CANDIDATE NAME & SURNAME	
ID NUMBER	
EISA REGISTRATION NUMBER	
ASSESSMENT CENTRE	
ASSESSMENT CENTRE ACCREDITATION NUMBER	
QUALIFICATION	Occupational Certificate: Health Products Sales Associate
SAQA ID	118739
CREDITS	112
NQF LEVEL	5
PAPER	1 Theory paper (Set 1)
DATE OF EISA TBC	
DURATION	140 minutes (2 h 20 min)
TOTAL MARKS	125
PASS MARK	60%

GUIDELINES TO ASSESSORS/MARKERS

- The assessor/marker to evaluate candidate responses based on guidelines provided.
- The assessor/marker may consider responses which are not in the same verbatim as in the guideline.
- The assessor/marker will draw from their practical industry experience, knowledge and skills to evaluate candidate's response if learners provide responses which are:
- not in the guideline but are within scope of maintenance planning or
- over and above what is provided on guideline but are within scope of maintenance planning.

Glossary:

Term	Simple meaning
ALT	Alanine Transaminase Liver enzyme used to spot liver injury
API	Active pharmaceutical ingredient (drug substance)
BMI	Body-mass index; weight-to-height ratio
DSP	Designated service provider – scheme-preferred facility
FPG	Fasting plasma glucose (measured morning blood sugar)
HbA1c	Glycated Haemoglobin- A blood test that provides an average of blood-sugar level over a period of 2-3 months
HCP	Healthcare professional
HPSA	Health Products Sales Associate
LDL (LDL-C)	Low density lipoprotein often referred to as “Bad” cholesterol that can block arteries
MCA	Marketing Code Authority (monitors promotional ethics)
NHI	National Health Insurance (South African plan for universal health coverage)
Pharmacovigilance (PV)	Monitoring side-effects after a medicine reaches patients (drug-safety watch).
PI	Professional Information for Human Use- Approved product information for HCPs (dosing, indications, risks).
PIL	Patient Information Leaflet—patient-friendly instructions & safety info.
PMB	Prescribed Minimum Benefits—must-cover diagnoses & treatments in SA medical schemes.
POPIA	Protection of Personal Information Act (2013). SA data-privacy law
RWE	Real world evidence
SAHPRA	South African Health Products Regulatory Authority (national regulator of medicines & devices)
SAMED	South African Medical Technology Industry Association (industry code)
SEP	Single-Exit Price (factory price cap set by National Department of Health (NDoH))
UDI	Unique device identifier on medical devices
β_2 receptor	Type of adrenergic receptor specifically β_2 receptor found in various tissues in body including lungs, heart and skeletal muscle A “relax button” on airway muscles

Question 1.

1.1. You are meeting a medical scheme clinical advisor to position a registered South African medicine or medical device of your choice. Provide responses that demonstrate evidence-based medicine, cost-effectiveness, formulary/ designated service provider (DSP) alignment, real-world evidence (RWE), adherence support, ethical promotion, objection handling, and risk-sharing.

1.1.1 Read the Scenario above and Answer sub-questions (a) to (e). Write approximately 2–3 sentences per sub-question. Marks are awarded exactly as shown. No half-marks.

Marking guideline: Each sub-question is worth a maximum of 2 marks. Award 1 mark for each criterion addressed correctly (as indicated below). No half-marks. Model answers are guides only, credit any equivalent, correct, and compliant response. **Total 10 marks (5 x 2 marks).**

Sub-question	Question	Marks
a	Draft a professional opening (greeting + purpose) for the meeting AND state how the product aligns with the scheme's formulary and/or designated service provider (DSP) pathway. Example: "Good morning, Dr Nkosi. Thank you for meeting w me today. I'd like to discuss how [Product] fits your scheme's [benefit tier/formulary] and DSP pathway for [condition]."	**(2)** 1 mark: greeting + purpose. 1 mark: formulary/DSP alignment stated clearly.
b	State one quantified cost-effectiveness or budget-impact claim (e.g., reduced admissions, fewer visits, lower total cost) AND quote one quantitative outcome or quality metric (e.g., QALY, HbA1c change, exacerbation rate, readmission rate). Example: "Using [Product] can reduce [resource use] by X% and lower total cost by approximately R___ per patient-year. In addition, [clinical/quality metric] improved by [value] in [study/source]."	**(2)** 1 mark: quantified cost/budget-impact claim. 1 mark: quantitative outcome/metric quoted.
c	Provide one South African real-world evidence (RWE) source for example that supports the product's value AND describe one practical patient-adherence support intervention you will implement. Example: "South African claims or registry data (e.g., scheme claims analysis, hospital audit, or a published SA study) showed fewer admissions/visits after switching eligible patients to [Product]. We will support adherence via SMS refill reminders and pharmacist technique checks."	**(2)** 1 mark: South African RWE source/example stated. 1 mark: adherence support measure stated.

d	Explain (briefly) how your promotional approach complies with relevant South African legislation and industry codes (e.g., Medicines and Related Substances Act 101 of 1965 and applicable marketing/industry codes) AND respond respectfully to one common payer/clinical advisor objection. Example: "I will provide only SA-approved information (PI/PIL), avoid any inducements, and ensure materials are code-compliant. If cost is your concern, we can target high-risk members first and review outcomes at 3 months."	**(2)** 1 mark: compliance statement (no inducements; SA-approved information; pre-clearance where relevant). 1 mark: respectful response to a payer objection.
e	Propose one collaborative, risk-sharing pilot/action with measurable outcomes AND close with a clear next step and a realistic timeline (e.g., email follow-up, meeting, data review). Example: "Let's run a 3–6-month pilot in X eligible members with outcomes tracked (admissions, HbA1c/exacerbations, total cost). I will email the evidence pack today and schedule a 10-minute follow-up next week to agree on the Key Performance Indicators (KPI) dashboard."	**(2)** 1 mark: risk-sharing pilot/action with measurable outcomes. 1 mark: close + next step + timeline.

10 marks

1.1.2. Choose the most correct option from (a) to (J) below that aligns with the corresponding in (a) to (j) below. Mark your choice with an "X".

One (1) mark for each of the ten (10) questions.

a) Which legislation governs the registration, scheduling and control of medicines in South Africa?	**(1)**
	A. Pharmacy Act 53 of 1974
	B. Consumer Protection Act 68 of 2008
X	C. Medicines and Related Substances Act 101 of 1965
	D. National Health Act 61 of 2003
	E. Occupational Health and Safety Act 85 of 1993

b) The ownership and professional practice requirements for community pharmacies are primarily set out in the:	**(1)**

X	A. Pharmacy Act 53 of 1974
	B. Medicines and Related Substances Act 101 of 1965
	C. National Pricing Regulations (Single Exit Price)
	D. Consumer Protection Act 68 of 2008
	E. Promotion of Access to Information Act 2 of 2000 (PAIA)

c) Which Act requires lawful processing and protection of personal information, including identifiable patient data?	**(1)**
	A. National Health Act 61 of 2003
X	B. Protection of Personal Information Act 4 of 2013 (POPIA)
	C. Pharmacy Act 53 of 1974
	D. Competition Act 89 of 1998
	E. Basic Conditions of Employment Act 75 of 1997

d) Which industry code sets standards for ethical promotion of health products and interactions with healthcare professionals in South Africa?	**(1)**
	A. South African Pharmacy Council (SAPC) Scope of Practice
	B. Advertising Regulatory Board (ARB) Code of Advertising Practice
X	C. Marketing Code Authority (MCA) Code of Practice for the Marketing of Health Products
	D. National Health Act 61 of 2003
	E. Medicines and Related Substances Act 101 of 1965

e) For participating companies, pre-clearance (pre-approval) of medicine promotional material is typically administered by the:	**(1)**
X	A. Marketing Code Authority (MCA)
	B. South African Health Products Regulatory Authority (SAHPRA)
	C. Council for Medical Schemes (CMS)

	D. Health Professions Council of South Africa (HPCSA)
	E. South African Pharmacy Council (SAPC)

f) A company proposes that both companies keep the same minimum selling price to 'avoid a price war'. Which Act most directly prohibits price-fixing agreements?	**(1)**
	A. Pharmacy Act 53 of 1974
	B. Consumer Protection Act 68 of 2008
	C. Medicines and Related Substances Act 101 of 1965
	D. National Health Act 61 of 2003
X	E. Competition Act 89 of 1998

g) Your marketing team wants to run a consumer advert for a health product. Which industry body/code provides standards and a complaints process for advertising to the public in South Africa?	**(1)**
	A. South African Health Products Regulatory Authority (SAHPRA)
X	B. Advertising Regulatory Board (ARB) Practice
	C. South African Pharmacy Council (SAPC)
	D. Council for Medical Schemes (CMS)
	E. Health Professions Council of South Africa (HPCSA)

h) A pharmacy asks why a medicine price on your invoice differs from a competitor's. Which Act sets the Single Exit Price (SEP) system for medicines in South Africa?	**(1)**
	A. Competition Act 89 of 1998
	B. National Health Act 61 of 2003
X	C. Medicines and Related Substances Act 101 of 1965
	D. Pharmacy Act 53 of 1974
	E. Consumer Protection Act 68 of 2008

i) During a meeting, an HCP reports a serious suspected adverse drug reaction linked to your product. To whom must pharmacovigilance reports ultimately be submitted in South Africa?	**(1)**
	A. Marketing Code Authority (MCA)

	B. Advertising Regulatory Board (ARB)
X	C. South African Health Products Regulatory Authority (SAHPRA)
	D. South African Pharmacy Council (SAPC)
	E. Council for Medical Schemes (CMS)

j) Which act or code/regulation is most directly associated with ethical interactions with healthcare professionals, including rules on hospitality and recording transfer of value, for medicines promotion?	**(1)**
X	A. Marketing Code of Practice
	B. Good Pharmacy Practice (GPP) Rules
	C. Nursing Act 33 of 2005
	D. Occupational Health and Safety Act 85 of 1993
	E. Companies Act 71 of 2008

10 marks

1.1.3 You are a Health Products Sales Associate (HPSA) promoting amoxicillin 500 mg capsules (Schedule 4 antibiotic) to a general practitioner. During your call, the health care professional (HCP) asks:
1. whether amoxicillin can be promoted directly to the public on social media?
2. if you can leave free samples for "trial use"?
3. and how amoxicillin compares to azithromycin for respiratory infections?

Read the scenario above and answer the following FIVE (5) questions (a to e). Marks are shown in brackets.

Marking Guidelines:

a (1): Names an appropriate governing law/code AND states why it applies (e.g., controlled scheduling + ethical promotion obligations).
b (1): Clearly states why direct-to-public social media promotion of a Schedule 4 antibiotic is not permitted (e.g., prescription-only medicine; advertising/ethical code limitations).
c (1): Correctly states sampling rule/limitation for Schedule 4 AND gives a compliant alternative (e.g., provide approved PI; refer to Medical Information; no samples).
d (1): Provides a compliant comparative response: stays within approved information, avoids unsubstantiated superiority claims/off-label advice, and indicates escalation/referral if needed.
e (1): States one plausible consequence (disciplinary/ legal/ reputational/ patient-harm risk) for misleading or off-label claims.

a) Identify ONE key South African law/industry framework that governs ethical promotion of Schedule 4 medicines and state (in one short phrase) why it applies here.

(1)

Medicines and Related Substances Act 101 of 1965 and/or the SA Code of Marketing Practice (MCA): governs promotion/claims for scheduled medicines; requires truthful, approved information.

b) In ONE sentence, explain why you may not promote a Schedule 4 antibiotic directly to the public on social media.

(1)

Schedule 4 medicines are prescription-only; you cannot market them directly to the public via social media; promotion must remain compliant and within approved information channels.

c) The HCP asks for free "trial" samples. State ONE rule/requirement about providing samples of a Schedule 4 antibiotic AND ONE compliant alternative action you can take.

(1)

Do not provide Schedule 4 "samples"; instead provide approved PI/leaflet and refer requests to Medical/Compliance; encourage lawful prescribing and patient assessment.

d) The HCP asks how amoxicillin compares to azithromycin. Write ONE compliant response that (i) stays within approved information, and (ii) indicate what you will do if comparative/off-label advice is requested.

(1)

Provide balanced, approved information only; avoid comparative superiority unless supported/approved; if the HCP wants comparative/off-label guidance, refer to Medical Information and approved resources.

e) State ONE potential consequence (legal, disciplinary, reputational, or patient-safety related) for an HPSA/company if misleading or off-label claims are made.

(1)

Possible consequences: disciplinary action, code sanctions, regulatory complaints, reputational damage, and patient-safety risk from inappropriate use.

5 marks

1.1.4 Case Study:
A South African start-up company has launched Dermascan-Lite™, a hand-held Class B imaging device for early melanoma screening (SAHPRA Device Register ref. 2025/03-B). The company plans to detail the device directly to general practitioners' rooms and rural clinics.

You are a Health Product Sales Associate (HPSA) at this start-up company, preparing to detail Dermascan-Lite™ to general practitioners' rooms and rural clinics. Answer the questions below. Keep your total response to approximately 150 words for a–c combined.
Quick-grading rubric

Sub-question	Criterion	Marks
1.1.4 a)	SEP rationale + compliance step (both required)	1
1.1.4 b)	Requirement #1	1
1.1.4 b)	Requirement #2	1
1.1.4 c)	Patient-outcome benefit	1
1.1.4 c)	Cost-saving argument	1

a) In one sentence, explain why the price of Dermascan-Lite™ is not regulated under the medicines Single Exit Price (SEP) framework, and in the same sentence name one (1) price-transparency or pricing-compliance step the supplier must still follow.	**(1)** **SEP rationale + one compliance step** Allocate one (1) mark only if BOTH elements are present: (i) a correct reason why medicines SEP does not apply to this product, AND (ii) one valid pricing-related compliance step still required. If one element is missing or incorrect: 0 marks. Acceptable answers include: • Reason (any 1): Dermascan-Lite™ is regulated as a medical device (Class B), not as a scheduled medicine; therefore, medicines SEP pricing rules do not apply. • Compliance step (any 1): provide a transparent written price (e.g., an official price list or quotation) and clearly show VAT / price components; OR keep pricing records available for audit; OR follow any applicable SAHPRA device pricing / transparency requirement.

b) State any two (2) requirements from the SAMED / Marketing Code Authority (MCA) Medical Device Code that the sales team must observe and do when demonstrating the device in a GP's rooms. Write each as a short "DO" statement.	**(2)** **SAMED / MCA Medical Device Code requirements (2)** Allocate one (1) mark per correct, distinct requirement (maximum two). No half-marks. If the learner repeats the same idea in different words, award one (1) mark only. Examples of acceptable requirements (any two): - DO ensure demonstration/exhibition devices are NOT used in patient care and are clearly labelled "Sample / Not for Human Use / Not for patient use." - DO provide the latest Regulatory Authority-approved Instructions for Use (IFU) when detailing for the first time and keep all statements/claims within the IFU (no additional claims). - DO use approved, factual information and the IFU only; avoid unsubstantiated or off-label claims. - DO avoid offering inappropriate gifts, inducements, or benefits to healthcare professionals. - DO record and control demonstration units (e.g., asset register) and retrieve the unit within the permitted period / as per company procedure. - DO ensure hospitality/meetings are appropriate and linked to legitimate training; avoid lavish hospitality. - DO respect patient confidentiality and POPIA when viewing or handling any patient information during demonstrations. - DO document and disclose transfers of value if required (e.g., meals, training support).
c) Provide one (1) patient-outcome benefit and one (1) cost-saving argument that would appeal to a managed-care funder. State each in one (1) sentence.	**(2)** **Patient-outcome benefit + cost-saving argument (2)** Allocate one (1) mark for a plausible patient-outcome benefit and one (1) mark for a plausible cost-saving argument. Each must be stated as one sentence and must be relevant to managed care. Examples (accept any reasonable equivalent):

	• Patient outcome: Earlier identification of suspicious lesions can speed referral and treatment, improving patient outcomes. • Cost saving: Earlier triage in primary care can reduce unnecessary specialist referrals and avoid costs associated with late-stage treatment.

5 marks

1.1.5. Using the hypothetical Market Trends Report below, answer all sub-questions (a)–(c).

Instructions

- Answer ALL sub-questions. **The total for Question 1.1.5 is 15 marks.**
- Write approximately 250 words in total across (a)–(c). Bullet points are acceptable.
- Use the data provided in the report. Where requested, you may add brief South African context from your own knowledge.

Market Trends Report

Global health-products landscape (2025)

Trend	Illustrative 2024-2025 datapoints
Artificial Intelligence (AI) diagnostics & wearables boom	• IDC forecasts ± 20 % Compound Annual Growth Rate (CAGR) for Artificial Intelligence (AI)-enabled medical devices through 2027. • Apple & Fitbit shipped 210 M smart-health devices in 2024 (↑ 18 %). • US FDA cleared 56 AI imaging tools in 2024 vs 12 in 2020.
Ageing populations & chronic-disease demand	• ≥ 65-year cohort now 10 % of world pop.; will reach 16 % by 2050 (UN). • Chronic-care drugs make up 42 % of global Rx spend (IQVIA).
Generic & biosimilar cost pressure	• Average list price erosion –8 % Compound Annual Growth Rate (CAGR) in mature markets. • 11 blockbusters lose exclusivity 2025-27 (e.g., apixaban, secukinumab).
Eco-regulation tightening	• European Union (EU's) Extended Producer Responsibility (EPR) plastic fee starts 2026; pharma pack waste must drop 10 %. • World Health Organization (WHO) calls for carbon-neutral supply chains by 2030.
Elective procedures softening	• Organisation for Economic Co-operation and Development (OECD) data: elective hip & knee

	surgeries still 7 % below 2019 volumes as payers shift funds to chronic care and vaccination.

Trend	Illustrative 2024-2025 datapoints
Focus on affordable cardio- & diabetes medicines	• Department of Health (DoH) 2025 tender: 3 largest lines = amlodipine, metformin, human insulin. • NHI pilot sites report hypertension prevalence 34 %; diabetes 13 %.
Slow AI-tool uptake	• < 5 % of public clinics have broadband ≥ 20 Mbps. • Only 120 radiographers trained on AI triage software (HPCSA data).
Fierce generic price-competition	• Top 5 generic firms cut Single Exit Price (SEP) by 12 % in 2024 to defend share. • Parallel import window expanded for 8 molecules.
Local-manufacturing incentives	• The Department of Trade and Industry's (DTI's) "Proudly Local-Active Pharmaceutical Ingredients (API)" scheme: 15 % tax credit + duty rebate. • Two new oral-solid plants break ground in Gauteng and KZN.
NHI roll-out to widen access	The Essential Medicines List (EML) update 2025 adds 18 more generics to facilitate bulk tenders.

South African market snapshot (2025)

After perusing the global and local trends from the hypothetical Market Trends Report provided above, answer the following three questions:

(a) Common thread (similarity): In ONE sentence, name ONE similarity that links the global and South African snapshots. Then provide FOUR short evidence bullets from the report (at least TWO global and TWO South African) showing this similarity and briefly state why each datapoint supports your similarity.	**(5)**
Similarity (5 marks) • 1 mark: similarity clearly named in one sentence (must relate to both global and SA snapshots). • 4 marks: four evidence bullets (1 mark each) that use datapoints from the report and explain how each supports the stated similarity (expect at least two global and two South African datapoints). **Illustrative answer (accept any equivalent accurate reasoning):** • Similarity example: Rising chronic-disease burden is increasing demand for affordable long-term medicines in both markets. • Global: 65+ population projected to rise to 16% by 2050, increasing chronic-disease prevalence and long-term treatment demand. • Global: chronic-care drugs comprise 42% of global prescription spend, indicating sustained demand for chronic therapies. • South Africa: DoH tenders prioritise amlodipine, metformin and insulin, showing a system focus on affordable chronic-disease medicines. • South Africa: NHI pilot sites report high hypertension (34%) and diabetes (13%) prevalence, reinforcing the chronic-care priority.	
(b) Contrast map (differences): Complete the table below for TWO differences between global and South African trends. For each difference: (i) state the difference clearly, (ii) cite ONE global and ONE South African datapoint from the report, and (iii) explain why the difference exists and what it implies for access/uptake. (complete BOTH rows): **Differences (5 marks)** • Two differences required (2.5 marks each). • Per difference: 1.0 mark for clearly stating the difference; 1.0 mark for correct supporting evidence (at least one global + one SA datapoint); 0.5 mark for a plausible explanation/implication (why it exists and what it means for uptake/access). **Illustrative differences (accept any two well-supported differences):** • Difference 1 (digital health maturity): Global AI diagnostics and wearables are growing fast (20% CAGR; 210M devices shipped; 56 FDA AI imaging tools cleared), whereas South African public-sector AI uptake is slow (<5% clinics with 20 Mbps broadband; only 120 radiographers trained). Reason/implication: infrastructure and	**(5)**

skills constraints slow adoption; HPSA education should prioritise low-tech pathways and realistic implementation.

- Difference 2 (policy emphasis): Globally, eco-regulation and carbon-neutral supply chains are tightening (EU EPR fee from 2026; WHO carbon-neutral supply chain call), while South Africa is incentivising local manufacture (15% tax credit + duty rebate; new oral-solid plants). Reason/implication: local policy aims at supply security and industrial development; value messaging should include local availability and reliable supply.

Difference (what is different?)	Evidence from the report (Global + SA)	Why the difference exists / implication for uptake

(c) HPSA launch mini-plan (generic metformin XR): Using the South African snapshot, propose TWO practical recommendations for launching a new generic metformin extended-release (XR) product. For EACH recommendation: name ONE relevant trend-related opportunity or challenge (0.5 mark) and list TWO actionable HPSA-level actions (1 mark each). Present your answer as two separate recommendation blocks with headings. **(5)**

Metformin XR launch recommendations (5 marks)

- Two recommendations required (2.5 marks each).
- Per recommendation: 0.5 mark for naming an SA trend-linked opportunity/challenge; 2.0 marks for two distinct, actionable HPSA-level actions (1 mark each).

Illustrative answer (accept any equivalent, compliant actions):

- **Recommendation 1: Win public-sector uptake by aligning with NHI/DoH chronic-disease priorities**
- Trend-linked opportunity/challenge: Opportunity: Department of Health (DoH) tenders prioritise metformin and NHI is expanding access for diabetes and hypertension.
  - Action 1: Provide short in-service education sessions for clinic prescribers on metformin XR positioning (once-daily dosing, improved GI tolerability vs IR in some patients) and appropriate patient selection, using approved materials.
  - Action 2: Support market-access colleagues by collecting facility-level utilisation/stock-out feedback and coordinating meetings where

formulary decision-makers can review pricing, pack configuration and bioequivalence evidence (within role scope).

- **Recommendation 2: Differentiate in a price-competitive generic market**
- Trend-linked opportunity/challenge: Challenge: SEP cuts and parallel imports intensify price competition and reduce brand loyalty.

  - Action 1: Run pharmacist 'counter-top' micro-trainings on counselling points that improve adherence (once-daily routines, managing GI side effects, what to do when doses are missed) and provide compliant patient information leaflets.
  - Action 2: Map competitor availability and pricing at key pharmacies/wholesalers and feedback weekly intelligence to the company to protect supply continuity and target high-volume sites.

(Use TWO blocks)

Recommendation	Trend-linked opportunity/challenge (0.5)	Action 1 (HPSA-level)	Action 2 (HPSA-level)

15 Marks

Question 1 Sub-Total: 45 Marks

Question 2.

2.1.1 Explain how you, as a Health Product Sales Associate (HPSA), would present a health product to educate customers. Focus on THREE major anatomical systems. For each system, use an example medicine (aligned with its most common indication in the Professional Information for human use (PI)) to guide your discussion. Your answers must be detailed, well-organised, and use appropriate terminology.

Anatomical Systems to be used to answer questions a-c below.

a) Cardiovascular system – example: Atorvastatin 20 mg tablet (or your selected medicine)
b) Respiratory system – example: Salbutamol 100 microgram/dose inhaler (or your selected medicine)
c) Endocrine system – example: Levothyroxine 50 microgram tablet (or your selected medicine)

Key areas to focus on (for each system):

- Anatomy and Physiology (3 marks): structure and function of the system relevant to the medicine/condition; use correct medical terminology.
- Pathophysiology (3 marks): ONE common condition affecting the system and how it disrupts normal function.
- Medicine application (4 marks): role in therapy, mechanism of action, two patient benefits, and significance for healthcare and sales contexts.

Detailed Marking Rubric (applies to each of the three systems)

Criterion	Weighting	Max marks (30)
Accurate explanation of anatomy and physiology	30%	9
Clear identification and analysis of pathophysiology	30%	9
Effective integration of health product information (MOA, benefits, sales relevance)	40%	12

Marking Guidelines

Mark each system independently (10 marks per system: 3 + 3 + 4). Award marks for any clinically correct equivalent explanation aligned to the PI and the system/condition chosen.

Granular marking guidance (per system)

Criterion	**Marks**	**What to look for (examples)**
Anatomy & Physiology	3	Key structures + correct function(s) relevant to the condition and the medicine's target.
Pathophysiology	3	Condition named/defined + how normal function is disrupted + one or more typical impacts/symptoms/risks.
Medicine application	4	MOA (1) + TWO patient benefits (2) + healthcare AND sales relevance (1) (e.g., adherence, affordability, access, technique training, market need).

a) Cardiovascular system (Example medicine: Atorvastatin 20 mg tablet/selected example)

Complete the Customer Education Card below. Use Professional Information for human use (PI)-aligned information for the medicine you choose (or the example provided).

1. Anatomy and Physiology: Explain the key structure(s) and function(s) of the cardiovascular system relevant to the condition and medicine.

- Heart pumps blood through arteries and veins; coronary arteries supply the myocardium.
- Lipids circulate as lipoproteins (LDL/HDL); LDL delivers cholesterol to tissues and contributes to atheroma formation.
- Atherosclerotic plaque can narrow arteries and reduce blood flow, increasing cardiovascular risk

(3)
2. Pathophysiology: Describe ONE common condition affecting this system (aligned to the medicine's most common indication) and explain how it disrupts normal functioning. • Dyslipidaemia: elevated LDL (and/or triglycerides) promotes cholesterol deposition in arterial walls. • Plaque formation leads to arterial narrowing and inflammation; plaques may rupture causing thrombosis. • Consequences include angina, myocardial infarction and stroke risk. (3)
3. Medicine application: Explain the medicine's role in therapy, its mechanism of action, TWO patient benefits, and why this is significant in healthcare AND sales contexts. • MOA: statin inhibits HMG-CoA reductase, lowering hepatic cholesterol synthesis and increasing LDL clearance. • Two patient benefits: lowers LDL and cardiovascular event risk; once-daily dosing supports adherence. • Healthcare & sales relevance: preventive, long-term therapy; adherence messaging, affordability/formulary access and risk-reduction counselling support appropriate uptake. (4)

b) Respiratory system (Example medicine: Salbutamol 100 microgram/dose inhaler/selected medicine)

Complete the Customer Education Card below. Use Professional Information for human use (PI)-aligned information for the medicine you choose (or the example provided).

1. Anatomy and Physiology: Explain the key structure(s) and function(s) of the respiratory system relevant to the condition and medicine. • Airways conduct air to alveoli for gas exchange; airway smooth muscle controls airway calibre. • Beta2 receptors on airway smooth muscle mediate relaxation (bronchodilation). • Normal ventilation requires open airways and efficient alveolar-capillary gas exchange (3)
2. Pathophysiology: Describe ONE common condition affecting this system (aligned to the medicine's most common indication) and explain how it disrupts normal functioning. • Asthma: airway inflammation with hyperresponsiveness triggers bronchoconstriction and mucus production. • These narrows airways, increases resistance and reduces airflow (wheeze, breathlessness). • Acute exacerbations can be triggered by allergens, infection, exercise or irritants. (3)
3. Medicine application: Explain the medicine's role in therapy, its mechanism of action, TWO patient benefits, and why this is significant in healthcare AND sales contexts. • MOA: short-acting beta2 agonist causes rapid bronchodilation by relaxing airway smooth muscle. • Two patient benefits: quick symptom relief during bronchospasm; improves ability to breathe during acute symptoms. • Healthcare & sales relevance: device/technique education is essential; appropriate positioning as rescue (not maintenance) supports safe use and customer trust. (4)

c) Endocrine system (Example medicine: Levothyroxine 50 microgram tablet/selected example)
Complete the Customer Education Card below. Use Professional Information for human use (PI)-aligned information for the medicine you choose (or the example provided).

1. Anatomy and Physiology: Explain the key structure(s) and function(s) of the endocrine system relevant to the condition and medicine. • Endocrine glands release hormones into the bloodstream; thyroid produces T4/T3 regulating metabolic rate. • T4 is converted to T3 in tissues; thyroid hormone influences heart rate, energy, temperature and growth. • Hormone levels are regulated by feedback via the hypothalamus-pituitary-thyroid axis (TSH). (3)
2. Pathophysiology: Describe ONE common condition affecting this system (aligned to the medicine's most common indication) and explain how it disrupts normal functioning. • Hypothyroidism: reduced thyroid hormone production (often autoimmune) lowers metabolic activity. • Disruption leads to fatigue, weight gain, cold intolerance, constipation and bradycardia. • Untreated disease can worsen lipid levels and cardiovascular risk; severe cases can be life-threatening. (3)
3. Medicine application: Explain the medicine's role in therapy, its mechanism of action, TWO patient benefits, and why this is significant in healthcare AND sales contexts. • MOA: levothyroxine is synthetic T4 replacement that restores circulating thyroid hormone and normalises TSH over time. • Two patient benefits: improves symptoms/energy and stabilises metabolic function; supports normal heart and lipid metabolism. • Healthcare & sales relevance: long-term therapy requires adherence and consistent dosing advice; counselling on timing, interactions and monitoring enhances outcomes and repeat supply. (4)

30 marks

2.1.2 The following questions test your knowledge of pharmaceutics and pharmacological terms and principles. Choose the single most appropriate option for each multiple-choice question (MCQ). Mark your choice with an "X".

a) Which statement best defines bioavailability (F)	**(1)**
1. Speed of tablet disintegration	
2. Fraction of an administered dose reaching systemic circulation unchanged	**X**
3. Total amount excreted in urine	
4. Volume of distribution	

5. Extent of protein binding	

b) Renal excretion of a weak acid is increased by which urine manipulation?	**(1)**
1. Acidifying the urine (e.g., ammonium chloride, NH4Cl)	
2. Alkalinising the urine (e.g., sodium bicarbonate, NaHCO3)	**X**
3. Increasing plasma protein binding	
4. Enzyme inhibition	
5. Enteric coating the tablet	

c) The minimum inhibitory concentration (MIC) is the:	**(1)**
1. Peak plasma level after a loading dose	
2. Amount that kills 99.9% of bacteria	
3. Lowest drug concentration that prevents visible microbial growth	**X**
4. Median toxic dose in humans	
5. Concentration needed for half-maximal receptor occupancy	

d) A partial agonist will:	**(1)**
1. Have no intrinsic activity	
2. Produce a sub-maximal response even when all receptors are occupied	**X**
3. Act only as an antagonist	
4. Irreversibly activate the receptor	
5. Always require a loading dose	

e) If a drug is highly protein-bound (≥95%), displacement by another drug will most directly:	**(1)**
1. Increase renal clearance immediately	
2. Decrease bioavailability	

3. Shorten elimination half-life	
4. Reduce volume of distribution	
5. Increase free (unbound) plasma concentration	**X**

f) The term EC50 represents the drug concentration that:	**(1)**
1. Kills 50% of test animals	
2. Saturates 50% of metabolic enzymes	
3. Produces 50% of the maximal pharmacological effect	**X**
4. Gives a half-life of 50 minutes	
5. Is cleared at 50 mL/min	

g) Enzyme induction (e.g., by rifampicin) usually leads to:	**(1)**
1. Higher plasma levels of the victim drug	
2. Lower plasma levels due to increased metabolism	**X**
3. Longer half-life of the co-administered drug	
4. Decreased hepatic blood flow	
5. Inhibition of renal secretion	

h) For most drugs given by constant-rate IV infusion, steady-state concentration is reached approximately after:	**(1)**
1. One elimination half-life	
2. 12 hours, regardless of half-life	
3. When loading dose equals maintenance dose	
4. 4–5 elimination half-lives	**X**
5. The drug is eliminated	

i) A high oil/water partition coefficient (log P) predicts better:	**(1)**

1. Renal clearance by filtration	
2. Solubility in intravenous fluids	
3. Binding to albumin only	
4. Stability in acidic pH	
5. Crossing of lipid membranes such as the blood–brain barrier	**X**

j) In competitive antagonism, the agonist dose–response curve typically shows:	**(1)**
1. A parallel rightward shift with no change in maximal effect (Emax)	**X**
2. A lower maximal effect (Emax)	
3. A leftward shift indicating increased agonist potency	
4. No change in EC50 or Emax	
5. An irreversible loss of receptors	

10 Marks

2.1.3 Hypothetical Clinical Trial Description

Title: A 24-week, double-blind, double-dummy, placebo-controlled, randomised study comparing Metformin XR [extended release]1000 mg once daily with Metformin IR [Immediate Release] 500 mg twice daily and placebo in adults with type 2 diabetes not at glycaemic target.
Methodology:
Design: Double-blind, double-dummy, placebo-controlled, randomised.
Participants: 600 adults with type 2 diabetes mellitus (mean age 57 years; 60% female; baseline HbA1c 9.1%; BMI 31 kg/m^2).
Interventions: (1) Metformin XR 1000 mg once daily + IR placebo; (2) Metformin IR 500 mg twice daily + XR placebo; (3) placebo (matching placebos).
Duration: 24 weeks.
Primary endpoint: Percentage (%) change in HbA1c from baseline to week 24.
Secondary endpoints: Fasting Plasma Glucose [FPG], proportion achieving HbA1c < 7%, body-weight change, adherence (pill count).
Safety: GI adverse events (nausea/diarrhoea) and vitamin B12 drop > 20%.

Results (summary):

Parameter	Metformin XR	Metformin IR	Placebo	p-value / note

HbA1c change	-1.8% ± 0.4	-1.5% ± 0.5	-0.4% ± 0.3	P < 0.001 (both vs placebo)
HbA1c < 7%	62%	54%	8%	-
FPG change	-2.6 mmol/L	-2.2 mmol/L	-0.5 mmol/L	-
Weight change	-1.2 kg	-0.8 kg	+0.3 kg	-
Adherence ≥ 90%	88%	74%	92%	XR vs IR p = 0.01
GI adverse events	7%	17%	4%	XR vs IR p = 0.003
Vitamin B12 drop	1.0%	1.2%	0.5%	n.s.

Conclusion: Metformin XR produced greater HbA1c reduction, better adherence, and fewer GI adverse events than Metformin IR in this hypothetical study.

Instructions:

- Answer Questions a to f in the spaces provided.
- Use the numerical results from the table where relevant.
- Marks are shown in the right-hand column. **Total 10 marks.**

a) State the study design and duration in one phrase Marking (1): 1 mark for correctly stating BOTH the design and duration in one phrase. **Model answer:** 24-week, double-blind, double-dummy, placebo-controlled, randomised trial.	(1)
b) State the primary endpoint and the numerical primary outcome for Metformin XR. Marking (1): 0.5 for the primary endpoint + 0.5 for the correct XR numerical outcome. **Model answer:** Primary endpoint = % change in HbA1c from baseline to week 24; Metformin XR HbA1c change = -1.8%.	(1)
c) Which arm showed better adherence and by how many percentage points compared with Metformin IR? (Show both percentages) Marking (2): 1 mark for identifying the correct arm and quoting both adherence values; 1 mark for the correct absolute difference (14 percentage points). **Model answer:** Metformin XR had better adherence (88%) than Metformin IR (74%), an absolute difference of 14 percentage points (88 - 74).	(2)
d) Interpret the safety data: which active treatment had more GI adverse events, and what is the absolute difference versus Metformin XR? Marking (2): 1 mark for identifying the arm with more GI AEs; 1 mark for the correct absolute difference (10 percentage points).	(2)

Model answer: Metformin IR had more GI adverse events (17%) than Metformin XR (7%); absolute difference = 10 percentage points (17 - 7).	
e) Based on the results, give ONE clinical advantage and ONE patient-experience advantage of Metformin XR over Metformin IR. Marking (2): 1 mark for a correct clinical advantage supported by the results; 1 mark for a correct patient-experience advantage supported by the results. **Model answer (examples):** Clinical advantage - greater HbA1c reduction (-1.8% vs -1.5%) or more patients reaching HbA1c < 7% (62% vs 54%). Patient-experience advantage - fewer GI adverse events (7% vs 17%) and/or once-daily dosing convenience.	(2)
f) List TWO study limitations that a Health Product Sales Associate should mention when presenting these data. Marking (2): 1 mark for each valid, specific limitation (any two). **Model answer (any two):** short duration (24 weeks, no long-term outcomes); hypothetical dataset; self-reported/pill-count adherence limitations; limited generalisability (baseline HbA1c 9.1%, BMI 31); key exclusions not described; some secondary endpoints lack p-values.	(2)

10 marks

2.1.4 Read the Scenario below and answer the questions that follow.

Your company is launching VitaPress Co-Q10 100 mg vegan capsules (Complementary Medicine Category D: health supplement). As a Health Product Sales Associate (HPSA), design a compliant, value-adding educational launch event for 30 general practitioners and 10 retail pharmacists.

The event must:

- Align with the Marketing Code and the SAMED Complementary Products chapter.
- use both internal and external resources; and
- highlight balanced evidence on co-enzyme Q10 in cardiovascular energy support (Category D compliant wording).

Complete the launch-planning table below. Be specific, measurable, and compliant.

Model answers and marking guidance

The examples below are illustrative. Award marks for any equivalent responses that are specific, measurable, and compliant with Category D marketing-code requirements.

Sub-question	Response	Marks
	1. Educate HCPs on what co-enzyme Q10 is, appropriate Category D wording, dosing, cautions and interactions (scientific focus).	**(1)**

a) Objectives: List four (4) SMART goals for the event.	2. Obtain documented feedback on the patient information leaflet/label (readability, vegan/allergen statements, dose instructions).	**(1)**
	3. Secure a measurable commitment from pharmacies (e.g., intent-to-stock / shelf-listing pledge within 2 weeks).	**(1)**
	4. Achieve 100% completion of the CPD quiz and signed value-transfer acknowledgement at registration.	**(1)**
b) Agenda: Provide a 5-item programme (time, session, speaker/role, and compliant catering/venue).	1. 18:00 Registration; tea/coffee/water; sign-in and value-transfer acknowledgement (business venue).	**(1)**
	2. 18:10 KOL talk (cardiologist/pharmacist): 'Mitochondrial energy and cardiovascular support - evidence boundaries for Category D'.	**(1)**
	3. 18:35 Medical Advisor: product quality, dose, contraindications/cautions, claims wording; Q&A (pre-cleared slides).	**(1)**
	4. 18:55 Interactive case discussion (polling): patient selection, counselling points, adherence barriers (unbranded cases).	**(1)**
	5. 19:20 Modest meal and networking (no alcohol; per-person cost cap); 19:40 CPD QR quiz + feedback survey; close.	**(1)**
c) Resources and roles: Name three (3) internal and three (3) external resources.	1. Internal: HPSA event lead (planning, invitations, logistics, stakeholder communication).	**(0.5)**
	2. Internal: Medical Advisor (claims/slide approval; scientific balance; adverse event process).	**(0.5)**
	3. Internal: Compliance Officer (pre-clear invite/agenda; value-transfer documentation and upload).	**(0.5)**
	4. External: Independent KOL speaker (e.g., cardiologist or clinical pharmacist) on evidence boundaries.	**(0.5)**
	5. External: Accredited CPD provider (accreditation, QR quiz, certificates).	**(0.5)**
	6. External: AV/polling service provider (equipment, microphones, polling platform).	**(0.5)**
d) Compliance safeguards: Describe five (5) actions that keep the event within SAMED/MCA Marketing Code rules.	1. Venue and hospitality: business-appropriate venue; no entertainment; no spouses; no alcohol; itemised per-person cost log within the cap.	**(1)**
	2. Pre-approval: all invites, slides and claims pre-cleared by Medical and Compliance; Category D wording only (support/adjunct wording; no disease-treatment claims).	**(1)**
	3. Transparency: sponsorship disclosed on the invitation; attendance register signed; value-transfer recorded and uploaded to MCA within required timelines.	**(1)**
	4. Scientific balance: agenda is primarily educational; includes evidence limitations and when referral is needed, Q&A moderated to avoid off-label or disease claims.	**(1)**
	5. No inducements: no branded gifts; only unbranded scientific handouts (PIL/label guide) and CPD certificate; manage sample handling per company policy.	**(1)**

e) Evaluation: List three (3) evaluation tools (one traditional + two digital).	1. Traditional: attendance vs RSVP and post-event shelf-listing/stock uptake over 8-12 weeks vs baseline.	**(1)**
	2. Digital: QR-code CPD quiz completion analytics and satisfaction survey (Likert + free text).	**(1)**
	3. Digital: email campaign open/click-through rates or event resource-download analytics (e.g., link tracking).	**(1)**

20 marks

2.15: Using the below Scenario answer the questions that will follow

You are a Health-Products Sales Associate (HPSA) promoting SleepWell™ Melatonin 5 mg vegan gummies (Category D complementary medicine; approved only for adults ≥ 18 years with short-term insomnia). During a surgery visit, a general practitioner (GP) asks:
1) whether SleepWell™ can be "safely recommended" for toddlers (aged 2 years) who struggle to sleep; and
2) if the company would sponsor the GP's family holiday flight tickets in return for making SleepWell™ the GP's "first-line" sleep aid.
Answer all questions. Use clear, professional language. Marks are shown in the right-hand column.

a) Ethical issue triage: Identify THREE ethical issues for the scenario above. For each issue, write: (i) the ethical issue (label it), (ii) the code/ethical principle breached (e.g., off-label promotion, inducement/value transfer, patient safety/integrity), and (iii) one sentence explaining why it is problematic.

(3)

Allocate 1 mark for each correctly identified ethical issue WITH a brief, correct description (max 3). Credit any equivalent, correct ethical issues aligned to codes.

- Off-label/unauthorised use request (paediatric use): product approved for adults ≥18 years only; providing paediatric dosing/recommendations would be promotion beyond the approved label and raises patient-safety risk.
- Inducement / bribery / improper value transfer: request for family holiday flight tickets in exchange for 'first-line' recommending creates a quid-pro-quo and breaches anti-corruption/value-transfer rules (gifts/personal benefit linked to prescribing).
- Conflict of interest and compromised professional integrity: accepting the request would undermine independent clinical judgement and the HPSA's integrity; patient welfare may be subordinated to financial gain; reputational and regulatory risk for the company.

b) PAUSE action plan (5 steps): Explain FIVE practical steps you will take to handle the GP's requests in line with Marketing and SAMED Codes. Use the framework below (one step per letter):
P – Pause & acknowledge professionally
A – Advise strictly within the approved label/indication
U – Unacceptable value transfer: decline the holiday-ticket request
S – Seek support: Medical Information/Compliance/Pharmacovigilance (as applicable)
E – Escalate & document: record, report, and retain evidence

(5)

Allocate 1 mark per practical, compliant step (max 5). Credit equivalent correct actions.

- Decline off-label advice and stay within label: explain the product is approved for adults ≥18 years only; do not recommend for toddlers or provide dosing; provide approved information and suggest the GP consult appropriate paediatric guidance/clinical pathways.
- Decline the holiday-ticket request clearly and professionally: explain that company policy and Marketing/SAMED rules prohibit personal gifts/inducements linked to prescribing or recommendations.
- Offer compliant alternatives: provide balanced, approved educational materials and non-promotional sleep-hygiene guidance (general education), and/or propose a compliant clinical/medical-information response for the GP's question.
- Escalate properly: refer the paediatric-use query to Medical Information; if any adverse event or safety concern is raised, follow pharmacovigilance reporting procedures.

  Document and report: record the interaction in CRM/visit notes; capture and report the attempted inducement to Compliance; retain evidence (date, attendees, request, your response) as per SOP.

c) EQ skills: Describe TWO ways you will apply emotional-quotient (EQ) skills to maintain a positive professional relationship with the GP. For each, include an example phrase you would use.

(2)

Allocate 1 mark per EQ application with an appropriate example phrase (max 2).

- Empathy + active listening: acknowledge the GP's concern and reflect it back without agreeing to off-label use (e.g., "I can hear sleep problems are a real challenge in your practice; let's look at what is approved and what support I can arrange.").
- Assertive boundary-setting with respect: remain calm, professional and firm when refusing inducements (e.g., "I'm not able to support any personal travel benefits—our codes don't allow that—but I can support you with compliant clinical information and educational resources.").

10 marks

Sub-Total: 80 Marks

Grand Total: 125 Marks