

Online Pharmacy in Kenya:

Regulatory Requirements, Benefits & Concerns

Sammy Masibo - MPSK



INTRODUCTION (1/2)

✓ E-Pharmacy is gaining acceptance in many LMICs, including sub-Saharan Africa

~ 200 innovators in Africa (direct to consumer solutions), with 80% related to online pharmacy

Online pharmacy revenue in Africa tripled from US\$ 190 M (pre-pandemic) to US\$ 560 M (2022)

✓ E-Pharmacies present an opportunity to address major SC challenges in Africa:

~ access

~ affordability

~ quality

INTRODUCTION (2/2)



However, e-pharmacy expansion has outpaced regulatory reform:

Lack of comprehensive regulations & policies



Concerns over consumer safety and public health



Negative effect on scalability & impact



There is need for NRAs in Africa to monitor the compliance of e-pharmacies with:

~ Regulatory requirements (where available)

~ Global best practices

Regulatory requirements in Kenya



Regulatory requirements - PPB

Kenya:

Guidelines for internet pharmacy services in Kenya (Jan 2022) – revised April 2023

Informed by:

1. CAP 244
2. Guidelines for the registration and licensing of premises in Kenya
3. Pharmacy and Poisons (Amendment) Rules, 2022
4. Guidelines for advertisement & promotion of HPTs (HPT/PDS/GUD/046)

Guidelines (1/7)



Registration and enlistment by PPB (registered online retailers)



Display on every website page PPB's health safety code



Owned by qualified Pharmacist or PT or superintended by Pharmacist or PT



Hybrid (brick-and-mortar +)

Guidelines (2/7)



No advertisement or promotion of POMs



Separate controlled-access HCW webpages ***



Decision to sell a medicine exclusively for the **Pharmacist** who:

- *Must be available for consultation with clients*
- *Must verify authenticity of all e-prescriptions*

Guidelines (3/7)



Hard copies of e-prescriptions must be recorded and filed



Recall of original prescriptions within 7 working days ***



Only process prescriptions from persons authorised to prescribe in Kenya ***



Home page:

*health safety code, physical & postal addresses, telephone #, name of responsible **Pharmacist**, hours that a pharmacist is available for consultation*

Guidelines (4/7)



Must provide policies and procedures for:

- *patient counselling*
- *delivery of medicines (logistics)*
- *return of medicines*
- *complaints (grievance redressal)*
- *confidentiality of patient information*
- *hours of operation*



Pharmacists remain professionally liable despite any website disclaimers



Online pharmacy records preserved for at least 5 years

Guidelines (5/7)



Mechanism to detect and restrict excessive or multiple orders



Supply of controlled drugs prohibited



Display of drug information (indications, CIs, interactions, SEs etc) beyond PIL ***



Patient verification

Guidelines (6/7)



Inform patient of the Pharmacist or PT supplying the medicines



Language – English or Swahili



Delivery mechanisms must safeguard patient confidentiality



Cold chain integrity for thermolabile products

Guidelines (7/7)



Verifiable audit trail from medicine request to delivery (and return for failed deliveries)



No resale of returned medicines



Daily data back-up



Data protection Act provisions

Why regulate?



Roselyn Sister Mutaki

The Good

Webuye, Western Kenya - 70



Katie Corrigan

The Bad

St. Erth, Cornwall, England - 38



Deepak Manish**

The Ugly

India - 24

Results from recent study in Kenya



General characteristics:

E-Pharmacy platform	Kenya
Website-only	23
Website + App	3
Website directing users to App	0



Most providers (85%) offered pharmacy services only

Regulatory compliance - summary



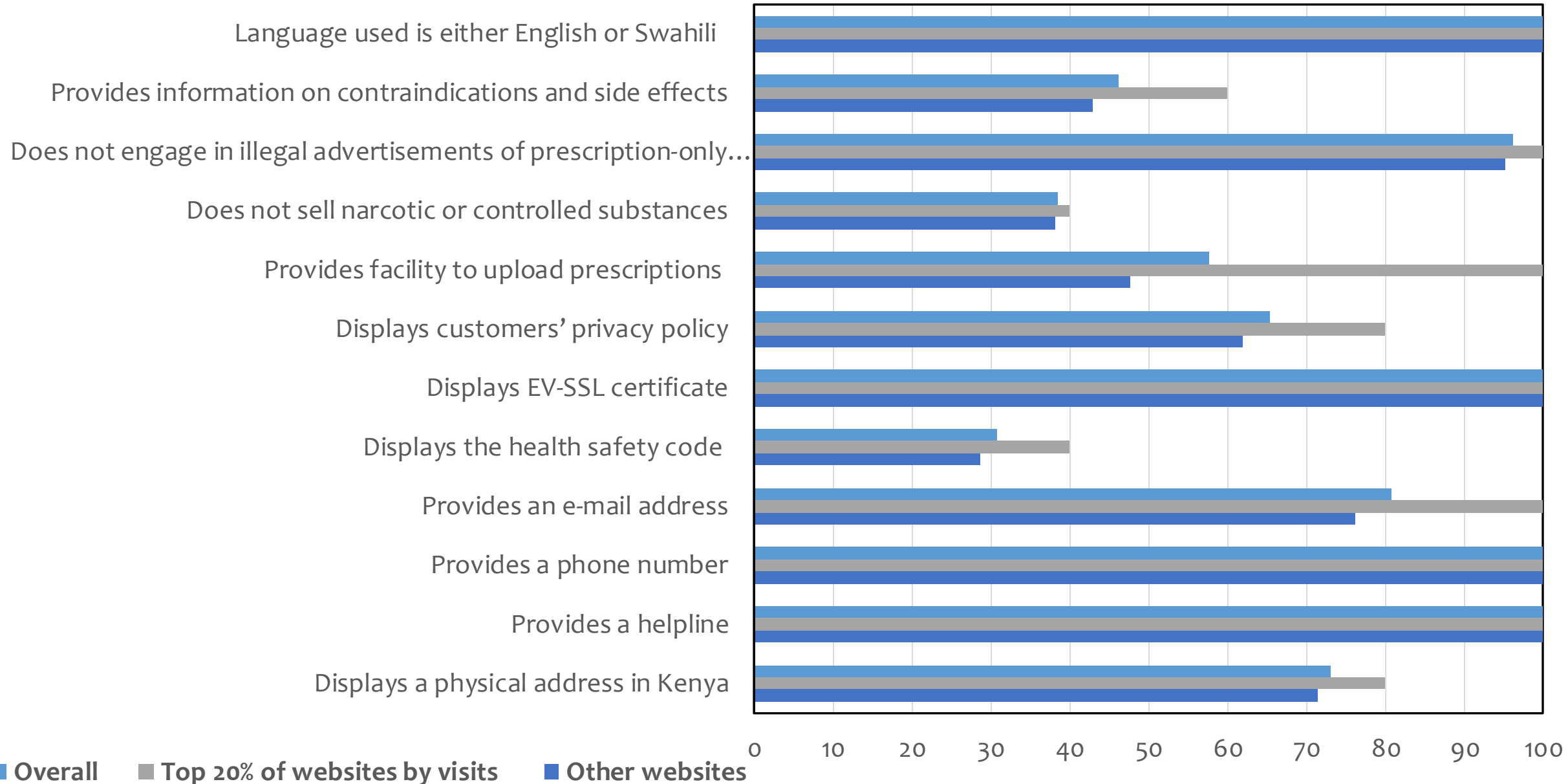
No e-pharmacy met all the regulatory requirements



Kenya:

- On average, e-pharmacies met **74%** regulatory requirements
- Top 20% of e-pharmacies (by visits) had better compliance
- Websites physically located in Kenya had better compliance

Regulatory compliance - Kenya



Regulatory non-compliance: key points



Online sale of narcotics or controlled substances

- 62% (Kenya) despite regulatory prohibition



Display of e-pharmacy registration information / status

- Only 19% of e-pharmacies in Kenya



Online advertisement of POMs

- One e-pharmacy in Kenya advertised POMs online

Best practices: key points



Provision of complete drug information (indications, contraindications, side effects, interactions)

- Only 42% of e-pharmacies in Kenya



Prescription upload facility

- 58% of websites in Kenya provided a facility



Refill reminders

- One e-pharmacy in Kenya



Display of pharmacist(s) details

- 1 website in Kenya provided details

Conclusion



There's considerable variation in the regulatory performance of e-pharmacies in Kenya



Recommendations:

- Need for stricter enforcement of regulations in Kenya
- Risk-based regulation
 - ✓ *Recognition of compliant (“good”) actors and working with them to enhance regulation*
 - ✓ *Enhanced scrutiny of partially-compliant (“bad”) actors*
 - ✓ *Termination of non-compliant (“ugly”) actors*

The END

THANK YOU