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A Comprehensive Framework for Eradicating Counterfeit, Substandard and Expired Medicines in Developing Countries

A customized program for the
Republic of South Africa

Program Concept

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One of the biggest threats to public safety is from circulation of counterfeit drugs

Africa is a major target of fake drugs

What are counterfeit (falsified) drugs?

- Counterfeit drugs are fake medicines intentionally made by unknown manufacturers who hide their identity
- Counterfeit drugs deceive consumers by closely resembling the look of a genuine drug and its packaging
- Counterfeit medicines have been found to be made:

  - missing key ingredients   - with dangerous contaminants
  - too strong or too weak   - in unsanitary or unsterile conditions
  - with wrong active ingredient   - using unsafe methods

Where do most counterfeit medicines come from?

- Seizures by World Customs Organization (WCO) found that >90 % of fake drugs originated from China and India
- Fake drugs arrive through clandestine routes that evade detection
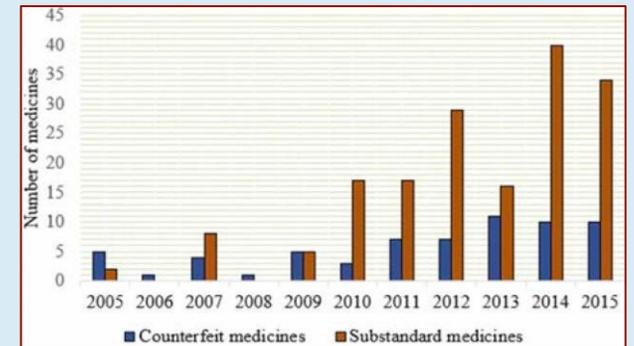- Another serious problem concerns circulation of expired medicines

Is South Africa spared from supply of counterfeit medicines?

- No; WHO claims 20-30% medicines in emerging countries are fake
- South Africa is not spared, especially from imported medicines from abroad
- Published reports and statistics are especially worrisome

Counterfeit drugs have become the new cash cow for organized crime because of the ease with which they can be distributed

The rise of fake medicines in Africa

India, China are leading sources of counterfeit medicines: report
'Up to 20 per cent of drugs sold in the Indian market are counterfeit'

Source: *The Week*, 2019 (based on analysis by World Health Organization)

Growth of counterfeit medicines in Southern Africa (above). New study is raising alarm.

Fifth of medicines in Africa may be sub-par or fake, research finds
The Guardian
04 Aug 2024

A solution based on security labels

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Security labels serve as the fundamental carrier of an integrated solution

Objective => design a security label that allows both supply tracking and uncompromising authentication

Security label
(15 x 40 mm)

Prototype only

The two key elements of the South Africa *Security Label*

QR code
- QR code provides the **traceability** function
- Simple content => unique serial number
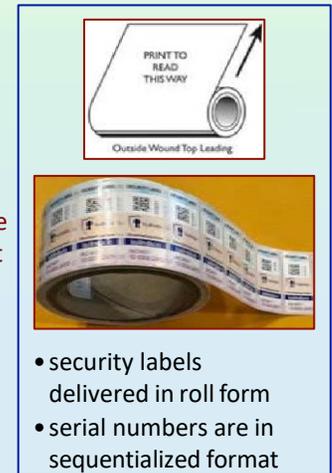- Essential for drug identity and other information

Non-clonable security technology
- Provides **authentication** functionality
- Fake labels will **fail** authentication
- Essential for anti-counterfeiting objective

QR code content

Serial number
Example:
ET114200000069

- security labels delivered in roll form
- serial numbers are in sequentialized format

Fundamental benefits of security labels to South Africa

1) Extremely fast launch => program can be deployed in < 4 months
2) Minimum capital expenses => no need for expensive equipment installation
3) Minimum operating expenses => no need for expensive maintenance & support
4) Cost parity across all companies => eliminates discrmination against small manufacturers; per item cost is same
5) Offers highest level of package security currently available => can accommodate multiple advanced security features
6) Visually salient label has widespread consumer familiarity => consumers already accustomed to tax stamps on liquor, etc.

The security label approach is the best way to tackle the twin threats of substandard and counterfeit medicines in South Africa.

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Eleven0Nine South Africa roll-out will start with a powerful program to stop all counterfeits

Both consumers and EFDA inspectors will be empowered to authenticate all labeled products with instant results

Consumer-based program

Kulinda South Africa Security Label

Scan QR code with Kulinda mobile app

Verification page

Security Code

5C053AE

Please compare the code above with the code on the label

Does the code above match the code on the Security Label?

Yes   No

Outcome reports

5C053AE

Please again compare with code on the label

If the two do not match, please inform the pharmacist and call the number below

800 55 44 33

Scan   Close

Thank you for helping to keep South Africa free of counterfeits?

Visit the EFDA website for latest information

https://efda.go.et

Scan   Close

Consumer messages shown are simulations only. There is considerable opportunity for EFDA to provide important health messages to citizens through this mobile portal.

All messages to be determined by EFDA.

Objective: Provide citizens of South Africa with a consumer-friendly mobile application that permits quick and seamless confirmation that a genuine product has been purchased.

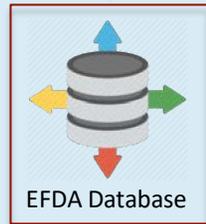The Kulinda app works in both online and offline modes.

Inspector-based program

Kulinda Security Label

Scan QR code with Kulinda mobile app

Verify optical taggant with reader

Outcome review

Security Code

5C053AE

Please compare the code above with the code on the label

Does the code above match the code on the Security Label?

Yes   No

Confirm taggant presence on label

Test outcomes visible to EFDA in real time

EFDA Database

Objective: The consumer program is supplemented by an inspector-based program. The Kulinda solution empowers inspectors with the same digital tools, but additionally with a powerful optical taggant that cannot be duplicated by counterfeiters.

Together, the two solutions will offer ultimate inspection ability and protection for South Africa.

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Eleven0Nine traceability program will provide an outstanding set of benefits to South Africa

An agile implementation program has been developed for launch of the traceability objectives in the second phase

Eleven0Nine traceability outcomes

Kulinda South Africa Security Label

Scan QR code with Kulinda mobile app

Eleven0Nine label authentication by consumer or inspector

Security Code

5C053AE

Please compare the code above with the code on the label

Does the code above match the code on the Security Label?

Yes **No**

Objective: Kulinda traceability program will provide substantial information after scanning, including:

1) Verification of serial # with actual product; provides additional level of protection against counterfeit.
2) Product name and image.
3) Batch details that include SKU, lot number, expiry date, and other information.
4) Opportunity to provide feedback to brand owner or agency.
5) Instant notification against multiple adversities that include expired, recalled, and diverted products.

Key points

- Eleven0Nine roll-out plan begins with authentication (anti-counterfeiting) program in Phase 1

  will provide instant protection against counterfeiting from the moment products are affixed with Eleven0Nine security labels

- after authentication program is launched, Eleven0Ninewill implement full traceability program in Phase 2

  will require tagging product metadata (manufacturer + batch details) to serial numbers on all affixed Eleven0Nine labels

- whereas Phase 1 is straightforward, Phase 2 will be more involved and require Eleven0Nine to be on site once program is set up, South Africa will have

Valid code but with adversity

o most outstanding programs anywhere

Warning

This is an EXPIRED product

Warning

This is a RECALLED product

Warning

For sale only in South Africa

Simulations of error messages. Actual messages to be determined by EFDA.

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Recommendations for moving forward

South Africa has the opportunity to deploy an innovative, effective and durable program for consumer protection

Three-Point Implementation Program

1) Must create a new **regulatory mandate** to protect all medicines in South Africa; voluntary adoption does not work. All <u>saleable medicine packs</u> must be affixed with a Kulinda Security Label (cartons, bottles, blisters …).

2) Set up a local entity (Private or PPP) which is then **directly appointed** by the MoH/EFDA as the single entity to deliver an end-to-end drug traceability and authentication program.

3) Move quickly with a **phased deployment** program to ensure success. Affix security labels on all drug packages => integrate data services => empower consumers => grow to cover cosmetics & personal care items.

Eleven0Nine's unique benefits to South Africa— 7 key points

1) **Low cost** — program has been specifically designed for emerging markets, unlike the costly programs rolled out in the U.S. and E.U.

2) **No government investment needed** — no costs to be borne by the South African government, now or at any time later.

3) **Government earns revenue** — agencies and partners receive ongoing revenue from the program; nothing like it anywhere else.

4) **Advance payment structure** — pharma companies make up-front payments for the security labels and accompanying data services; immediate revenue realization to all stakeholders, including government agencies and partners.

5) **Fast deployment** — program can be rolled out in its entirety in less than 4 months; Eleven0Nine solutions are fully GS1 compliant.

6) **Maximum effectiveness** — Eleven0Nine has drawn on two decades of experience fighting counterfeiters to design a solution that will fully arrest the infusion of substandard and counterfeit medicines and medical products into South Africa.

7) **Consumer + inspector empowerment** — EFDA inspectors easily undertake market surveillance; key feature is that consumers can also verify authenticity of a medicine pack right at point of sale. Excellent politics => government seen as protector of citizens.

The Kulinda Drug Protection Program will represent an unparalleled consumer safety development