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

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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.
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.

- **Business models**

  - Provider-facing (business to business)
  - Consumer-facing (business to consumer)
  - Inventory model
  - Marketplace model
  - Pure e-commerce
  - Hybrid
Results: regulatory response

Regulation of e-pharmacies

<table>
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<tr>
<th>Country</th>
<th>Regulations</th>
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| 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| Nigeria | - Unpublished regulations for e-pharmacy since 2016 |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

<table>
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<tr>
<th>Regulatory challenges</th>
<th>Regulatory opportunities</th>
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<tr>
<td>Regulatory capacity</td>
<td>Consolidation</td>
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<td>Danger of medicine provision in context of little regulatory oversight</td>
<td>Traceability and transparency</td>
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<tr>
<td>Data security</td>
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<td>Under/over-regulation</td>
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“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.

- Some independent organisations have set up international verification systems
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.
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