

The Good, the Bad & the Ugly:

An assessment of regulatory compliance and best practices in e-pharmacies operating in Kenya & India

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INTRODUCTION



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



E-Pharmacies present an opportunity to address major SC challenges in Africa: **access, affordability, quality**



However, e-pharmacy expansion has outpaced regulatory reform:
Inadequate regulation & policies → *Concern for consumer safety & PH* → *Negative effect on scalability & impact*



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

~ *Regulatory requirements (where available)*

~ *Global best practices*

Methods



The universe of providers identified in Kenya and India

Search using specific strings / terms:

Replicated typical consumer behavior

Google search engine in incognito mode

First 30 pages of results manually screened

*Eligible websites/apps based on **definition***

Online business that:

- ✓ Sells modern/allopathic POMs directly to consumers
- ✓ Operates through a website or app wherein the ordering is initiated
- ✓ Has mechanism for remote payment (online or on delivery)
- ✓ Offers delivery through mail or courier



Data extracted independently and in duplicate (Jan – May 2023) using REDCap



Similarweb.com used for traffic data (Mar – May 2023)

Regulatory requirements and best practices



Regulatory requirements

Kenya:

Guidelines for internet pharmacy services in Kenya (Jan 2022) – revised April 2023
Guidelines for the registration and licensing of premises in Kenya

India*:

No specific e-pharmacy regulations
FICCI self regulation code of conduct (2016) & e-pharmacy draft rules/laws – yet to be enforced
IT Act (2000, amended 2008) , E-commerce rules (2020), physical pharmacy laws



Best practices

General care standards e.g. provision of patient-level drug information for tracer medicines
International e-pharmacy standards e.g. LegitScript checklist, prescription requirement rules, details of the providers/pharmacist(s), refill reminders etc.

***India – contrasting market structure & regulatory development; large emerging player operating without regulations**

Results



General characteristics:

E-Pharmacy platform	Kenya	India
Website-only	23	61
Website + App	3	33
Website directing users to App	0	4

Kenya: 26 websites, 3 Apps **India:** 61 websites, 37 Apps

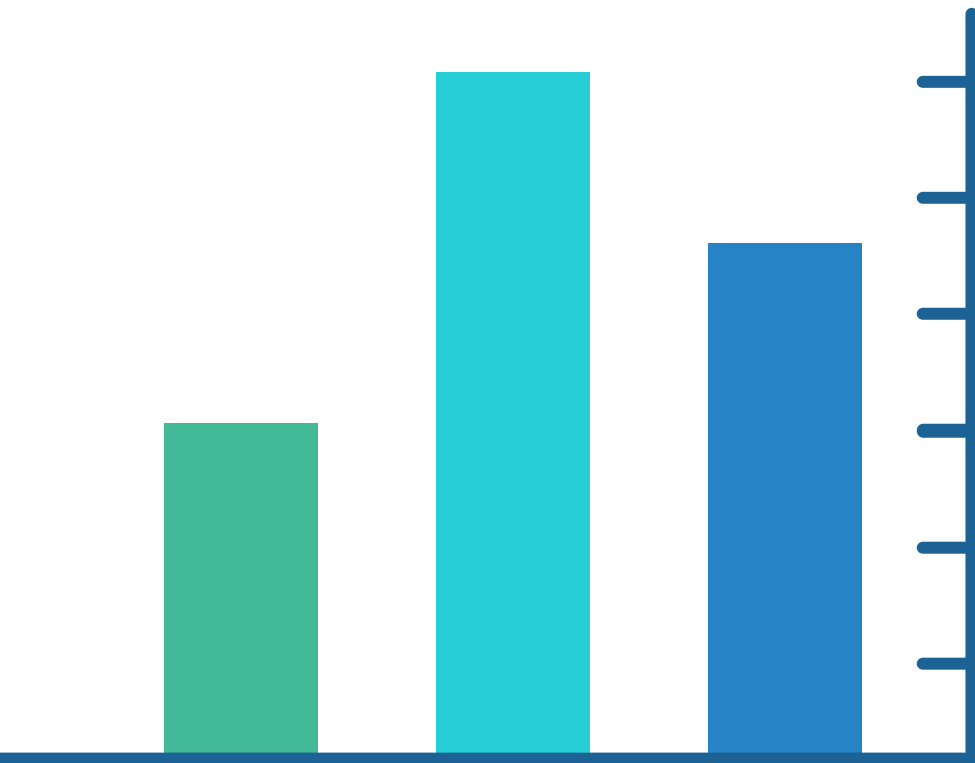


Most providers (85% Kenya and 61% India) offered pharmacy services only

Online consults (12% Kenya & 34% India)

Laboratory services (8% Kenya & 25% India)

Best Practices



Medicine info

Kenya 42%

India 16%

Rx upload option*

Kenya 58%

India 90%

Narcotics display*

Kenya 61%

India 34%

Order tracking

Kenya 58%

India 62%

Refill reminders

Kenya 4%

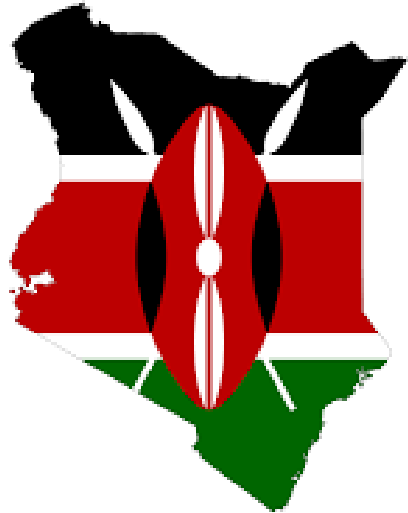
India 13%

Registration details

Kenya 19%

India 5%

Regulatory Compliance



Kenya

31%	Display of health safety code (PPB)
65%	Display of customer privacy policy
58%	Prescription upload feature
100%	Language – English or Swahili
46%	Contraindications & side effects
77%	Display of physical address
100%	Provision of helpline
100%	Provision of phone number
81%	Provision of e-mail address
100%	Displays EV-SSL certificate
39%	Does not sell narcotics or controlled substances
96%	Does not engage in illegal advertisement of POMs

74%
μ

0%
All

Regulatory Compliance

“proposed requirements”



India

0%	Display of authorization (CDSCO)
87%	Display of customer privacy policy
87%	Display of return policy
20%	Display grievance redressal procedure
56%	Does not deliver externally (outside India)
100%	Does not display POM advertisements
84%	Has a physical address in India
5%	Displays registration number of pharmacy
28%	Provides details of owner/director/superintendent
0%	Displays registration details of pharmacist
66%	Does not sell schedule X substances
93%/93%/80%	Displays complete contact information –phone/email/physical address

54%
μ

0%
All

Compliance – Location & Traffic



Kenya

78%

> 20%

83%



India

54%

> 20%

62%

Conclusion



There's considerable variation in the regulatory performance of e-pharmacies in and across both Kenya and India

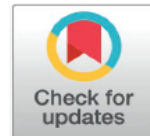


Recommendations:

- Need for stricter enforcement of regulations in Kenya
- Need for regulatory advancement in India (e-pharmacy specific guidelines)
- Risk-based regulation
 - ✓ Regulators **work with the largely compliant** (“good”) actors to improve regulation
 - ✓ **Improved enforcement of the partially-compliant** (“bad”) actors
 - ✓ **Elimination of non-compliant** (“ugly”) actors

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The END



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RESEARCH ARTICLE

The good, the bad, and the ugly: Compliance of e-pharmacies serving India and Kenya with regulatory requirements and best practices

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Abstract

As with most technology-driven change, e-pharmacy markets have expanded faster than the pace of regulation, particularly in low- and middle-income countries. We developed and applied a checklist to assess compliance with best practices and regulations by e-pharmacies serving clients in India and Kenya, two countries with contrasting regulatory environments. We defined e-pharmacies as businesses selling prescription-only medicines directly to consumers through websites or apps. We identified the universe of e-pharmacies through online searches, and captured data using a structured questionnaire (Jan–May 2023). We then assessed e-pharmacies against a set of global ‘best practice’ standards, as well as national regulations (for Kenya) and ‘proposed requirements’ from local guidelines and draft bills (for India, which had no e-pharmacy-specific regulations). We identified 61 websites and 37 apps serving India, and 26 websites and 3 apps serving Kenya. Regarding best practices, a facility to upload prescriptions was provided by 90% of websites serving India and 58% serving Kenya. Only 16% (India) and 42% (Kenya) provided complete drug information. On average, websites serving Kenya met 8.9 of the 12 (74%) Kenyan regulatory requirements, while those serving India met 7.5 of the 14 (54%) ‘proposed requirements’. Only 31% serving Kenya and none serving India displayed required registration numbers. Contrary to regulations/guidelines, many e-pharmacies serving Kenya (62%) and India