

Regulating e-pharmacy: challenges and opportunities for access and quality of care in LMIC health systems

April 23

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



Improving Health Worldwide



Strathmore
UNIVERSITY
BUSINESS SCHOOL

The
George
Institute
for Global Health



E-pharmacy - Background

- Rapid growth in LMIC settings, further catalysed by COVID
- Potential advantages:
 - better access to medicines
 - enhanced traceability of pharmacy records
 - market consolidation leading to lower prices & better regulatory control
- Concerns:
 - sales without prescription
 - sale of substandard and counterfeit medicines
 - inadequate provision of patient information, and risks to data and financial security
 - rogue pharmacy networks - global operations with hundreds of related, and constantly changing, websites

drugstore.^{EG}
the uncommon drugstore

Pharmacy2U
Your prescriptions, taken care of.

1mg

MYDAWA[®]
mPower Your Health


pharmacynet
medicine at your doorstep

Technology preceding regulation...



- Globally national regulators are struggling with finding the best way forward
- Regulation tends to initially be based on brick-and-mortar pharmacy regulation; this itself is poorly implemented
- Pharma regulators lack the skills to monitor online transactions; and lack the power and resources to control large companies
- Challenges of using national regulatory frameworks to control fast-moving market that operates across national boundaries, with no global regulatory body

Miller et al, When technology precedes regulation: the challenges and opportunities of e-pharmacy in low-income and middle-income countries, BMJGH 2021

E-pharmacy Regulation

India

REGULATIONS IN PLACE

- Mandatory registration with DCGI's central licensing authority
- Online sale of schedule X drugs remain prohibited
- Pharmacy Practice Regulations (2015) are applicable

PROCESS

- Drugs consultative sub-committee submitted its report in 2016
- Federation of Indian Chambers of Commerce and Industry (FICCI) - voluntary 'self-regulation code of conduct' 2016
- Regulatory framework being proposed : The Drugs, Medical Devices and Cosmetics Bill, 2022 (draft)

Kenya

- MOH provides policy direction
- Pharmacy and Poisons Act (PPA) - primary legislation
- PPA establishes the Pharmacy and Poisons Board (PPB)
- E-pharmacy governed by Rules provided by PPB
 - Emphasis – online pharmacies must be linked to physical pharmacy premises that are licensed
 - Rules cover registration, documentation, dispensing practice, product delivery, record keeping, data security, QA and technological capabilities

This study

Regulating e-pharmacy: challenges and opportunities for access and quality of care in LMIC health systems



- Grew out of an earlier Seed Award from Wellcome Trust
- Funded by UK FCDO, UK MRC and Wellcome Trust
- 3 years – mid-2022 to mid-2025



Mohammed Abdul Salam
Devaki Nambiar
Gautam Satheesh
Sashikumar Tirutthani



Frank Wafula
Emmanuel Kweyu
Sammy Masibo
Irene Khayoni



Catherine Goodman
Ben Palafox

Objectives & Work-Packages

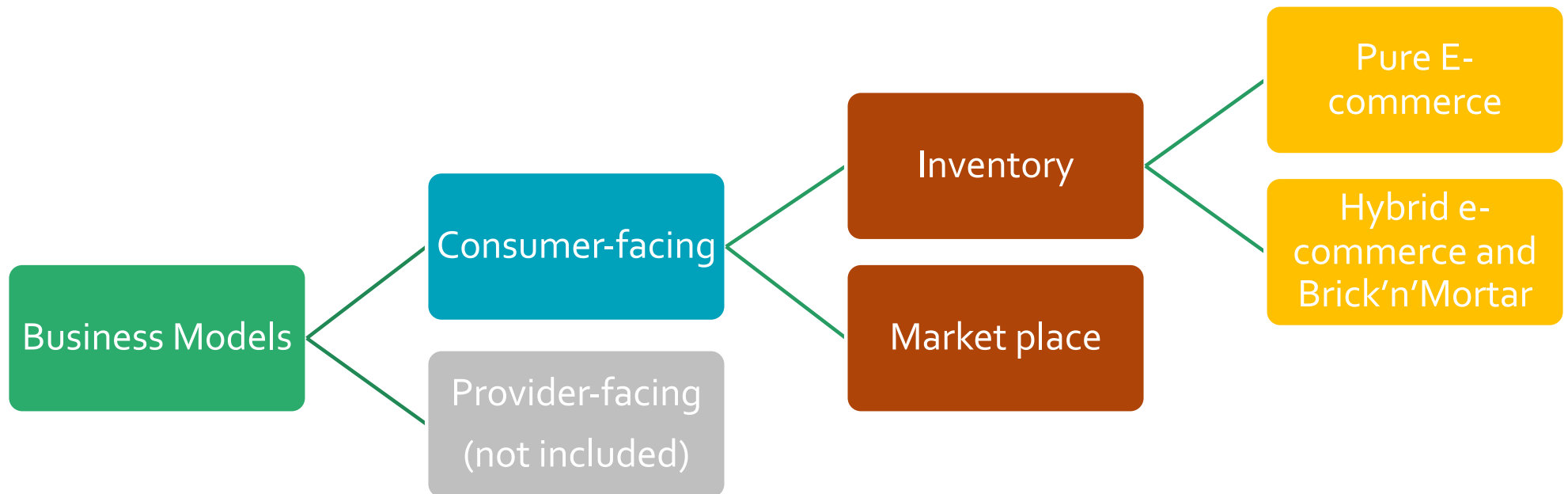
WP₁ - Characterise
e-pharmacy markets

WP₂ - Assess
performance of
e-pharmacies

WP₃ - Critical
appraisal of
regulatory systems

WP₄ - Understand
policy processes
influencing
regulation

Defining E-pharmacy in this Study



Defining E-pharmacy in this Study

Criteria

- Sells modern POMs directly to consumers (with or without OTCs)
- Operates through an internet site or mobile app, through which the ordering process is initiated (though maybe completed by whatsapp or phone)
- Offers a mechanism for making payments remotely – online or cash on delivery
- Offers delivery through mail, shipping companies, or courier service

Includes

- Legitimate e-pharmacies operating within local regulations, and those operating without licence or outside of regulations

Excludes

- Brick'n'mortar pharmacies which have website for promotional process only (not possible to initiate an order)

WP1 - Characterise e-pharmacy markets

- **Identify sampling frame of e-pharmacies serving customers in Kenya/ India** – internet-scraping using common search terms to identify providers and volume of “hits”
- **Website & App review**
 - Document scope of products and services; payment methods; delivery strategies; links to other businesses (eg online advertising, payment gateways)
 - Assess compliance with national regulations and best-practice standards using a combined checklist
- **In-depth interviews (IDIs) with e-pharmacy staff** - to understand business models and competitive strategies
- **Consumer experience** – monitor online feedback on websites and social media

WP₂ - Assess performance of e-pharmacies

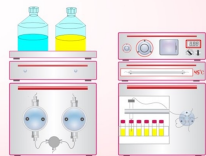
Random sample of 100 e-pharmacies in India and 20 in Kenya

Study staff act as SPs, varying customer and delivery details

Proceed through encounter as a normal online shopper would up to the point of payment

Complete final purchase for a sub-sample of cases

HPLC



Quality of 200 medicines tested for dissolution and availability of active pharmaceutical ingredient

Standardised Patient Cases

Medicine-driven requests

- **Antibiotic** - drug resistance concern
- **Opioid or narcotic** - controlled prescription drug; danger of addiction
- **CVD medicine** - affordability concern for long-term use
- **Insulin** - requires cold chain
- **Medical abortion** – importance of counselling

- Each presented **3 times**:
 - no prescription
 - prescription with error
 - valid prescription

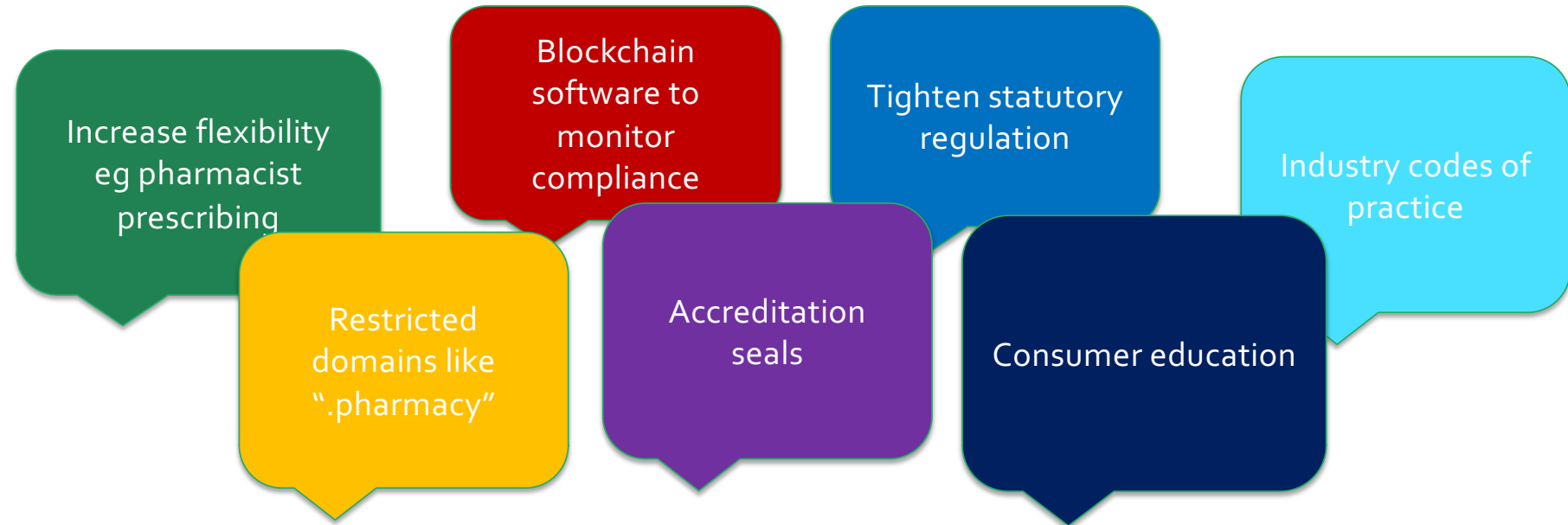
Symptom-driven requests

- **Gonorrhoea symptoms** in a male - expect recommendation of antibiotic
- **Chronic knee pain** in a pregnant woman - expect recommendation of painkillers such as diclofenac

WP3 - Critical appraisal of regulatory systems

- Critical appraisal of current regulatory systems for e-pharmacy and potential amendments / alternatives
- Scope - global governance mechanisms, national level in Kenya and India, and state-level in Telangana and Delhi
- Draw on range of regulatory theories (risk-based regulation, responsive regulation, Table of Eleven, Behavioural economics, regulatory capture)
- Review of epharmacy regulations in selected countries which could act as models
- IDIs with staff from e-pharmacies, regulators, government, industry, professional associations, patient groups, international agencies
- Explore perspectives on performance of current regulation, and potential alternatives...

Regulatory alternatives might include...



Options assessed in terms of:

- fit with regulatory objectives
- likely regulatory compliance
- likely impact on quality of care
- implications for affordability and access
- regulatory capacity and funding requirements
- impact on innovations

WP4 - Understand policy processes influencing regulation

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

ALL INDIA CHEMIST STRIKE

- Chemists are on nation-wide strike to protest against the Centre's move to regularise online pharmacies.
- All India Organisation of Chemists and Druggists (AIOCD) opposes the decision, stating e-pharmacy poses threat to their business.
- Online pharmacies lead to the risk of drug abuse.
- E-pharmacies can increase the cases of illegal sale of medicines.
- Online pharmacies registered with the Central Drugs Standard Control Organisation (CDSCO) will only obtain a trade licence.



WP4 - Understand policy processes influencing regulation



- Study the policy processes influencing the design and implementation of e-pharmacy regulation
- Review of policy documents, legal proceedings and media coverage to develop a timeline of key policy events
- Identify specific 'policy moments' where regulation has advanced or been stalled/ contested
- Use IDIs to explore policy moments and their connections through process tracing and the 3I+N framework (institutions, interests, ideas, networks)

Communication and Policy Impact



- National stakeholders in India and Kenya:
 - National Advisory Committees, engagement through IDIs, national stakeholder workshops
- Global stakeholders:
 - International Advisory Committee, regular interaction, conferences
- The “public”:
 - Simple information materials on codes of conduct, identifying trustworthy providers and using online services
- Academic community
 - Open access publications, teaching materials, publicly available tools and metadata