



1. Licenses Required When Using a Contract Manufacturer for Complementary Health Products

In South Africa, complementary health products fall under Category D (complementary medicines) regulated by SAHPRA under the Medicines and Related Substances Act, 1965 (Act 101 of 1965). When planning to use a contract manufacturer (also known as a contract manufacturing organization or CMO), both the contract manufacturer and you (**the sponsoring company** or marketing authorization holder) must obtain specific licenses. These are issued under Section 22C(1)(b) of the Act and are Category D-specific, valid for 5 years, and subject to compliance with Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), or Good Wholesaling Practice (GWP) standards.

1.1 Licenses for the Contract Manufacturer

- **Type of License:** Manufacturing license (Type DL01).
- **Why Required:** The contract manufacturer is directly responsible for the production processes, including total or partial manufacture, packaging, and presentation. This license ensures they adhere to GMP standards, verified through attestations, desktop reviews, and periodic inspections (at least once every 5 years). It guarantees the products meet quality, safety, and efficacy requirements, preventing substandard or unsafe items from entering the market. Without this, manufacturing activities are prohibited.

1.2 Licenses for You (the Sponsoring Company)

- **Type of License:** Depending on your role in the supply chain:
 - Import/Export license (Type DL02) if you handle importing raw materials or exporting finished products (e.g., if the contract manufacturer is overseas or if you export).

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- Wholesaler/Distributor license (Type DL03) if you are involved in wholesaling, distributing, or storing the products post-manufacture.
 - Note: If your activities are limited to holding the product registration and marketing without direct handling, you may still need a DL03 license for distribution oversight.
- **Why Required:** As the sponsoring entity, you maintain overall accountability for the product's compliance throughout the supply chain, even if manufacturing is outsourced. The license ensures you comply with GDP or GWP for any handling, storage, or distribution activities. It verifies your ability to maintain product integrity, traceability, and regulatory oversight via required documentation (e.g., site master files, responsible pharmacist details, and product lists appended to the license). This protects public health by holding all parties responsible and allowing SAHPRA to enforce standards, such as removing non-registered products from licenses after registration deadlines.

Additional Considerations

- **Application Process:** Apply electronically via SAHPRA's portal (www.sahpracm.org.za), including details per Regulation 23 (e.g., staff qualifications, compliance attestations, and fees for applications, reviews, and renewals). Amendments are needed for changes like site alterations or product additions.
- **Transitional and Ongoing Compliance:** Existing entities had a priority window until February 2022; new applicants must submit GMP/GDP/GWP review outcomes. All products must also be registered via call-up notices (timelines vary by risk level), and unregistered products must carry a disclaimer label. Failure to license halts all activities, ensuring only compliant entities operate.

- **Product-Specific Requirements:** Beyond licensing, the product itself requires registration in CTD format, with you as the holder submitting evidence of the contract manufacturer's GMP compliance.

These requirements align with SAHPRA's roadmap to phase in regulation, prioritizing low-risk products while enforcing accountability across the value chain. Consult SAHPRA directly for your specific scenario, as fees and processes may update.

2. More detail on the sponsoring entity:

In the context of **South African Health Products Regulatory Authority (SAHPRA)** regulations for health products like complementary medicines (Category D under the Medicines and Related Substances Act, 1965), the term "**sponsoring entity**" (sometimes simply called the "sponsor" or "applicant/sponsor") refers to the company, organization, or individual that takes overall responsibility for bringing a product to market in South Africa.

This is especially relevant when using a **contract manufacturer** (as in your scenario), where manufacturing is outsourced. The sponsoring entity is **not** the actual manufacturer but the party that owns or controls the product commercially and regulatory-wise.

2.1 Key Role and Responsibilities of the Sponsoring Entity

The sponsoring entity acts as the primary point of accountability to SAHPRA. Their main duties include:

- **Submitting the product registration application** — They prepare and lodge the dossier (in ZA-CTD format) for registration of the complementary medicine, including quality, safety, and efficacy data. They are listed as the **applicant** during the submission process.

- **Holding the Certificate of Registration** — Once approved, they become the **Holder of the Certificate of Registration (HCR)**. This is the official entity named on the registration certificate, responsible for the product's ongoing compliance, post-market surveillance (e.g., pharmacovigilance/adverse event reporting), variations/amendments, renewals, and any recalls.
- **Overseeing the supply chain** — Even though a contract manufacturer handles production, the sponsoring entity ensures the manufacturer complies with **Good Manufacturing Practice (GMP)**. They provide evidence of this (e.g., GMP certificates, quality agreements) in applications and maintain traceability and quality oversight.
- **Obtaining necessary licenses** — they typically need a **DL02 (Import/Export)** or **DL03 (Wholesaler/Distributor)** license under Section 22C(1)(b) if involved in importing materials, distributing, or marketing the finished product. This is separate from the contract manufacturer's **DL01 (Manufacturing)** license.
- **Ensuring overall regulatory compliance** — They handle interactions with SAHPRA (e.g., responding to queries during evaluation), maintain records, ensure labeling and advertising comply, and report any safety/quality issues. SAHPRA holds them accountable for the product's integrity throughout its lifecycle in South Africa.

2.2 Why This Distinction Matters in Contract Manufacturing

- The **contract manufacturer** is licensed to produce but does **not** own the registration or bear primary liability for the marketed product.
- The **sponsoring entity** bridges the gap: They "sponsor" the product by funding, managing, and representing it to regulators and the market. This setup is common for brands, importers, or marketers who don't have their own manufacturing facilities.

- Without a properly appointed sponsoring entity (as the HCR), the product cannot be legally registered or sold in South Africa, even if manufactured compliantly.

In SAHPRA documents (e.g., guidelines for Category D/complementary medicines registration and licensing), terms like "applicant (proposed Holder of Certificate of Registration)" or "sponsor" are used interchangeably in this context. For your plan with complementary health products, **you (or your company)** would typically be the sponsoring entity — appointing a South African-based entity if you're not local — and you'd need to nominate yourself as the HCR when submitting the registration.

For the most current details or your specific case, check SAHPRA's Complementary Medicines section on their website (www.sahpra.org.za) or consult a regulatory expert, as requirements can evolve with new guidelines or call-up notices.

3. Step-by-Step Instructions for Obtaining a Manufacturing License (Based on SAHPRA Rules)

This applies primarily to medicines and scheduled substances but extends to other health products like medical devices under similar frameworks. The process is detailed in SAHPRA's Guideline on How to Apply for a Licence to Manufacture, Import and/or Export Medicines and Scheduled Substances.

1. **Determine Eligibility and Exemptions:** Assess if you need a license. Manufacturing includes operations like purchasing raw materials, processing, packaging, storage, and shipment. All manufacturers must apply unless exempted (e.g., via Section 36 of the Act for specific cases like pharmacy compounding for retail). Submit exemption requests to SAHPRA's CEO with motivation. Contact SAHPRA's Inspectorate and Regulatory Compliance for advice.
2. **Obtain the Application Form:** Download the standard form (e.g., GLF-LIC-01A) from the SAHPRA website (www.sahpra.org.za) or the

Inspectorate section. For medical devices, use a specific form like GLF-MD-06A.

3. **Prepare and Submit Documentation:** Compile:
 - Proof from the South African Pharmacy Council (SAPC): Owner details, responsible pharmacist registration, and pharmacy certificate.
 - National Department of Health (NDOH) premises license (deemed granted for pre-2003 operations).
 - Staff qualifications and proof of GMP compliance.
 - Site Master File (SMF) including site plans, equipment inventory, and quality procedures manual.
 - List of products to be manufactured. Submit via SAHPRA's portal or email, along with application and inspection fees (gazetted on the website; e.g., new licenses require an additional inspection fee).
4. **Undergo Evaluation and Inspection:** SAHPRA reviews the application. GMP inspectors conduct a site visit to verify compliance. You have at least 20 days to address any deficiencies.
5. **Receive License Decision:** If compliant, SAHPRA issues the license (valid for 5 years). Renew at least 180 days before expiry with updated docs and fees. Notify SAHPRA of changes (e.g., premises alterations) within 30 days. Licenses can be refused or revoked for non-compliance.
6. **Ongoing Compliance:** Appoint key personnel (e.g., Responsible Pharmacist, Production Manager, Quality Assurance Manager). Maintain GMP, allow inspections, retain records (e.g., batch docs for 5+ years), and distribute only to licensed entities. Pay annual retention fees.

4. Step-by-Step Instructions for Product Registration (Based on SAHPRA Rules)

After obtaining a manufacturing license, register individual health products. This ensures they meet safety, efficacy, and quality standards. The process uses the Common Technical Document (CTD) format and may leverage reliance

pathways (e.g., approvals from WHO or EU regulators) for faster review. Details are in SAHPRA's General Information Guideline and Orthodox Medicines page.

1. **Classify the Product and Select Pathway:** Identify as new chemical entity (NCE), generic, biological, line extension, or complementary medicine. Choose review type: Full (comprehensive), Reliance/Abridged (based on prior approvals from recognized authorities like EMA or FDA), or Priority (for urgent needs like public health emergencies).
2. **Appoint a Local Holder and Confirm Prerequisites:** Nominate a South African entity as the Holder of the Certificate of Registration (HCR). Ensure manufacturing sites are GMP-certified and licensed. For generics, prepare bioequivalence data.
3. **Prepare the Dossier:** Compile in eCTD format: Administrative info, quality data (Module 3), non-clinical studies (Module 4), clinical data (Module 5), and summaries. Include GMP certificates, biostudies, and reliance evidence if applicable. For medical devices, submit technical files based on class (e.g., conformity assessments).
4. **Submit the Application:** Use SAHPRA's Engagement Portal (portal.sahpra.org.za). Pay fees (e.g., screening and evaluation; gazetted annually). Applications undergo administrative screening for completeness.
5. **Evaluation and Queries:** SAHPRA experts review (timelines: 18-24 months for full; shorter for reliance). Respond to queries within specified times (e.g., 90 days). Inspections or additional data may be requested.
6. **Approval and Post-Registration:** If approved, receive a Certificate of Registration. Monitor post-market (e.g., pharmacovigilance reporting). Variations (e.g., formula changes) require amendments. For complementary medicines, follow a phased roadmap with quality and safety focus.

Always check SAHPRA's website for updates, as processes evolve. Consult professionals for complex cases.