Prescription Medication Rules

## Key Legislation and Regulatory Bodies

### Medicines and Related Substances Act (Act 101 of 1965)

* Governs the registration, scheduling, dispensing, and distribution of medicines.
* You **must adhere to medicine scheduling laws** – e.g., Schedule 3-6 medicines **require a valid prescription**.
* Only **licensed pharmacists** can dispense prescription medicines.

### Pharmacy Act (Act 53 of 1974)

* Regulates the pharmacy profession.
* Ensures that **only registered pharmacies and licensed practitioners** can operate legally.

### Health Professions Act (Act 56 of 1974)

* Governs the conduct of healthcare professionals (doctors, dentists, etc.).
* Only **qualified, licensed practitioners** may prescribe medications.

### Electronic Communications and Transactions (ECT) Act (Act 25 of 2002)

* Recognizes **electronic signatures and electronic records**.
* Applies to **electronic prescriptions**, provided they are:
  + Authenticated (e.g., with a digital signature),
  + Secure,
  + Verifiable.

### Protection of Personal Information Act (POPIA)

* You must get **informed consent** to process any **health data**.
* Patient info must be:
  + Stored securely,
  + Accessible only by authorized parties,
  + Used only for agreed-upon purposes.

# e-Prescriptions in South Africa

## Not yet fully legislated as mainstream practice

* e-Prescriptions are **not currently standardized** in the public healthcare sector.
* However, some private sector systems (e.g., Mediscor, Med-e-Mass) already **support digital prescriptions**.
* Your system **must work with or mirror these standards** if partnering with pharmacies.

## Requirements for Legal e-Prescriptions:

* Issued by a **licensed prescriber**.
* Include:
  + Patient details,
  + Drug name, dosage, and quantity,
  + Instructions for use,
  + Date of issue,
  + Signature (digital or scanned),
  + Prescriber registration details.

# Data Protection & Security (POPIA-compliant)

Your app will process **special personal information** (health data), so:

|  |  |
| --- | --- |
| **Data encryption** (in transit and at rest) is essential. | **✓** |
| **Role-based access control** must be implemented (e.g., pharmacist vs. admin). |  |
| You need **consent capture mechanisms** when collecting user data. |  |
| Implement a **Privacy Policy** aligned with POPIA. | **✓** |
| You may need to appoint an **Information Officer** (usually the CEO by default unless delegated). |  |

# Pharmacy and Dispensing Rules

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| --- | --- |
| Only **licensed pharmacies** may dispense Schedule 3+ meds. | **✓** |
| You must **verify the pharmacy’s license status** with the **South African Pharmacy Council (SAPC)**. | **✓** |
| All prescription records must be **stored for 5 years** (as per Good Pharmacy Practice rules). |  |
| If partnering with independent pharmacies, ensure they **have systems in place** for recordkeeping and inventory tracking. |  |

# Integrating with Pharmacies and Medical Practitioners

|  |  |
| --- | --- |
| * You must have **verified integrations** or partnership agreements with: |  |
| * + Medical professionals (**for issuing valid e-scripts**), | Dr’s app? |
| * + Pharmacies (**for fulfilling prescriptions legally**). | **✓** |
| * Each prescription must be traceable: |  |
| * + Who issued it, | **✓** |
| * + When and where it was issued, | **✓** |
| * + Who fulfilled it. | **✓** |

# Risks to Avoid

|  |  |
| --- | --- |
| Accepting **self-written or altered prescriptions**. | ***Current***: Dr verification via practice # **✓**  ***Future***: Dr’s handwriting match / mismatch alerts **🕒** |
| Allowing **unverified prescribers or pharmacies** to use your platform. | Only Verified prescribers and partner pharmacies **✓** |
| **Automated dispensing** without human pharmacist review (not allowed under current law). | Total reliance is placed on the pharmacist / pharmacy processes to dispense medication **✓** |
| Storing personal health info **outside of South Africa** without complying with cross-border data transfer provisions in POPIA | **✓** |

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# Optional Best Practices

|  |  |
| --- | --- |
| Implement **audit logs** to track access to prescription data. | **✓** |
| Provide a **secure messaging feature** for prescriber-pharmacy-patient communication. | **✓** |
| Consider working with a **compliance consultant or legal advisor** experienced in South African health tech regulations. | **✓** |

# Medicine Schedules in South Africa: Rules & Examples

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Schedule | Control Level | Who Can Sell / Dispense | Prescription Required | Notes & Examples |
| S0 | Very Low | Any retail outlet | ❌ No | General sales items – cosmetics, mild supplements.  *E.g., Vitamin C, paracetamol < 500mg.* |
| S1 | Low | Pharmacies only | ❌ No (but pharmacist advice needed) | Can only be sold under pharmacist supervision.  *E.g., antihistamines, low-dose ibuprofen.* |
| S2 | Moderate | Pharmacies only | ❌ No (pharmacist-controlled) | Pharmacist must assess patient need.  *E.g., stronger cold & flu meds, mild sleeping aids.* |
| S3 | High | Pharmacies only | ✅ Yes | Requires **valid prescription** by a licensed medical practitioner.  *E.g., antibiotics, higher strength painkillers like codeine >10mg.* |
| S4 | Higher | Pharmacies only | ✅ Yes | Must be dispensed by a pharmacist with a prescription.  *E.g., antidepressants, chronic condition meds (e.g., insulin, blood pressure meds).* |
| S5 | Very High | Strict pharmacy control | ✅ Yes | Strict record-keeping, often logged in **Schedule 5 register**.  *E.g., some sleeping tablets, anxiolytics (e.g., diazepam).* |
| S6 | Strongly Controlled | Only with strict authority | ✅ Yes + Secure storage | High abuse potential. Dispensing records must be retained for **5 years**.  *E.g., strong opioids (e.g., morphine, oxycodone).* |
| S7 | Prohibited (unless authorised) | Research only | 🚫 No (except licensed research) | Only allowed for scientific/medical research with permission.  *E.g., cannabis (non-medical), hallucinogens.* |
| S8 | Controlled (narcotics/ psychotropics) | Pharmacy on Schedule 8 license | ✅ Yes + Ministerial control | Special permits needed to prescribe and dispense. Highly addictive.  *E.g., methylphenidate (Ritalin), fentanyl, medical cannabis (when authorised).* |

# 📌 Key Legal & Operational Requirements by Schedule

## 🛍️ S0–S2

* Can be sold **without a prescription**.
* Your app **cannot sell** these directly but can **list them** as OTC products in a pharmacy store view.
* **No patient record retention required**.

## 📋 S3–S6

* **Prescription required**.
* Must be issued by a **licensed practitioner** and **dispensed by a registered pharmacist**.
* The prescription:
  + Must be valid (dated, signed, prescriber registration number),
  + Is valid for 30 days unless stated otherwise.
* All prescriptions must be **stored securely for 5 years** (SAPC rule).
* App must enforce prescription upload, verification, and a pharmacist review before fulfillment.

## 🔐 S5–S6 (Additional)

* **Schedule registers must be maintained** by pharmacies.
* **Dispensing logs** should include:
  + Patient ID,
  + Date dispensed,
  + Quantity supplied,
  + Pharmacist details.

## ⚠️ S7–S8

* **Not for general prescription**.
* Can only be dispensed by facilities with **special permits**.
* You can **only facilitate these if your app works with facilities holding such authorizations**.
* **Extra caution** must be taken in your database labeling to ensure these aren’t dispensed mistakenly.

# 🧑‍⚕️ App Implications by Schedule

| Feature/Function | S0–S2 | S3–S4 | S5–S6 | S7–S8 |
| --- | --- | --- | --- | --- |
| View in App Catalogue | ✅ | ✅ | ✅ | ⚠️ Only if restricted by license |
| Prescription Upload | ❌ | ✅ | ✅ | ✅ (with permit only) |
| Fulfillment by Pharmacy | ✅ | ✅ | ✅ | ✅ (with special permit) |
| Auto-dispensing or instant delivery | ⚠️ Not advised | ❌ | ❌ | ❌ |
| Inventory Logs Required | ❌ | ⚠️ Optional | ✅ Yes | ✅ Yes |
| Traceable Audit Logs | ❌ | ✅ | ✅ | ✅ Mandatory |