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Poor-quality medical products: social and ethical issues in accessing 'quality' in global health

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Assuring access to medicines, vaccines and medical devices of adequate quality is a key pillar of any well-functioning health system and a prerequisite to achieving universal health coverage. However, high prevalence of substandard and falsified (SF) medical products, particularly in low-income and middle-income countries (LMICs),[1 2] and widespread inadequate practices in the management,[3] prescription and use[4] of medical products along their life cycle, all undermine access to quality-assured medical products and the performance of health systems. In addition, what counts as 'quality' can be highly variable and greatly contested, with perceptions of what constitutes 'good standards' shaped by a range of geographical, contextual, sociopolitical and cultural factors.

In more technical domains, significant advances towards a common understanding of quality are taking place. In 2017, at the Seventieth Assembly of WHO, a key step forward was made in clarifying and gaining WHO Member States' agreement on the use of the terms "Substandard and Falsified (SF) medical products" to describe medical products of unverified or poor quality, adding clarity to previous unspecific wording in regulation and practice.[5] "*Substandard*" medical products are those authorised by national regulatory authorities, but lacking adequate quality standards, while "*falsified*" medical products deliberately or fraudulently misrepresent their identity, composition or source. The emphasis on clear definitions is reflective of greater concerns about the ambiguity surrounding poor-quality medical products, examples of which are the conflict between an approach centred on the protection of public health versus intellectual property rights, and the gaps between actual risk and perceived threats of SF medical products.[6]

The perceived efficacy of antimalarial medicines influences therapy choices and health-seeking itineraries, potentially limiting access to good quality biomedical care.[7] And it has been argued that poor-quality antimalarials are an important driver of antimalarial resistance and of under-five malaria mortality.[8] Moreover, substandard antibiotics result in suboptimal antimicrobial exposure and are thus likely to significantly contribute to antimicrobial resistance (AMR). However, product quality surveillance is rarely integrated in normative guidance on AMR.[9] Suboptimal antimicrobial exposure can also be due to poor prescription or use of antibiotics, but it may be difficult to evaluate existing patterns, especially when antibiotics are procured through the informal sector. Even less is known about 'quality' along the life cycle of other medical products, given the limited capacity to measure and monitor the quality, management and use of medical products in many LMICs.

It is positive that the WHO benchmarking tool for National Medicines Regulatory Authorities (NMRAs) was initiated to provide an impetus for improving their maturity and competency.[10] But to date, only a few NMRAs worldwide are considered able to adequately perform oversight of quality, supply and use of medical products. The potential health risks of SF medicine coupled with insufficient regulatory capacity produce considerable uncertainty as to whether and to what extent national pharmaceutical systems can be considered trustworthy—an uncertainty that diffuses across a broad range of stakeholders: from individual patients and front-line practitioners to national and international policy-makers.

In addition to the (limited) technical capacity for pharmaceutical manufacture, distribution and regulation, SF medical

products are shaped by a complex set of socioeconomic factors, such as geographical and financial accessibility, cultural beliefs, historical experiences (that impact the communities' trust in health systems), standards of governance and poor ethical practices through to corruption. The highly variable and contextual nature of the assessment of the quality of medical products and of their use signals the need for greater examination of the social and ethical features in which they are embedded.

In 2018, a session on ethical and social aspects of SF medicine was presented at the first ever conference on *Medicines Quality and Public Health*, held at Oxford University, UK (https://www.tropicalmedicine.ox.ac.uk/events/medicine-quality/mqph2018). This conference resulted in a *Medicines We Can Trust* campaign (https://medswecantrust.org/the-campaign), launched to provide an international platform to create synergies among all actors committed to strengthening health systems by understanding and improving the quality of medical products and of their use. Recent developments have created a powerful momentum around the need of adequately used, quality-assured medical products.[11] To build on this current momentum, *BMJ Global Health* will publish a Special Issue on *Social and ethical issues of poor quality and poor use of medical products.*

This Special Issue seeks to highlight the ethical and social challenges that shape universal access to quality-assured, adequately used medical products throughout their full-life course. We aim to pursue an in-depth and interdisciplinary exploration of the structural, political, economic and ethical factors that influence the detection and prevention of SF medical products, the access to quality-assured medicines and their adequate use along their full life cycle, that is, from manufacturing sites until completion of a treatment course.

This collection is open to research papers on subjects including the ethical challenges in medicines regulation, procurement, supply, rational use and health-seeking behaviour; the social life of medicines (uses and perceptions of quality and effectiveness of interventions); and the determinants of trust in medicine and in medical products. While we will examine global health and feature several examples from LMICs, we consider the discussion relevant to all countries and at the global level.

This Special Issue will promote dialogue between researchers in different disciplinary communities whose work touch on the ethical and social dimensions of achieving universal access to quality-assured, adequately used medical products, throughout their full-life course. We look forward to considering your papers, dedicated to offering novel and timely insights into an important but still sidelined issue in global health. Papers should be submitted by 15 April 2020. The usual article processing charges and waiver policy will apply. However, authors who require but are unable to obtain waiver through the regular *BMJ Global Health* processes are welcome to contact the corresponding author of this editorial for additional considerations.

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