussions and negotiations with

3.3 The provisions of this clause shall not apply to such information which:

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3.3.1 is in the public domain at the time of disclosure; or

3.3.2 has, after disclosure, become part of the public domain by publication or otherwise through no fault of recipient; or

3.3.3 is already known to recipient, as can be established from the written records of recipient at the time of such disclosure.

4. DURATION

The obligations of the recipient under this agreement shall survive the termination of this agreement.

5. RIGHTS

The release of the confidential information to recipient shall not be deemed to confer any rights whatsoever on recipient other than those contained herein, nor shall be obliged to enter into any subsequent agreement with recipient.

6. WHOLE AGREEMENT

6.1 This agreement constitutes the whole agreement between the parties relating to the matters dealt with herein. On the date of last signature hereof, it supersedes any previous agreement the parties may have in respect of the subject matter. No party shall assert that it had an understanding inconsistent with, or that goes beyond, or falls short of, any provisions herein.

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6.2 No amendments, variations, additions or consensual cancellation of this agreement or any provisions or term thereof and no extension of time, waiver or relaxation of any of the provisions or terms of this agreement shall be binding unless recorded in a written document signed by the parties. Any such extension, waiver or relaxation which is so given or made shall be construed as relating strictly to the matter in respect whereof it was made or given.

6.3 No extension of time or waiver or relaxation of any of the provisions or terms of this agreement shall operate as an estoppel against any party in respect of its rights under this agreement, nor shall it operate so as to preclude such party from exercising its rights strictly in accordance with this agreement.

7. DOMICILIA

7.1 Any notices or communications to or from the respective parties required or permitted to be given hereunder shall be deemed to have been received:

7.1.1 if mailed by registered prepaid post to the recipient at the address given herein, seven (7) working days after date of mailing unless the contrary can be proved.

7.1.2 if sent by telefax to the recipient at the number given herein and evidence exists of receipt thereof, on the day of sending unless the contrary can be proved and provided that such telefax message is confirmed by registered prepaid post.

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7.1.3 if sent by telex to the recipient at the number given herein and evidence exists of receipt thereof, on the day of sending unless the contrary can be proved.

7.2 The parties hereto choose *domicilia citandi et executandi* for all purposes in terms of this agreement as follows:

7.2.1 the recipient

43 WAGENAAR STREET
MONTE VISTA
7460
Cape Town

7.2.2

7.3 Any party shall be entitled to change the *domicilia citandi et executandi* chosen by it by giving the other party thirty (30) days notice of such change of address.

7.4 A working day shall be every day with the exception of Saturdays, Sundays and statutory Public Holidays.

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8. **GOVERNING LAW**

This agreement shall be interpreted in accordance with, and governed by, South African law.

THUS DONE AND SIGNED AT CAPE TOWN this 26th day of JANUARY 1995 in the presence of the undersigned witnesses.

AS WITNESSES

1. _____

2. _____ _____

Recipient
duly authorised thereto

THUS DONE AND SIGNED AT _____ this _____ day of _____ 1994 in the presence of the undersigned witnesses.

AS WITNESSES

1. _____

2. _____ _____

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