



The Good, the Bad & the Ugly

Regulatory compliance of Indian and Kenyan online pharmacies

Online sale of medicines

- Rapid growth in LMIC settings, especially after COVID-19
- Potential advantages:
 - **better accessibility:** last-mile delivery of medicines
 - market competition leading to **lower prices**
 - **enhanced traceability** of pharmacy records



Online pharmacy in Kenya

- E-pharmacy is gaining acceptance in LMICs
 - ~ 200 e-pharmacies currently operational in Africa
- Revenue tripled during the pandemic
 - from USD 190M (2019) to USD 560M (2022)
- **Kenya, Ghana** and **South Africa** have already **established regulations**
 - No data on e-pharmacy performance or regulatory enforcement



Online pharmacy in India

- India is the **fastest growing** emerging market for e-pharmacies
 - >5 million users per month; market valued at USD 453M
- India struggles to regulate online sales
 - Only brick-and-mortar regulations exist (poorly enforced)
 - India's **Drug and Cosmetics Act, 1940** established before the internet

Concerns



Sale of medicines without prescription



Sale of substandard and falsified medicines



Inadequate provision of patient information



Risks to data and financial security



Emergence of rogue players

Rogue players

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Rogue players





Over 80% pharmacies observed bandh in National Capital

Thousands of pharmacist gather at Jantar Mantar opposing online sale of medicines



Medical shops A view of closed shops during a day-long nationwide strike called by the All India Organisation of Chemists and Druggists on Friday - BB Yadav, DNA



Severe Backlash

Brick-and-mortar pharmacy associations protest against e-pharmacies

Need of the study

- Limited evidence on e-pharmacy from LMICs despite the rapid expansion
- Need for evidence to inform
 - regulatory enforcement in Kenya
 - Development of a regulatory framework in India

Aim

To review of e-pharmacies currently serving customers in India and Kenya and evaluate their compliance with regulations and best practices

Definition of e-pharmacy

We included online providers that met all these criteria:

- Sells **prescription-only medicines** directly to consumers in India and Kenya
- Operates through an **internet website or associated app**
- Offers delivery through mail, shipping companies, or courier service

Methods

- In each country, we conducted targeted searches using specific strings.
 - The first 30 pages of the results were screened
- Websites were reviewed first
 - If the website had an app, it was downloaded from the Google PlayStore
- Similarweb.com was used to collect website traffic data.
- All analyses were performed on Stata v18.0



Regulatory requirements in Kenya

Two regulations:

- Guidelines for internet pharmacy services in Kenya (2023)
- Guidelines for the registration and licensing of premises in Kenya (2023)

12 regulatory requirements identified

Displays a physical address	Displays customers' privacy policy
Provides a helpline	Provides facility to upload prescriptions
Provides a phone number	Does not sell narcotic or controlled substances
Provides an e-mail address	Does not advertise prescription-only medicines
Displays the health safety code	Provides drug information
Displays Extended Validation (EV-SSL) certificate	Language used is either English or Swahili

Relevant regulations and guidelines in India

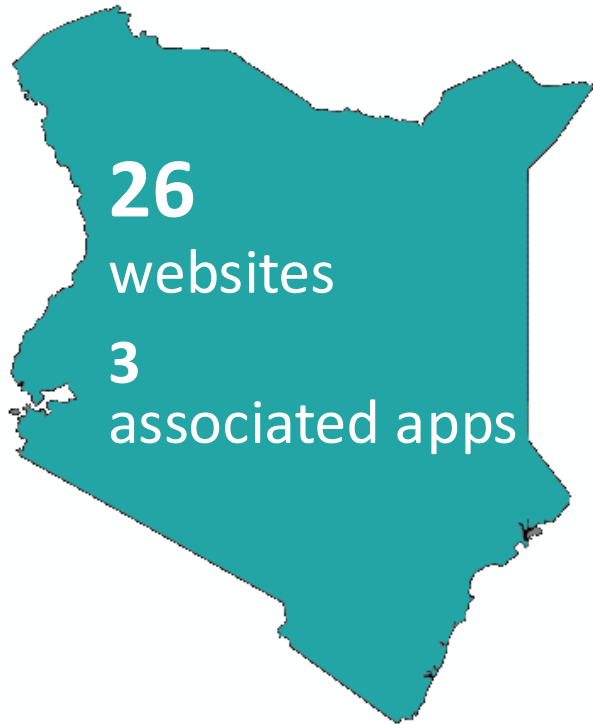
Draft regulations	Guidelines	Other relevant regulations that apply
Draft Drugs, Cosmetics, and Medical Devices Bill (2023)	Federation of Indian Chambers of Commerce & Industry - Code of conduct (2016)	Information Technology Act (2000) (IT Act and IT Amendment Act; 2008)
Department of Pharmaceuticals' National Pharmaceutical Policy Approach	Ministry of Health and Family Welfare Telemedicine Practice	Consumer Protection (E-Commerce) Rules (2020)
Ministry of Health and Family Welfare's draft bill (2018)		Drugs and Magic Remedies Act (1954)
		Drugs and Cosmetics Act (1940) and Rules (1945)

NOTHING IS ENFORCED!

14 'proposed requirements' identified

Results

General characteristics



15%	Offered services beyond pharmacy	40%
100%	Offered traditional/alternative medicines	80%
69%	Offered attractive medicine discounts	85%

Adherence to best practices



42%

Provided complete drug information

17%

58%

Provided a facility to upload prescriptions

90%

19%

Displayed a registration number

5%

Adherence to Best Practices



58%



62%



65%



29%

Regulatory compliance among e-pharmacies

No e-pharmacy in Kenya or India met all the regulatory requirements!

8.9 out of 12 (75%)

7.5 out of 14 (54%)

Average compliance of websites to requirements

10.0 vs 8.7

8.7 vs 7.1

Most visited* websites had better compliance

9.4 vs 7.7

7.6 vs 5.6

Websites **physically located** within the country had better compliance

Limitations

- We included the e-pharmacy universe in each country and not just a sample
 - Yet, we may have missed a few that did not appear on these search strings
- We reported the information drawn from the websites/apps at face value
 - We did not assess the sales behaviour in practice (separate study, ongoing)
- We reported the availability of drug information but not its accuracy

Conclusions

Compliance with regulations in Kenya and 'proposed requirements' in India was **low**.

Better compliance by the most visited e-pharmacies and those based within the study countries.

Implications

- Direct targeted and efficient regulatory enforcement in Kenya
- Inform development of a comprehensive regulatory framework for e-pharmacy in India

Recommendations

Risk-based regulatory approaches such that regulators:

- work with the largely compliant (“good”) e-pharmacies,
- improve enforcement among the partially compliant (“bad”)
- eliminate the largely non-compliant (“ugly”) e-pharmacies.

Organized Session at HSR2024

"Click here for meds! How to effectively govern the digital transformation of the pharmacy market"



Date: 22nd November 2024



Time: 11:40–13:10



Location: 110, Dejima Messe conference center

