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The need for comprehensive and multidisciplinary training in substandard and falsified medicines for pharmacists

Alessandra Ferrario,[1] Ebiowei Samuel F Orubu,[2,3] Moji Christianah Adeyeye,[4] Muhammad H Zaman,[5] Veronika J Wirtz[6]

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For numbered affiliations see end of article.

Correspondence to
Dr Alessandra Ferrario; alessandra_ferrario@harvardpilgrim.org

The global burden of substandard and falsified (SF) medicines is only beginning to be better understood. A 2017 literature review by WHO estimated a 10.5% observed failure rate of the analysed medical product samples in low-income and middle-income countries.[1] The report also estimated that between 72 430 and 169 271 deaths in children under 5 with pneumonia could be attributed to the use of SF antibiotics and between 31 000 and 116 000 estimated deaths from malaria in sub-Saharan Africa could be due to SF antimalarials.[1] Further, the economic impact due to reduced effectiveness of SF antimalarial products was estimated at about US$38.5 million in sub-Saharan Africa.[1] Another literature review and meta-analysis estimated the overall prevalence of SF medicines at 13.6% in low-income and middle-income countries with economic burden ranging from US$10 billion to US$200 billion.[2] Further, SF antibiotic medicines containing inferior amount of active ingredient can promote antimicrobial resistance.[3] While more limited evidence is available on the prevalence of SF medicines in high-income countries,[1] and the extent to which SF medicines affect countries at various stages of health system development is different, the problem is really global.[4 5] The true prevalence of SF medicines is unknown due to methodological limitations affecting a number of published studies (eg, inadequate sampling techniques and inadequate analytical procedures), varying or unclear definition of what constitutes a substandard or falsified medicine, uneven coverage of geographical and therapeutic areas and limited availability of up-to-date data.[6 7] Even so, the available evidence illustrates the fact that SF medicines are a threat to individual and public health, can undermine trust in the healthcare system and waste resources.[1 5]

Substandard medicines are defined by WHO as "authorized medical products that fail to meet either their quality standards or specifications, or both".[8] The reasons for being out-of-specification vary and can range from unintentional errors due to poor knowledge to negligence with good manufacturing and distribution practices. Falsified medicines, on the other hand, are "medical products that deliberately/fraudulently misrepresent their identity, composition or source".[8] In each instance, SF medicines represent safety, quality and efficacy risks.

While capable and adequately resourced national drug regulatory authorities are pivotal, the response to the problem goes well beyond enhanced regulation alone. It is increasingly recognised that addressing the problem of SF medicines will require the coordinated action of multiple stakeholders (eg, different Government bodies including customs, law enforcement, legislature, judiciary, regulatory; health professionals, including pharmacists and public health professionals; patients and the general public) and disciplines at the international, national and the local level[5 9 10] as well as awareness and advocacy by different members of the society.[11] The latter is particularly important in settings where unlicensed drug retailers and non-qualified staff dispense medicines. In this editorial, we discuss the need to enhance the pharmacy curriculum as an entry point to contribute to the educational needs of regulatory and non-regulatory staff in SF medicines.

Worldwide, pharmacists are the professionals charged with the final custody of medicines, before they are dispensed to patients,

as well as ensuring the proper use and administration of medicines. They may also take up different roles in the supply chain from manufacturing to procurement of medicines.[12] Being experts, they are properly positioned to stem the tide of SF medicines.

The burden of SF medicines mandates increased awareness on the part of pharmacists. Although training varies by country, region and institution, pharmacists' education, by default, emphasises quality in the production and use of medicines. The spread of SF medicines, however, necessitates inclusion of (compulsory) modules teaching techniques and skills for identifying and reporting SF medicines—as a means of creating or consolidating professional awareness among pharmacists.

The current strategies on addressing quality of medicines largely focus on regulatory issues; however, there is an urgent need for a system-wide approach including consideration of sociopolitical, economic, ethical and public health aspects and involving stakeholders and professionals—pharmacists and others—within and outside the national regulatory agencies. This is because there are broader, system-wide causes providing market incentives affecting medicines' quality.[13] Those responsible for processes and policies around procurement, prescribing and dispensing of medicines need to be aware of these factors. For example, health system underfunding and aggressive price reductions (on the buyer side) can incentivise the production of substandard medicines and jeopardise good distribution.[13] Also, unmet market needs due to shortages or unaffordable prices, in addition to weak regulatory systems, can create a market opportunity for falsified products.[13] Online medicines purchases can also be associated with a greater risk of acquiring a SF product.[14] In this context, pharmacists have important roles to play in strengthening procurement processes, in educating and warning patients about the risk of purchasing medicines from unknown sources (eg, the internet or from unlicensed medicine shops or itinerant medicine hawkers), advising patients and providers to report on changes in the efficacy of medicines, and advising healthcare organisations[9] and policy-makers in the design and implementations of policies to prevent entry and improve detection of and response to SF medicines. However, a concerted effort among all stakeholders is required. Those responsible of procurement need to focus on their quality assurance services, and prescribers and dispensers need to show increased vigilance. A collective action guided by diligence and deontology is thus called for. Co-operation among all those responsible for public health recognises this system-thinking approach.

The inclusion of a systems approach and thinking in the educational curricula for many pharmacy schools is lacking.[5] A desk review of the national pharmacy curricula in eight selected countries—six Sub-Saharan African and two Asian—found that only one specifically mentioned training in SF medicines.[15] Across the UK, training in SF medicines—where available—is usually limited to elective global health modules rather than the core pharmacy curricula (as opposed to medicines safety which is a core component of the Masters of Pharmacy degree).[16] There are now some initiatives to enhance training on SF medicines in pharmacy curricula. For instance, the International Pharmaceutical Federation together with WHO are developing a compulsory education component on SF medicines in four African countries as part of a pilot project. Further, the United States Pharmacopoeia is working with Nigerian Universities on strengthening the Pharmaceutical Quality System component of the pharmacists' curriculum.[17] Including mandatory education on SF medicines (eg, a module on 'Quality of Medicines and Public Health') in basic pharmacists' training would ensure that all incoming workforce are exposed to the same foundation. This would be more sustainable than ad hoc training on the job (eg, for regulatory authorities), which requires additional resources.

Education on SF medicines should not be limited to low-income and middle-income countries, although the prevalence of SF medicines is higher in these settings. Considering the growing knowledge gap in the relationship between quality of medicines and therapeutic outcomes, the curriculum in high-income countries should include this very important issue. Importantly, health professionals, pharmacists and citizens in high-income countries have come to take quality of medicines for granted. Yet, with growing use of online pharmacies and a global supply chain where medicines move through many different channels and countries around the globe, active ingredients may be sourced from one country, the production happens in other and the selling market in yet another country,[5] medicines quality cannot be taken for granted. Further, shortages and the high price of new medicines such as those for cancer can lead those in charge of procurement and patients to look for alternative suppliers.[18 19] In addition to education of pharmacists on SF medicines, there are other key programmes and professionals that may be targeted including Masters of Public Health and certificate and professional development courses, among which there are future policy-makers and healthcare professionals, engineers developing the relevant technologies and community health workers active on the ground.

There are various steps which can be undertaken to strengthen the training of pharmacists in Quality of Medicines and Public Health. First, governments, in collaboration with professional associations, institution of higher education and other relevant stakeholders should identify their own educational needs and gaps in the curriculum. Second, a discussion at the international level could galvanise support and help identifying common requirements in pharmacy education. Third, countries should develop goals and implementation plans for curriculum reforms including accountability mechanisms to demonstrate progress.

Universal health coverage aims to achieve access to essential quality health services and medicines without

incurring excessive financial hardship. There is no access to medicines without quality and more emphasis on training of pharmacists in SF medicines is urgently needed.

Author affiliations
[1]Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts, United States of America
[2]Institute for Health System Innovation and Policy, Boston University, Boston, Massachusetts, United States of America
[3]Faculty of Pharmacy, Niger Delta University, Amassoma, Nigeria
[4]Director-General, National Agency for Food and Drug Administration and Control (NAFDAC), Abuja, Nigeria
[5]Department of Biomedical Engineering and Howard Hughes Medical Institute, Boston University, Boston, Massachusetts, United States of America
[6]Department of Global Health, Boston University School of Public Health, Boston, Massachusetts, United States of America

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