QUESTION 2 **50 marks**

Ignore taxation.

1 Background

1.1 Company background

PharmaConcepts (Pty) Ltd ('PharmCon') is a private company that performs pharmaceutical research and development. As a leading pharmaceutical company in sub-Saharan Africa, the company develops, produces and sells branded pharmaceutical products. PharmCon has a 30 June year end.

1.2 Industry background

Pharmaceutical companies are businesses that research, develop, produce, market and/or distribute pharmaceutical products that are used to prevent infections or treat and cure diseases affecting humans. Most pharmaceutical companies' activities relate to prescription medication (medicines prescribed by doctors and other registered healthcare professionals), over-the-counter (OTC) medicines (medicines that can be purchased without a prescription) and medical devices.

Pharmaceutical products impact the health of millions of people and the industry is highly regulated. In South Africa, the industry is regulated by the South African Health Products Regulatory Authority (SAHPRA).

The development of prescription and OTC medicines can be a long and expensive process. Before a pharmaceutical product can be sold commercially, it must undergo several steps, including research, pre-clinical testing, clinical trials and regulatory review. Each stage in the process is informed by the outcome of the previous stage, and this can result in additional costs to refine the product formula or in the complete abandonment of the development.

Pharmaceutical companies invest considerable capital sums in research and development of new pharmaceutical products. Their intellectual property (the pharmaceutical product's formula) is protected by means of legal mechanisms such as patents, which give a company the exclusive right to produce and sell the specific pharmaceutical product. Patents have a useful life of 20 years from the time they are issued, which is usually in the early stages of the development of a pharmaceutical product. In some countries, patents may be extended by the regulatory body for a short period after the end of the pharmaceutical product's initial patent protection period.

When a pharmaceutical product formula reaches the end of its patent protection period, the exclusive right expires, allowing other pharmaceutical companies to produce generic versions of that pharmaceutical product. A generic pharmaceutical product is created using the formula of an existing approved brand-name pharmaceutical product and is the same as far as dosage, format, safety, strength, method of administration, quality and efficacy are concerned.

PharmCon faces fierce competition from international companies and its success is driven by research into biotechnologies, bringing new pharmaceutical products to the market and maintaining the market position of existing products.

2 FluSlay patent and formula

FluSlay is PharmCon's top-selling influenza medication in Southern Africa. PharmCon obtained a 20-year patent on the FluSlay formula on 30 June 2003. However, according to PharmCon's business plan, economic benefits will be derived from the use of the FluSlay formula until 30 June 2031. PharmCon accordingly applied for an extension of the patent for a further eight years. Both the patent and formula have been correctly recognised as intangible assets in the accounting records and are accounted for using the cost model, in accordance with International Financial Reporting Standards.

2.1 Business restructuring and dispute with Pax Pharmaceuticals Ltd ('PaxPharm')

During April 2021, PharmCon investigated the prospect of undertaking a process of general business restructuring, which would commence on 1 October 2021. The potential restructuring would require greater promotional product support for FluSlay among doctors and pharmacists. It would only be possible to achieve this through a promotional product support campaign. The cost of such a campaign was estimated at R285 000, and would be incurred during the 2022 financial year (FY2022). By 30 June 2021, the board had yet to decide whether the proposed restructuring would be undertaken.

PharmCon also increased its insurance cover for litigation, following a dispute with PaxPharm. This followed from a threat of legal action by PaxPharm against PharmCon during May 2021. PaxPharm accused PharmCon of anti-competitive behaviour in the influenza drug market. PharmCon had incentivised medical practitioners to prescribe FluSlay as the preferred influenza drug for their patients. The insurance premium for the additional litigation cover, which is payable in respect of FY2022 and FY2023, amounts to R50 000 and R52 000 respectively, all payable in arrears. The cover is expected to be cancelled when FluSlay's patent rights expire.

On 30 June 2021, the carrying amount of the FluSlay formula was R37,85 million.

2.2 Non-renewal of patent

In June 2021, PharmCon received an official communication from SAHPRA stating that the patent for FluSlay would not be extended. In addition, RazorPharm Ltd ('RazorPharm'), a competitor, is developing a more advanced influenza medication that would be released on the market on 1 January 2023. PharmCon's management assessed the impact of the non-renewal of the patent and the development of the RazorPharm medication on FluSlay and has reliably predicted that FluSlay will consequently experience lower sales than previously estimated.

The following schedule reflects management's revised projections of the estimated future cash flows that PharmCon expects to derive from the continued use of the FluSlay formula for the period FY2022 to FY2026. After FY2026, the annual long-term rate of decline in the net cash flows related to the production and sales of FluSlay is expected to be 12% per year until 30 June 2031, when all production of FluSlay will be halted. The projected cash flows have been adjusted for the risk of reduced sales resulting from the effects of the RazorPharm product. All cash flows will occur at the end of each financial year.

Projected cash flows expected to be generated from (incurred by) the continued production and sale of the FluSlay formula					
Details	**FY2022**	**FY2023**	**FY2024**	**FY2025**	**FY2026**
	R'000	**R'000**	**R'000**	**R'000**	**R'000**
Total inflows from FluSlay sales	15 800	11 900	9 300	6 800	6 150
Additional FluSlay sales from enhancements to the formula	0	2 850	3 180	4 340	4 950
Pharmaceutical product production costs	(4 800)	(3 620)	(2 830)	(2 069)	(1 870)
Costs necessary to maintain expected sales	(1 200)	(1 050)	(980)	(760)	(700)
FluSlay formula enhancement costs and additional production and sales costs directly related to additional FluSlay sales	(450)	(580)	(630)	(898)	(915)
Incremental litigation insurance cover	(50)	(52)	–	–	–
Promotional product support campaign	(285)	–	–	–	–

The following pre-tax discount rates are applicable to the cash flows expected from the FluSlay formula:

- 7% – this rate does not take the risk of reduced sales into account; or
- 9% – this rate takes the risk of reduced sales into account.

There is no principal market for the re-sale of the FluSlay formula in Southern Africa. However, PharmCon has identified an opportunity to sell the FluSlay formula to one of two prospective companies, one based in Madagascar, the other in Kenya. The acquiring company would obtain the sole rights to the FluSlay formula, make some modifications to it and thus develop a more complex pharmaceutical product that could then be patented in its particular region. PharmCon is legally permitted to transact with these pharmaceutical companies.

As at 30 June 2021, the selling prices of the FluSlay formula, and related costs, for Madagascar and Kenya may be summarised as follows:

Summary of selling prices of FluSlay formula in identified markets and related costs		
	Madagascar	**Kenya**
	R'000	**R'000**
Selling price	39 440	38 800
Pharmaceutical product regulatory review costs*	(2 880)	(2 880)
Legal fees attributable to sale of the formula	(1 960)	(1 070)
New chemical registration fees payable to regulator*	(650)	(650)

* Payable by PharmCon before the FluSlay formula can be sold in either of these two countries.

3 AllexMed and AllexKids production process

PharmCon produces two types of antihistamine medication that treat allergic conditions such as hay fever and skin rashes. AllexMed and AllexKids are prescribed by doctors and are also available OTC at pharmacies. These two products contain an active ingredient, meclastine. An active ingredient is the component of any medication that is responsible for the healing or preventative effects of the medication. Active ingredients are usually combined with other ingredients to improve the taste and appearance of the medication and its absorption properties.

AllexMed is recommended for adult use only. AllexKids is recommended for children. It is similar to AllexMed except that it contains a sweetener, has a lower concentration of the active ingredient, and can be dissolved in water.

3.1 Production process and costs

Both AllexMed and AllexKids are produced using the same type of machinery.

Both types of tablets are produced using 'direct compression'. In this process, a powdered form of meclastine, a filler and a binding powder are combined by a compressor to form a soft, granular mixture. In the case of AllexKids a sweetener is also added to the mixture. Before the mixture hardens completely, it is compressed into tablets by the compressor. A normal loss of 2% of the input is expected for the AllexKids mixture only. This is because of a mild chemical reaction between the sweetener and the binding powder. Losses are detected at the end of the process. To increase the efficiency of the production processes, each product type is usually produced on its own dedicated machinery.

The effectiveness of any pharmaceutical product can be influenced by the slightest of changes in the proportion and quality of inputs. The standard inputs for the production of AllexKids per 100 grams of meclastine are provided in table 1. Each AllexKids tablet weighs 1 gram.

Table 1: Standard Inputs for AllexKids

Ingredients	**Grams**	**Cost per gram**	**Total cost**
		R	**R**
Active ingredient	100	5,8	580
Filler	200	2,9	580
Binding powder	100	1,2	120
Sweetener	100	1,6	160
	500		**1 440**

Due to the high risk of theft from the factory warehouse, PharmCon tries to keep low levels of finished goods and material inventory on hand. There was no opening stock of finished or partially completed goods on hand on 1 September 2020. The budgeted production volume of AllexKids tablets was 46 060 tablets for September 2020.

3.2 AllexKids

Due to the supply-chain disruptions caused by the Covid-19 pandemic worldwide, PharmCon's Brazilian suppliers of sweeteners were unable to fulfil its monthly orders. PharmCon therefore had to use an alternative, local sweetener. PharmCon subsequently decided to continue to use this alternative sweetener in the production of AllexKids as part of the cost-saving initiatives it put in place in view of the expected global recession. However, because of production delays while switching to the local product, the standard cost card was not updated for this change. Hence, the recording of production transactions and variances arising from September's production and sale activities were based on the prior period's standard cost card.

A human error occurred in the production process during September 2020: The compressor machinery was incorrectly calibrated, which resulted in a change in the proportion of filler and binding powder used. Machine time was extended to compensate for the error. As a result of this error, an abnormal loss of 13% on total input (before normal losses) was recorded at the end of the process.

The actual inputs for AllexKids during September 2020 were as follows:

Table 2: Actual Inputs for AllexKids			
Ingredients	**Grams**	**Cost per gram**	**Total cost**
		R	**R**
Active ingredient	10 000	5,8	58 000
Filler	24 000	2,9	69 600
Binding powder	9 000	1,2	10 800
Sweetener	10 000	1,2	12 000
	53 000		**150 400**

There was no closing stock of material or finished goods on 30 September 2020.

A favourable fixed overhead volume (or efficiency) variance was recorded for the AllexKids production costs.

3.3 AllexMed

During September 2020 the production cost variances for AllexMed included a favourable fixed overhead volume variance. During the lockdown in South Africa, the demand for medication increased. Unfortunately, PharmCon could not adequately respond to the increased demand for AllexMed because its production facilities were already operating at full capacity. As a result, an adverse market share variance for sales was noted.

4 Key-stakeholder relationship manager

At a recent board meeting, members proposed that PharmCon employ a key-stakeholder relationship manager who would form part of the company's executive management. The role of the key-stakeholder relationship manager would be to build close, influential relationships with industry bodies and lawmakers in the South African healthcare industry.

The board is conscious of the growing socio-economic pressures faced by pharmaceutical companies globally, where they face scrutiny for the alleged predatory pricing of prescription medicines. The Chief Executive Officer (CEO) of PharmCon is concerned that this international pressure will have a direct effect on South African pharmaceutical companies, especially in view of the potential introduction of a national health insurance (NHI) scheme. The introduction of an NHI is expected to result in downward price pressure on pharmaceutical companies such as PharmCon.

The CEO contends that the high prices of pharmaceutical products are justified to compensate pharmaceutical companies for the risk of investing large sums of capital in researching and developing pharmaceutical products, some of which never even reach the market.

During the board meeting, the CEO stated that he has had informal conversations with a former Member of the Executive Council for Health in Gauteng, who would be an ideal key-stakeholder relationship manager. She has existing relationships with government, regulatory and industry bodies. These relationships would place PharmCon in a position to influence lawmakers to –

- minimise the extent of scrutiny and number of investigations into medicine prices in South Africa; and
- grant enhanced patent protection rights for longer periods, which would lessen the number of available generic pharmaceutical products. The resulting reduction in competition would allow developers of pharmaceutical products to maintain the prices of their pharmaceutical products.

The chief operations officer supported the CEO's view and added that SAHPRA should be made to realise that pharmaceutical companies are for-profit companies and that over-regulation could inhibit their ability to invest in research and development of life-saving pharmaceutical products. Mr Zondi Wise, the financial director, has been tasked with ensuring that sufficient funds are made available in the budget for the next financial year for the appointment of a key-stakeholder relationship manager.

The board also resolved that an additional amount be set aside in the budget to fund strategic donations to legislative and regulatory bodies at the discretion of the key-stakeholder relationship manager.

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INITIAL TEST OF COMPETENCE, SEPTEMBER 2021

PROFESSIONAL PAPER 1

PAPER 1 QUESTION 2 – REQUIRED		**Marks**	
		Sub-total	**Total**
(a)	Prepare the journal entry/entries required to recognise the impairment loss on the FluSlay formula in the accounting records of PharmCon for FY2021. • Support your answer with a detailed impairment calculation. • Round all calculated amounts to the nearest R1 000. *Communication skills – presentation*	20 *1*	21
(b)	Evaluate the impact of the production challenges in September 2020 by – (i) calculating all relevant variances in respect of material for the AllexKids production, as follows: • Material price and mix variances in detail per material type; • A material yield variance based on the total variance only; and (ii) recommending improvements that could be made to the production and procurement processes for AllexKids medication, based on the variances calculated in (b)(i), as well as those noted by management. • Round all amounts to the nearest cent. *Communication skills for (b)(ii) – logical argument*	 8 4 6 *1*	19
(c)	Discuss any ethical considerations that would arise for PharmCon from employing a key-stakeholder relationship manager, based on the discussion and resolutions at the recent board meeting of the company.	10	10
Total for question 2			**50**
TOTAL FOR PAPER 1			**100**