Global access to quality-assured medical products: the Oxford Statement and call to action

Substandard and falsified medical products (including medicines, vaccines, biologics, and diagnostics[1]) represent a significant and growing threat to human health. Substandard medical products result from errors, corruption, negligence, or poor practice in manufacturing, procurement, regulation, transportation, or storage. By contrast, falsified products result from criminal fraud. Although substandard and falsified medical products have been traded for many centuries, in the last few decades the problem has grown with the increased complexity of the global pharmaceutical economy and internet sales.[2]

Every person has the right to expect that when they use a medical product, it works as intended. But too often, it does not. Recent research evidence paints a bleak picture of global patient harm and economic damage: a systematic review and meta-analysis[3] estimated that 12·4% of antibiotics and 19·1% of antimalarials in low-income and middle-income countries (LMICs) were substandard or falsified, with an estimated economic impact ranging from US$10 billion to $200 billion; in 2015 WHO found alarming failure rates (64%) for vital oxytocin injections;[4] a large epidemic of dystonic reactions occurred in central Africa due to mass substitution of diazepam tablets with haloperidol, probably inserted criminally;[5] recent data from Europe highlight key neglected issues with the quality of medical devices;[6] and the SEVEN study in sub-Saharan Africa found that 16·3% of 1530 randomly sampled cardiovascular medications (anticoagulants, antihypertensives, and statins) failed Active Pharmaceutical Ingredient content analysis.[7]

In the face of mounting harm, regulatory bodies are alarmingly underequipped. WHO recently stated that "Fewer than 30% of the world's medicines regulatory authorities are considered to have the capacity to perform the functions required to ensure medicines, vaccines and other health products actually work and do not harm patients."[8] Few national medicines regulatory authorities (NMRAs) have a policy of publicly releasing data on substandard and falsified medical products and there has been minimal discussion of local policies on how to engage appropriately with the public about such reports.

In September, 2018, the first international Medicine Quality and Public Health Conference was held at Oxford University, UK, to discuss opportunities and solutions to ensure that all people have access to affordable and quality-assured medical products. Delegates developed the short Oxford Statement, calling for investment, policy change, and action to eliminate substandard and falsified medical products. The statement was born out of discussion between governments, national and international agencies, non-governmental organisations, professional associations, and academic institutions who together examined the latest evidence on the epidemiology and public health implications of substandard and falsified medical products. Here, we expand this statement with a call to action (panel) and research agenda (appendix 2).

These actions will require advocacy and political commitment spanning diverse sectors, to mobilise sustainable investment in people and infrastructure through collaborative capacity building, sustainable financing mechanisms, and good governance. Partnerships between NMRAs, regional bodies, and other key stakeholders need significant strengthening. Although NMRAs are keystones for many actions, they need to work in close collaboration with related actors including Ministries of Health, Finance and Trade, and Science and Technology; pharmaceutical manufacturers and distributors; medicine procurers; funding and implementation agencies; central medical stores; pharmacists; innovators; academics; law enforcement agencies; the judiciary; and civil society, including patients' organisations.

Accountability and transparency by all is critical to promote progress towards country and international development goals. Initiatives such as the #MedsWeCanTrust campaign are building awareness, serving as a tool so that patients, health workers, governments, policy makers, the pharmaceutical industries, and others understand the role they can play in calling for and making the commitments and policy changes necessary to ensure that the medical products that reach people work.

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For the French translation see **Online** for appendix 1

For the **Medicine Quality and Public Health Conference** see https://www.tropicalmedicine.ox.ac.uk/events/medicine-quality/mqph2018

For the **short Oxford Statement** see https://www.iddo.org/news/mqph-short-statement-2018

See **Online** for appendix 2

For the **#MedsWeCanTrust campaign** see https://medswecantrust.org/

Panel: The Oxford Statement on Medicine Quality and Public Health

Building on growing evidence of the prevalence and impact of substandard and falsified medical products, it is time to make access to quality medical products an immediate global priority and encourage research informing policy and implementation.

We support:
(a) The recommendation from all WHO Member States, accepted by the 2017 World Health Assembly, that defines substandard and falsified medicines in public health terms
(b) WHA Resolution 67.20, calling on Member States and WHO to strengthen national medicines regulatory authorities (NMRA)

And we call for accelerated progress towards global access to quality-assured medical products through:
(a) Adoption of WHO's "Prevent, Detect and Respond" strategy under the Member State Mechanism framework[1]
(b) Collaboration and harmonisation for the global strengthening of medicines regulatory systems, guided by the WHO Global Benchmarking Tool for NMRAs
(c) Increased investment by nations, regional bodies, and international donor agencies in financial and capacity building mechanisms that facilitate:
- All national NMRAs achieving the highest possible WHO Maturity Level
- Appropriate expansion of local manufacturing capabilities implemented according to Good Manufacturing Practice
- Strengthening medical product supply systems and post-market surveillance

(d) Increased investment by research funders for assessing the impact of substandard and falsified medical products, especially on patient outcomes, economic cost, and antimicrobial resistance, and the cost-effectiveness of interventions to eliminate substandard and falsified medical products

Key needs in the prevention domain:
- Equitable access to affordable quality-assured medical products, without stockouts
- Robust quality assurance systems for registration, production, procurement, distribution, pharmacovigilance, post-marketing surveillance, and enhanced data sharing of medical product quality
- Consistent quality requirements for production and procurement across public and private sectors, nationally and internationally, for both domestic use and export
- Improved regulatory action, governance, accountability, and transparency across the medical product lifecycle, including appropriate public access to data on registered quality-assured medical products, inspection outcomes, product recalls, and for internet sales
- Sustained enhanced funding and support for the WHO Essential Medicines and Health Products Department, including the WHO Pre-qualification Team and the Substandard and Falsified Medical Products Group
- Education of health workers, policy-makers, and the public on the importance and impact of quality-assured medical products, safe procurement, and distribution, and incorporation of thes elements into pharmacy, nursing, and medical curricula
- Global convergence of standards and medical products regulation regionally and globally

Key needs in the detection domain:
- Increase in laboratory capability to perform timely risk-based monitoring and detection of substandard and falsified medical products throughout supply chains and collaboration between inspecting organisations
- Increased investment in innovative field screening devices for the rapid detection of substandard and falsified products and their standardised evaluation including cost-effectiveness analysis

Key needs in the response domain:
- Strengthened administrative and legal frameworks of NMRAs to respond promptly and appropriately
- Mandatory timely reporting by all of substandard and falsified medical products to relevant NMRAs and WHO Substandard and Falsified Medical Products Group by all state and non-state actors
- Clear plans for governmental and international organisations responses to substandard and falsified medical product "outbreaks", including procedures to engage with the public and health workers, to ensure timely and appropriate public health response
- Analysis of substandard and falsified epidemiology data to improve prevention, detection, and response

Substandard and falsified medical products cause maltreatment, harm patients, weaken health systems, undermine universal health coverage and the Sustainable Development Goals, and are counter to the fundamental principles of people's right to health. With significant human health and economic consequences at stake, urgent action is needed now.

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We declare no competing interests.

For the full list of signatories see appendix 3. We are very grateful to the Vice-Chancellor of the University of Oxford, the Nuffield Department of Medicine's Centre for Tropical Medicine & Global Health, the MORU Tropical Health Network, the Infectious Diseases Data Observatory, and Keble College, for their help in hosting the conference and all those who attended and gave such wonderful contributions. We thank Eshe Hill for her marvellous help. Generous support was provided by the Bill & Melinda Gates Foundation, Wellcome Trust, United States Pharmacopeial Convention, the Medicines for Malaria Venture, the Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management, Rwanda, and Concept Foundation to support attendees from LMICs. The opinions expressed are those of the authors and do not necessarily represent the opinion of their employers.

1 World Health Organization. WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization, 2017. http://apps.who.int/medicinedocs/en/m/abstract/Js23373en/ (accessed Oct 16, 2019).

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See **Online** for appendix 3

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Supplementary appendix 2

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Research agenda

Research on SF medical products is in its infancy and there is an urgent need for multi-disciplinary research to inform policy and implementation. Here we highlight some of the gaps that need urgent answers:

Evidence to inform prevention

- Epidemiology of SF medical products in different countries, in different sectors of the health system for different categories of medicines/medical products, including changes through time and space, their determinants (including poor transport/storage conditions, and poor stability of products due to inappropriate manufacturing and packaging), and their health and economic impact. What will the economic impact of maintaining status quo rather than key interventions.

- Standardised study design and data reporting/sharing to facilitate data comparison and interpretation to protect public health [1].

- Relationship between SF medicines, and other sympatric drivers such as irrational prescribing and adherence, and impact on the emergence and spread of antimicrobial resistance (AMR).

- Identify social, political, sociocultural, institutional and economic drivers for access to and the quality of medical products [2]. How could prequalification system be implemented, funded and expanded?

- Relationship of country governance and SF epidemiology and effective interventions to strengthen governance including addressing corruption as a driver for SF medical products.

- Impact of all donors and partners adopting stringent QA requirements in laws for exported medicines. Strategic mapping of policies, practices, tools and legislations.

- How to incentivize the private sector to uniformly invest in quality

- Perceptions of medical product quality across communities, determinants of trust in medical product quality, effective interventions to increase trust in medical product quality and how to mitigate harm in 'outbreaks' of SF medical products.

- Comparison of the effectiveness of existing and innovative interventions to reduce SF burden and impact, for example, from public engagement to enhanced PMS. What are the impediments and advantages of SF-related legal convergence between nations.

Evidence to inform detection

- Appropriate selection of post-marketing medicine quality surveillance strategies, and their cost-effectiveness, in different scenarios.

- Test effective interventions, including collaborations between NMRA through regional harmonisation, to support NMRA to gain high maturity level, depending on local constraints, and have sustainable, implementable human, technical and financial capacity.

- Test interventions for the procurement of quality-assured medical products, including collaborations between procurement agencies, manufacturers, non-governmental, national and international organizations, programmes such as the WHO Prequalification of Medicines Programme, and health centres

- Standardised independent evaluation, across a wide range of APIs, of innovative screening devices for detecting SF medicines in the 'field'.

- Innovation to create devices that reliably and accurately detect medicines with lower or higher API amount than stated without destroying the packaging–a holy grail of PMS methodology-and for devices that can screen for medicine dissolution, degradation and impurities, neglected key aspects of medicine quality.

Evidence to inform response

- Differential detection of poor quality medical products resulting from degradation in the supply chain from those resulting from poor manufacturing practices [1].

- Innovative forensics to identify location of manufacturing of falsified medical products and their trade routes.

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