When technology precedes regulation: a scoping study of the challenges and opportunities of e-pharmacy in LMICs

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E-pharmacy: background

History and expansion

- The first e-pharmacies started selling medicines directly to consumers in the late 1990s (US/UK).

- This marketplace has since proliferated.

- The past decade has seen start-ups flourishing in LMIC settings.

- Global pharmacy market was said to be worth $29.4 billion in 2014, growing to $128 billion by 2023.

- COVID-19 catalyst.

E-pharmacy: background

- Significant public health concern
  -Sale of POM without prescription
  -Sale of substandard and counterfeit medicines
  -Inadequate provision of information
  -Non health-related issues eg data privacy

-Also carries opportunity
  -Purchasing medicines online is quick, convenient, simple and private
  -Competitive pricing
  -Improve access medicines

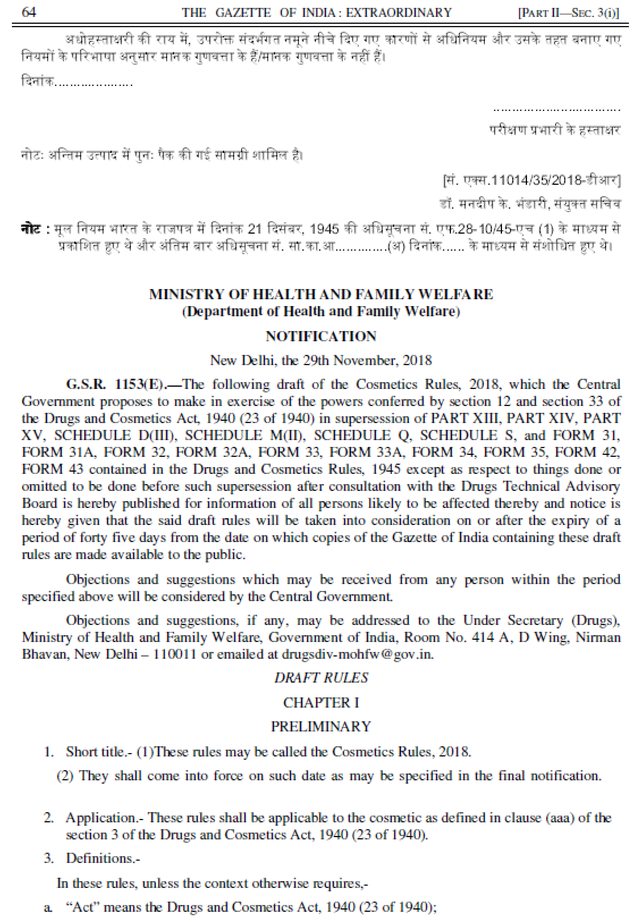
-Regulatory environment will likely have a major effect on its impact

Scoping study aims and methods

- Set out to review the regulatory challenges and opportunities posed by e-pharmacy, and the regulatory response to date in 3 low- and middle-income countries.

- 18 key informant interviews (conducted in 2018)

- Key documents reviewed alongside interviews
  - Eg guidelines, legislation, policy documents.



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दिनांक.....

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नोटः अन्तिम उत्पाद में पुनः पैक की गई सामग्री शामिल है।

[सं. एक्स.11014/35/2018-डीआर]

डॉ. मनदीप के. भंडारी, संयुक्त सचिव

नोट : मूल नियम भारत के राजपत्र में दिनांक 21 दिसंबर, 1945 की अधिसूचना सं. एफ.28-10/45-एच (1) के माध्यम से प्रकाशित हुए थे और अंतिम बार अधिसूचना सं. सा.का.आ.....(अ) दिनांक..... के माध्यम से संशोधित हुए थे।

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th November, 2018

G.S.R. 1153(E).—The following draft of the Cosmetics Rules, 2018, which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) in supersession of PART XIII, PART XIV, PART XV, SCHEDULE D(III), SCHEDULE M(II), SCHEDULE Q, SCHEDULE S, and FORM 31, FORM 31A, FORM 32, FORM 32A, FORM 33, FORM 33A, FORM 34, FORM 35, FORM 42, FORM 43 contained in the Drugs and Cosmetics Rules, 1945 except as respect to things done or omitted to be done before such supersession after consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration on or after the expiry of a period of forty five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

CHAPTER I

PRELIMINARY

1. Short title.- (1)These rules may be called the Cosmetics Rules, 2018.

(2) They shall come into force on such date as may be specified in the final notification.

2. Application.- These rules shall be applicable to the cosmetic as defined in clause (aaa) of the section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

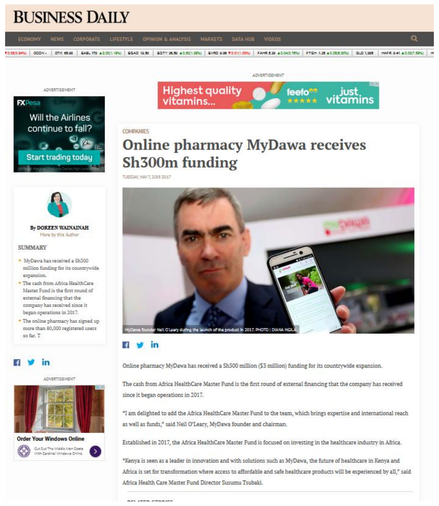
3. Definitions.-

In these rules, unless the context otherwise requires,-

a. "Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940);

Results: scale and scope

- E-pharmacy was rapidly growing three countries.
- ~20 firms in Kenya, up to 200 in India, and no estimates for Nigeria.
- Data scarcity and lack of clear information.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Online pharmacy MyDawa receives Sh300m funding

TUESDAY, MAY 7, 2019 20:57

By DOREEN WAINAINAH

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SUMMARY

- MyDawa has received a Sh300 million funding for its countrywide expansion.
- The cash from Africa HealthCare Master Fund is the first round of external financing that the company has received since it began operations in 2017.
- The online pharmacy has signed up more than 80,000 registered users so far. T

MyDawa founder Neil O'Leary during the launch of the product in 2017. PHOTO | DAVID NDII

Online pharmacy MyDawa has received a Sh300 million ($3 million) funding for its countrywide expansion.

The cash from Africa HealthCare Master Fund is the first round of external financing that the company has received since it began operations in 2017.

"I am delighted to add the Africa HealthCare Master Fund to the team, which brings expertise and international reach as well as funds," said Neil O'Leary, MyDawa founder and chairman.

Established in 2017, the Africa HealthCare Master Fund is focused on investing in the healthcare industry in Africa.

"Kenya is seen as a leader in innovation and with solutions such as MyDawa, the future of healthcare in Kenya and Africa is set for transformation where access to affordable and safe healthcare products will be experienced by all," said Africa Health Care Master Fund Director Susumu Tsuhaki.

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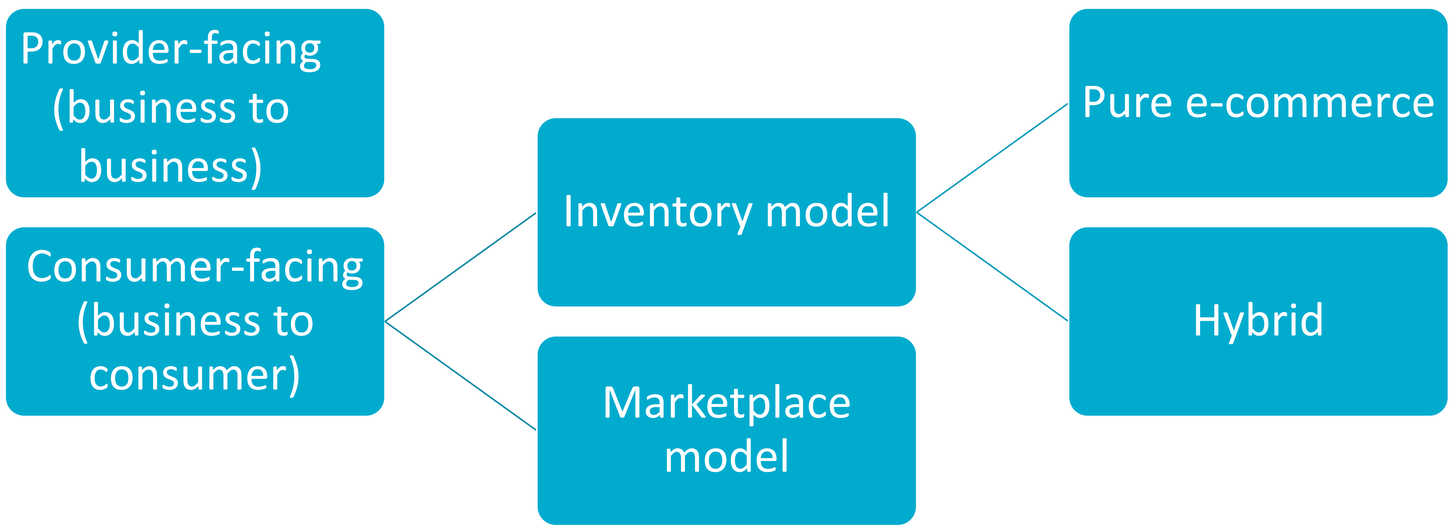

Results: regulatory response

Regulation of e-pharmacies

Country	Regulations
India	- Drugs and Cosmetic (Amendment) Rules, 2018 (pending) - Federation of Indian Chambers of Commerce and Industry (FICCI), self-regulation through voluntary code of conduct, 2016
Kenya	- Informal letter of no objection from PPB; basic registration process recently introduced
Nigeria	- Unpublished regulations for e-pharmacy since 2016

(sporadic) self regulation

Consumer-facing firms

- mechanisms to ensure POMs not sold without a prescription
- restricting the quantity of medicines sold in a single transaction
- using pharmacy technicians to deliver medicines

Provider facing firms

- background checks, inspections, confirmation of licences.
- only working with registered pharmacies
- sending reminders when licenses due to expire

Results: regulatory challenges and opportunities

Regulatory challenges	Regulatory opportunities
Regulatory capacity	Consolidation
Danger of medicine provision in context of little regulatory oversight	Traceability and transparency
Data security	
Under/over-regulation	

"The misuse of online pharmacies should not be countered with over-regulation…ultimately the prerogative of the drug regulators is to make drugs more accessible and affordable for the needy patients. Moreover, regulations should be formulated in such a manner that they serve a particular purpose and are easy to implement. Having strict regulations in place without the requisite manpower and infrastructure will make the whole process redundant and ineffective."

Interviewee, India

LMIC e-pharmacy in context: the global picture

- Challenges of using national regulatory frameworks to control a market that operates across geographical boundaries.

- There is a lack of consensus on appropriate restrictions on e-pharmacy, with higher income countries adopting varied approaches.

- Several HICs have placed emphasis on verification systems
eg ‘EU common logo’, US Digital Pharmacy Accreditation and Canada’s CIPA certification mark.

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- Some independent organisations have set up international verification systems

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Conclusions

- E-pharmacy is growing in LMICs and this trend is likely to continue.

- There are risks associated with unregulated e-pharmacy markets but it also offers the opportunity to expand access to medicines.

- Current regulation has not kept pace with this technological innovation and HICs are yet to construct and enforce effective regulatory frameworks.

- LMICs face this new challenge alongside endemic regulatory infringement in brick and mortar pharmacy markets.

- E-pharmacy could potentially prove to be a catalyst for re-thinking regulatory approaches in this sector.

Next steps: a research agenda

1. Provide a better understanding of the performance of e-pharmacies, for example studying how they fare in terms of quality of service provision, price and access to medicines in comparison to brick and mortar pharmacies;

2. Analyse and inform the regulatory response as this market continues to evolve and grow;

3. Consider the broader political and economic context of e-pharmacy markets.

Thank you for listening!

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