OTC Health Products Regulatory Framework in Africa

Securing AMRH’s Role to Facilitate Wider Consumer Access to Nonprescription Medical Products

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Overview

- AMRH has sparked unprecedented transformational changes to the African regulatory landscape in the past decade.
- Access to priority medicines and regulatory oversight have had meaningful progress.
- African Patients/Consumers should also benefit from improved access to self-care solutions.
- Regulatory fragmentation, hurdles for registration and life-cycle management remain major obstacles to timely access to non-prescription or over-the-counter (OTC) medicines.
- OTCs unique needs should be addressed by the AMRH to comprehensively address Africa’s multiple public health challenges and pave the way to strong healthcare systems on the continent.
What are Over-the-Counter Products?

Nonprescription or *Over-the-Counter (OTC)* products are made available to Patients/Consumers without the direct supervision/prescription of a Healthcare Professional (HCP)

Subject to **Quality, Efficacy and Safety requirements** as Rx medicines

An extended safety profile is the primary consideration since these products are in widespread use by individuals without HCPs’ intervention

Either direct-to-OTC products, or mostly «well-established» or «legacy» products that were reclassified or «switched» from prescription (Rx) to nonprescription status

Subject to similar post-marketing requirements as Rx medicines
OTCs Benefits

For Patients/Consumers
Increased awareness and access to solutions for treatment/prevention of a large array of self-treatable and chronic conditions

- Pain relief
- Cough & Cold
- Allergies
- Sleeping disorders
- Cardiovascular diseases
- Migraine
- Obesity

For Healthcare Systems
Management of self-treatable and some chronic conditions by the Patient/Consumer allows healthcare systems to re-purpose resources on more important healthcare priorities

- Sexual health
- Oral health
- Smoking cessation
- Gastrointestinal disorders
- Skin diseases
- Vitamins & minerals deficits

Common ailments covered by OTCs – *Examples*

**Challenge**

- Awareness and Access to these products remains limited in many African countries
- Insufficient, weak or even absent regulatory frameworks to support the beneficial outcomes self-care products bring to Patients/Consumers
OTC Regulatory Framework

Effective Regulatory Framework that support self-care includes two major components

1. Regulations that recognize OTCs unique attributes
   - Used for preventative, acute and symptomatic conditions that can be self-diagnosed by the consumer
     - History of safe use
   - Consumer-friendly product information to help make informed decisions
   - Enhanced access through unique sales channels (beyond just HCP mediated provision)

2. Adapted and streamlined regulatory pathways
   Registration processes with simplified pathways proportionate to risk for well-established substances
   - Efficient regulation (avoiding over-regulation)
     - Processes/framework that facilitate medicine rescheduling/"switch"
       - Defined Scheduling criteria/Classifications
   - Advertising to improve awareness of self-treatable conditions
   - Labelling policies that provide the essential information needed for proper use
     - Harmonization/Convergence
Scheduling

Medicines are classified into Schedules according to the level of regulatory control over the availability of the medicine required to protect public health and safety

National classification system

- categorizes the various types of OTC and prescription medicines
- controls how OTCs are made available to the public

In most African countries:
- A General Sale List (GSL)/OTC Schedule is a new concept
- Almost all active ingredients for consumer health products are scheduled under medicines
- There is a lack of switch guidelines – and policies on intellectual property incentives

Opportunity

- Harmonized implementation of a GSL/OTC Schedule in all African countries would positively impact the accessibility of OTC products to consumers across the region, allowing more consumers to get the health benefit they require

Challenge

- Only 8 countries have a GSL/OTC schedule while the rest of Africa has a Medicines schedule with pharmacy-only and prescription products
  - Access disparities whereby some products classified as OTC in some countries, are classified as prescription-only medicines in others...

Example - Biscacodyl tablets are Rx in Nigeria while they are OTC in other African markets
Registration time

**OTC products experience long registration timelines**

- **Average registration timelines** in most African countries for consumer health products is around 12-18 months...but can be up to 7 years
- **Fast track registration** is available for around 5% of countries
- Some countries have **dependency & work sharing on regional hubs**
  - **Example** - A product registered in Nigeria can be quickly registered by notification & marketed in Gambia

**Opportunity**

- Expand harmonized fast track registration & line extension processes to more countries
- Promote and adopt further shortened risk-based evaluation processes for **ALL products with a well-known/trusted safety profile**
- Through work sharing & harmonization schemes, **use risk-based evaluation for products to be registered in Africa**
  - **Example** - These initiatives have seen registration timelines reduced to 8 months
- Clarify and **harmonize fast-track registration fee structures** (e.g. double payment for fast track fees for registration)
Life cycle management

Variations
- Classifications of variations remain uneven throughout the various national guidelines

**Example** – Categorization as “minor variation” in a reference country is considered as major variation in another

- Variations also suffer from long review timelines

Re-registration/Renewals
- Regulatory Authorities deliver renewals of various validity
- Common re-registration period is 5 years for most African countries

**Example** - Marketing authorizations in Ghana have a 3-year validity

**Opportunity**
- When re-registration is required, harmonize requirements and validity period to minimum 5 years across all countries
- Alternatively, consider unlimited registration with annual notifications, unless a new Q, S, E issue changes the conditions of licensing
- Harmonize pharmacovigilance requirements to align with global standards and formats to streamline and support vigilance
Communication

Communication between regulatory authorities and industry stakeholders can be strengthened

- Change in guidelines and processes are often not adequately disseminated in good time
- Discussions with industry ahead of major changes are limited, which often lead to lengthened evaluations, especially where guidelines may not be clear on requisite supporting quality and clinical documents

Example

- Major registration procedures changes
  - New/Revised guidelines impacting products manufacturing & packing lines
  - Release of new tariff
  - CTD, Bioequivalence for very old registrations with lesser time of implementation

Opportunity

- Set up regular regulatory authorities/industry consultations and exchanges to discuss and align on regulatory strategy/approach for registration of medicines and facilitate dossier preparations and reviews
- Share through these exchanges, global companies’ best practices adopted worldwide on OTCs that have been developed as a result of working closely with various HA to formulate OTC guidelines
Advertising & Promotion

*OTC products face restricted communication to Consumers due to uneven regulations currently in place in various countries*

- Advertising and promotion of OTC medicines primarily serves the dissemination of information about products’ availability.

- Advertising is regulated to ensure claims are aligned with approved indications and do not mislead Patient/Consumers, and is generated from two main sources:
  
  (a) healthcare providers - primarily physicians, pharmacists and nurses, and
  (b) the pharmaceutical industry - in Africa, due to restrictions based on the medicine schedule, this source remains relatively limited and varies among countries.

*Example 1 - South Africa*

- Only Schedule 0, 1 and 2 medicines are categorized as OTC
- Direct-To-Consumer advertising is limited to Schedule 0 and 1 medicines

This provision prevents companies from creating awareness and educating consumers on Schedule 2 OTC products, such as cough and cold products, which if awareness was endorsed could alleviate the burden placed on healthcare providers.
Advertising & Promotion

Example 2 – Francophone Africa

Unlike Sub-Saharan Africa in which consumers can be made aware of a few number of OTC products through advertising and promotion, French-speaking African countries’ current regulation prohibits direct-to-consumer advertising which may heavily influence easy access to commonly used health products and well-being of consumers in those regions.

Digital Marketing
- As Africa moves toward a technologically advanced state regulation, endorsing digital advertising could be beneficial. However, no such guidelines exist yet.

Points of sale
- In most African markets, self-care products are sold only through pharmacies.
- Option for general sales is not permitted, although this would increase easy access and awareness on OTC products.

Opportunity
- Harmonization of regulations which endorse OTC products would be beneficial to manufacturers, both local and foreign, and would allow them to directly provide information and awareness of a product to the customer.

Challenge
- Absence of recognition of digital platforms/marketing risks generating long approval times.
Regionally, Southern Africa’s internet penetration is at 51%, making it the highest on the continent.

In the past 6 years, Egypt’s internet user population has increased by 15.1 million users:
- 78% of internet users searched online for a product/service in January 2019.
- 56% of adults (age 13+) can be reached by advertisement through Facebook.

24.48 million Algerians had access to internet in January 2019, 58% of the total population.

Out of a Population of 11.72 million in Tunisia, 7.90 million Tunisians have access to internet each month:
- In Morocco, (of total population)
  - 63% of Moroccans live in Urban areas
  - 62% of Moroccans have access to internet

**Opportunities**
- Africa has high mobile phone and Internet penetration, and this can be leveraged to distribute health information.
- Self-care apps can help Consumers to manage their health where traditional healthcare is hard to access and is relatively expensive.

**Potential Enablers**
- AMRH to issue harmonized guidances on digital health topics with input from industry and HAs leading in this area.
- Adopt lean/effective regulatory schemes to regulate fast moving digital health space.
- Grow expertise within Africa HAs.
AMRH Framework and Processes

Currently, harmonized medicines registration procedures (i.e. East and Southern Africa) are restricted to essential medicines (HIV, TB, malaria etc.)

- Longer go-to-market lead-times observed for OTC medicines
- No examples of OTC medicines authorized for the harmonized registration process
- Legislation, guidelines and application forms are not harmonized across the regions and countries’ requirements vary (e.g. CMC documents, labelling, variations classification, etc.)

Disparities and lengthy processes impact dossier development and submission strategies, go-to-market strategies, launches and timelines; and ultimately, accessibility of OTC medicines to Patient/Consumer

Harmonization using reliance models could accelerate OTC products being released to the public

However, this is not documented in the current guidelines and it remains the Health Authority’s prerogative to either reject or approve the motivation based on their own risk-based system that is not public

Yet, some Health Authorities are adopting a reliance approach (e.g. SAHPRA adopting EMA variation guidelines), however, the implementation thereof can be challenging
1. Regulatory issues for OTC products do not differ to a large extent from those experienced for priority medicines at the inception of AMRH.

2. The full potential of self-care is still to unfold in Africa to meet the growing population demand for taking ownership of their health and engaging more proactively in the management of self-treatable conditions, in health prevention and well-being, but at the same time, to help alleviate and sustain already much solicited health systems on the continent.
3. The regulatory framework supporting self-care products is either to be built in most African countries, or needs to be strengthened and harmonized to ensure timely and wider access to self-care products across the regions.

The already hugely developed mobile digital platforms in Africa could already be an advantage to deliver greater self-care access.

4. AMRH scope extension would ensure a wider availability of safe and effective OTCs to the African population. It will also enable AMRH to address new regulatory challenges posed by digital health or e-commerce, largely utilized by Patients/Consumers accessing the self-care segment.
Thank you!
ADDITIONAL SLIDES
The Global Self-Care Federation (GSCF) formerly known as the World Self-Medication Industry (WSMI), is a federation of national associations and manufacturers from across the globe in the self-care industry, working closely with its members and relevant stakeholder groups to ensure evidence-based self-care products and solutions are recognized as key contributors to health for individuals and systems worldwide.

GSCF work ensures key policy and decision-makers embrace self-care, recognize its values and use its broad range of benefits as the building blocks to deliver better and more sustainable health outcomes for all.

The name change positions the organization to be more outward focused and actively engaging with stakeholders and make it understood that self-care is broader than medication.
GSCF - Three-Pillar Strategic Plan

To reach its goal, GSCF has adopted a 3-pillar strategic plan to drive the growth of the self-care in the future:

**Trust**
Enhancing trust across the healthcare industry by engaging with global stakeholders such as the WHO to better position self-care.

**Sustainability**
Driving an evidence-based self-care policy agenda to set up self-care as an essential building block of sustainable healthcare.

**Health data**
Engaging GSCF in the debate on regulation and use of health data to enable the full value of self-care.