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Uncertainties about the quality of medical products globally: lessons from multidisciplinary research

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The world was shocked when it emerged that at least three hundred young children, all under the age of 5, died of acute kidney injury between 2022 and 2023 in The Gambia, Indonesia and Uzbekistan. They had ingested cough syrups heavily contaminated with diethylene glycol and ethylene glycol.[1] Even if the prevalence of substandard and falsified (SF) medical products and their impact on health are well known, these cases spanning different contexts and continents are alarming, given the victims' age, the impact on their families and to the apparently innocuous and prevalent nature of this type of medicine—cough syrups are widely available and generally perceived as low risk. This example shows that there remains much to do and learn about the social and ethical conditions that produce and exacerbate SF medicines, and makes the focus of this Special Issue especially timely and important.

In 2019, shortly before the COVID-19 pandemic, we launched a multidisciplinary call for a Special Issue on Poor-quality medical products: social and ethical issues in accessing 'quality' in global health. We were seeking in-depth explorations of the structural, political, economic and ethical factors that influence the quality and use of medical products.[2] We wanted to draw attention to the problem that while universal health coverage aims to ensure that all people have access to the full range of health services they need, when and where they need them, without financial hardship, there was often little attention and infrastructure in place to ensure the quality of essential medical products.[3 4] Since 2019, there has been unprecedented technical work to reinforce pharmaceutical regulatory capacities at national[5] and regional[6] level. Nonetheless, confidence and quality is still far from secure on the global pharmaceutical market, as shown in the case of contaminated cough syrups.[1] A poorly regulated environment creates fear and great uncertainty, where stakeholders at all levels in health systems are grappling to make informed decisions on what actions should be prioritised, at which level, to protect individuals, communities and countries from SF medical products.

The Special Issue includes nine articles: one commentary, one 'practice' paper, one 'analysis' paper and six original research papers from around the world. The papers are from sociologists, public health pharmacists, anthropologists, economists and other scholars. They address a variety of topics relevant to quality—and quality use—of medical products, either from an international or national angle in countries such as India, Indonesia, Pakistan, Turkey, Tanzania and Romania. The key themes include a description of the ethical and practical issues involved in international procurement policies and their impact on the quality of products procured for national and international non-governmental organisations; the importance of formal education on SF medical products for pharmacy students; the pharmaceutical marketing and financial incentivisation to general practitioners; the regulatory circumvention on the quality assurance of pharmaceutical ingredients (a neglected but relevant aspect: excipients were at the root of the incidents in The Gambia, Indonesia and Uzbekistan[1 7]); and the political and economic determinants of SF medicines vs the role of technology and regulators.

First, Macé *et al* and Enright discussed international procurement policies. On the one hand, Macé *et al* reflected on how international procurement policies could incorporate the concept of regulatory 'maturity level', so as to acknowledge the efforts of countries that invest in regulatory strengthening, without taking undue risks for medicines

users.[8] On the other hand, Enright explored some ethical dilemmas that could, directly or indirectly, compromise the quality of medical products procured for the medical programmes of international non-governmental organisations.[9]

Second, also from an international angle, Kusynová *et al* called for the scale up of a new educational course on SF medical products for undergraduate pharmacy students, which may empower all pharmacists across health systems to proactively protect communities from SF medical products.[10]

Third, the remaining articles present national case scenarios of global relevance. Noor *et al* presented the findings of a study in *Pakistan,* which reveals and explains the potential distortion of prescribing behaviour, caused by pharmaceutical marketing and financial incentivisation to general practitioners.[11] Hamill *et al* drew on interviews with manufacturers and regulators in India to investigate the under-studied issue of quality of active pharmaceutical ingredients, and called for increased attention to the risks of regulatory circumvention.[12] Nistor *et al* discussed how political and economic factors influence the risk of falsified medicines in Romania: they warned against exclusive focus on enforcing quality-assurance, reminding that ensuring access to affordable medicines is equally critical to eliminate the factors that incentivise falsified medicines.[13] Hasnida *et al* presented an investigation of the political and economic determinants of SF medicines in Indonesia: the political pressure to reduce prices and certain healthcare provider incentives can drive markets for SF medicines, and policymakers should carefully consider the potential impact of rules governing health financing, procurement, taxation and industry, on medicines quality.[14] Kootstra and Kleinhout-Vliek presented a realist review of pharmaceutical track-and-trace systems, with the Turkish system used as a benchmark; their findings emphasise the interplay between technical solutions, contextual factors, and the need to align incentives for all actors in a continuous implementation process.[15] Finally, Hamill *et al* looked at the 'on the ground' effectiveness of the WHO Global Surveillance and Monitoring System for SF medicines in Tanzania; they provided important insights into how the theorised mechanism between technical reporting and a reduction in undesirable behaviours plays out in a low-income setting, and revealed hidden assumptions about regulator behaviour and motivations.[16]

Overall, the nine papers provide a well-balanced representation of different countries and regions, and a good balance between disciplines, research methods, and global reflection vs national analyses. The variety of contexts suggests that no region can consider itself exempted from the risk of SF medical products, even if the determinants vary in nature and weight, for example, by country income, regulatory maturity level, social protection and health insurance, and the overall ecosystem of education, health financing, market and taxation system. Analyses and corrective interventions related to purely technical aspects, such as implementing Good Manufacturing Practice and enhancing the performance of regulatory oversight, will not suffice to counteract SF medical products, because technical, social and ethical determinants are strictly interconnected. This complexity confirms the need for a systemic policy approach to SF medical products, informed and guided by interdisciplinary research in this field.[17]

It is encouraging that most contributions to this Special Issue came from the disciplines of pharmacy and social science. The interest of social scientists is particularly welcome. Sociology, anthropology and health economy are needed to uncover, disentangle and document the non-pharmaceutical factors that favour or hinder SF. The rapidly growing body of social science studies in this field is outstanding, especially given the limited funding opportunities. We hope that the work published here will inspire more collaborative groups. Although ethical considerations are embedded in many of the papers in the Special Issue, there were no contributions from ethicists. This is not surprising for an emerging field in global health. However, it is important that future collaborative work include ethicists, who provide an important lens to build a value-based approach[18] and to guide researchers in this field.[19] Efforts could also be made to stimulate research in apparently underrepresented areas, such as Central Asia and the Americas.[20] More awareness and support is needed from all the stakeholders in global health, including but not limited to governments, donors and academia, to facilitate dialogue between researchers who, in different disciplinary communities, contribute to the achievement of universal access to quality-assured, adequately used medical products.

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