

O2.Product Formulation,Safety andCompliance



How to Use The Handbook:

This handbook is short and practical. Each section gives you essential knowledge, African examples, and key takeaways that help you understand how beauty is regulated and why it matters. You don't need a legal background; just curiosity about how law shapes the beauty industry and a desire to build, protect, and grow within it.

This handbook is part of a 5-part Beauty Law series by the Fashion Law Academy Africa (FLAA), created to make beauty law accessible to African entrepreneurs, legal professionals, and creatives shaping the continent's beauty sector.

Purpose:

Designed for brands, formulators, and entrepreneurs who seek a clear path through the varied requirements across the continent. Product safety is the first obligation of any cosmetic business. Without it, every subsequent commercial or creative effort becomes vulnerable. This volume offers practical structure within a region where standards differ, laboratories vary in capacity, and enforcement is steadily strengthening.

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Product Formulation, Safety and Compliance

Introduction

Why Product Safety Comes First

Every jurisdiction treats product safety as the starting point for cosmetic regulation. If a product is unsafe or improperly classified, a brand can be removed from shelves, fined, or permanently barred from the market. Establishing safety early is both a legal and commercial necessity.

Cosmetic vs Drug Classification

African regulators often follow a similar logic to the EU or the US. A cosmetic is intended to cleanse, beautify, perfume, or maintain appearance. A drug is intended to treat, alter, or restore physiological functions. Misclassification is a common source of enforcement actions, especially when beauty

products make therapeutic claims such as anti-acne, healing, or growth stimulation.

Regulatory Fragmentation Across Africa

African markets operate under national rules with regional influences. Some countries follow detailed cosmetic regulations.

Others rely on regional or broader statutes. For example, there are ongoing regional efforts, such as those by the Economic Community of West African States (ECOWAS) and the East African Community (EAC), to harmonise cosmetic regulations across member countries.

Brands that work across borders must navigate differences in approvals, ingredient lists, and labelling formats. Understanding these variations is the first step toward compliance.

Ingredient Laws and Restricted Substances

Reading Ingredient Lists and INCI Names

Most regulators require ingredients to be listed using the International Nomenclature of Cosmetic Ingredients. This standard ensures uniformity across markets and reduces ambiguity.

Banned or Restricted Ingredients in Africa

While each country maintains its own list, several patterns are consistent:

- Hydroquinone is restricted or prohibited above the specified levels.
- Mercury compounds are banned due to toxicity.
- Steroids are not permitted in cosmetics because they function as drugs.

Comparison With EU and US Standards

African restrictions often align with EU rules, although not always with the same level of detail. The US operates under a different system that permits certain ingredients not accepted elsewhere. Brands that intend to export must understand these distinctions from the beginning.

The Challenge of Imports

Imported raw materials and finished products introduce risk when documentation is incomplete or inconsistent with local laws. Brands should verify certificates of analysis, safety data sheets, and supplier compliance records.

How To Track Ingredient Restrictions

Responsible brands maintain updated ingredient databases, monitor regulatory changes, and request supplier updates at least once every year.

Formulation Standards and Good Manufacturing Practices

GMP for Beauty Products

Good Manufacturing Practices ensure that products are consistently produced and controlled. Regulators expect:

- Clean production environments
- Standard operating procedures
- Trained personnel
- Documented quality control systems

Small Batch and Artisanal Production

Small producers are subject to the same safety principles, although regulators may allow scaled requirements. Clean water, accurate measurement, and contamination control are essential regardless of volume.

Documentation

At a minimum, brands should maintain:

- Batch production records
- Formulation sheets
- Safety data sheets for raw materials

Quality control logs

Working With Contract Manufacturers and Labs

Brands remain legally responsible for any product sold under their name. Contracts should address confidentiality, testing, quality assurance, and responsibilities for noncompliance.

Labelling Requirements

Mandatory Label Information

Most African regulators require:

- Full ingredient list
- Manufacturer or distributor details
- Country of origin
- Batch number and production date
- Expiry or best-before dates
- Warnings or instructions for use

Country Variations

Nigeria, Kenya, South Africa, and Ghana each have distinct formats and minor differences in mandatory disclosures. Brands must tailor labels to each market.

Claims on Labels

Regulators review claims carefully. Statements that imply therapeutic benefit may reclassify a product as a drug. Claims must be truthful, evidence-based, and not misleading.

Common Labelling Errors

Frequent mistakes include incomplete ingredient lists, missing dates, exaggerated claims, and improper translations.

Registration and Approvals

When Approval Is Required

Many African countries require premarket approval or notification for cosmetics. Authorities include:

- NAFDAC
- SAHPRA
- PPB
- KEBS
- Ghana FDA

Basic Registration Process

Typical steps include:

- Submission of application forms
- Provision of product samples

- Review of label and formulation
- Payment of fees
- Issuance of a certificate or a listing number

Costs and Timelines

Timelines range from a few weeks to several months, depending on the product category and the regulator.

Products Under Looser Standards

Some handcrafted or low-risk products may fall under lighter processes. Brands should approach these pathways carefully, as incomplete registration may limit expansion or expose them to enforcement risks.

Renewals and Ongoing Obligations

Certificates require periodic renewal. Brands must notify authorities when formulations or labels change.

Certifications and Claims

Types of Certifications

Certifications may include organic, natural, cruelty-free, or halal. Some are legally defined, and others are market-driven. Brands must ensure accuracy and avoid misleading consumers.

Claims Substantiation

Terms such as lightening, anti-acne, growth-stimulating, or anti-ageing require evidence. Claims that suggest therapeutic benefit may trigger drug classification.

Influencer Claims Enforcement

Regulators are increasingly focused on claims made through influencers. Brands are responsible for ensuring that promotional partners reflect accurate and lawful statements.

Safety Testing

Core Tests for Cosmetics

Testing may include:

- Patch testing
- Microbial analysis
- Stability testing
- Challenge testing for preservatives

Legal Requirements Versus Best Practice

Some tests are legally required in specific markets while others fall under best practice standards.

Regardless, brands should be prepared to produce proof of safety upon request.

African Realities

Where local laboratory access is limited, brands may outsource to accredited labs elsewhere.

Documentation must be complete and traceable.

Record Keeping

Every test should be stored in a product information file or equivalent internal record.

Import, Export, and Cross-Border Compliance

Import Rules

Regulators may require certificates of analysis, product declarations, or pre-import permits.

Regional Variations

ECOWAS, EAC, and SADC each hold different standards affecting border movement and recognition of approvals.

Export Readiness

Brands targeting EU or US markets must adopt higher documentation and testing standards. Early preparation reduces future cost and delay.

High Risk Areas for African Beauty Brands

Several product categories attract heightened scrutiny:

- Skin lightening or tone targeting products
- Chemical relaxers and straighteners
- Herbal products suggesting medicinal benefits
- Counterfeit or grey market parallel imports

Brands operating in these categories must exercise additional care with claims, testing, and

documentation.

Compliance Strategy for Small and Growing Brands

Building Compliance From Day One Compliance becomes more expensive when brands attempt it late. Integrating safety and documentation early supports longterm growth.

Priorities When Budgets Are Limited

At minimum, brands should:

- Verify ingredient legality
- Ensure proper labelling
- Conduct basic stability and microbial testing
- Maintain production and batch records

Self-Auditing Practices

Regular reviews help identify gaps before regulators do. Templates such as label checklists and testing logs provide structure.

Conclusion

Compliance strengthens trust, protects consumers, and supports industry integrity. African beauty brands are advancing rapidly and deserve regulatory systems that reflect their creativity and ambition. Adopting strong standards at any scale allows businesses to grow with confidence and prepares them for regional and global markets.

The next handbook in the series will explore advertising law, digital marketing, and claims regulation in the beauty sector.

Glossary

Term	Meaning
INCI	International Nomenclature of Cosmetic Ingredients
Claims Substantiation	Evidence supporting a statement about a product
SDS	Safety Data Sheet
Batch Record	Document showing how each batch of product was produced
Good Manufacturing Practice (GMP)	Standards ensuring products are consistently produced and controlled for quality.
Cosmetic Product	Product intended to cleanse, beautify, or maintain appearance
Drug Classification	Legal category for products that treat or alter physiological functions
Microbial Test	Test for contamination by microorganisms
Pre Market Approval	Regulatory certification required before a product can be sold
Grey Market Goods	Products are imported without the authorisation of the brand owner
Challenge Test	Test to confirm the effectiveness of a preservative system
Stability Test	Assessment of how a product performs over time under different conditions.

