

KEY POINTS

- Substandard and falsified medicines pose a threat to malaria elimination, and also to regional health security. They harm patients, undermine health systems, and are likely to contribute to antimicrobial resistance.
- In the Greater Mekong Subregion, national regulatory authorities (NRAs) are underresourced and need tools to help improve their capacity and efficiency in post-market surveillance of medicines. Portable medicine quality screening devices hold promise in this regard.
- A consortium from Oxford University and Georgia Institute of Technology assessed the comparative sensitivity, specificity, cost-effectiveness, and usability of a range of devices and technologies to detect poor quality antimalarial and antimicrobial medicines.
- All devices tested were capable of detecting falsified medicines containing the wrong or no active ingredient, but they were not able to reliably detect substandard medicines. They were cost-effective from a societal perspective based on a hypothetical scenario in the Lao PDR.
- Stakeholders and partners should collaborate to support independent testing, development of policy guidance, and establishment of centers of excellence to assist NRAs realize the potential of portable medicine screening devices.

Portable Screening Devices for Medicine Quality: Putting Power into the Hands of Regulators in Low-Resource Settings

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INTRODUCTION

The Harms of Substandard and Falsified Medicines

Across Asia and the Pacific, countries are striving to achieve Universal Health Coverage (UHC)—equitable access to quality medical care without undue financial hardship—in order to meet their population’s right to health. The quality medical care component of UHC relies on accessible and good quality supplies of essential medicines that treat patients as intended, and do not expose them to additional adverse effects. When medicine standards are not upheld, patients are placed in harm’s way, and waste out-of-pocket payments. Moreover, the community’s trust in the health-care system is also undermined.

Ensuring that medicines allowed onto the market will be manufactured according to high standards is the role of national regulatory authorities (NRAs), as well as the periodic inspection and monitoring of manufacturers, importers, and distributors to ensure that standards are upheld. Another key role of the NRA is the conduct of post-marketing surveillance to monitor the supply chain, inspection of premises where medicines are stored or sold, and testing of samples to ensure that poor quality products, which could be from unregistered and untrustworthy sources, do not enter the supply chain.

Poor quality medicines can be categorized into two main groups: (i) substandard medicines (usually legal and registered products which have been poorly manufactured or have degraded through inappropriate storage and do not meet the normal or regular standards), and (ii) falsified medicines (illegal products that purport to be real medicines but are fake).

Substandard medicines frequently contain less (in some cases, more) of the stated active ingredients and may also suffer from contamination as a result of inadequate quality management systems during manufacture.

Falsified medicines (sometimes referred to as “fake” or “counterfeit” medicines) are usually the result of organized criminal gangs who may manufacture the product in unsanitary conditions. These products often contain no active pharmaceutical ingredient (API) or an incorrect API. These may also include stolen or expired medicines that are misleadingly relabelled as still suitable for use and resold.

A Pressing Problem for the Greater Mekong Subregion

Substandard and falsified (SF) medicines are a pressing problem in many countries, and they are of particular concern in low- and middle-income countries, where they can have a serious negative impact on public health and attempts to attain UHC. It is estimated that the observed failure rates of SF medical products in low- and middle-income countries are approximately 10.5%.¹ If this is applied to unweighted estimates of market size in low- and middle-income countries, the estimated spend is in the order of \$30.5 billion.²

These countries are at higher risk from SF medical products because their NRAs frequently lack the capacity and tools to adequately perform the pre- and post-marketing activities needed to maintain a safe supply of quality medicines. To monitor the supply chain for SF medical products, NRAs must have enough trained staff, resources to inspect premises including far-flung

pharmacies and border posts, and access to an adequately equipped sample testing laboratory. Where testing is delayed due to long transportation times or backlogs, by the time poor quality medicines are identified it is often too late: they have already been distributed, sold, and used.

In the Greater Mekong Subregion (GMS), underresourced NRAs and porous border regions, some suffering from conflict, have enabled SF medicines to enter the supply chains. This has made malaria control in the region a more formidable task, as poor quality antimalarial medicines have undoubtedly contributed to the development of resistance to artemisinin derivatives, that with partner drugs are the first choice and often only remaining effective treatment in some countries for uncomplicated *Plasmodium falciparum* malaria.³

Criminal gangs and unscrupulous manufacturers have contributed to what has been described as an epidemic of multiple types of falsified artesunate tablets, both primitive and highly sophisticated copies.⁴ Data from Cambodia, the Lao People’s Democratic Republic (Lao PDR), Myanmar, and Viet Nam indicate that 33%–53% of sales of artesunate (an artemisinin) were falsified products with either no or very little of the active compound present.⁵ While some action has been taken in these countries, this remains a problem in some areas and artemisinin resistance threatens efforts to eliminate malaria in the GMS. Should it spread beyond the region, the effects could be devastating to global malaria control.⁶

Since the threat of artemisinin-resistance in Asia was first recognized and a concerted action plan developed to try and address it in 2013 by the World Health Organization, much has been achieved in the regulatory sphere to address the issue.⁷ The production and sale of oral artemisinin monotherapy (oAMT), one driver of resistance, has been largely eliminated, with NRAs in the GMS having taken action to prevent its manufacture or sale.⁸ However, as there may still be some old stock or falsified products in circulation, vigilance and action to remove these products must be maintained.⁹

¹ World Health Organization (WHO). 2017. *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products*. Geneva. http://www.who.int/medicines/regulation/ssffc/publications/SE_Study_EN.pdf?ua=1; and WHO. 2017. *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products*. Geneva. http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf?ua=1.

² Footnote 1.

³ WHO. 2017. *World Malaria Report 2017*. Geneva. <http://apps.who.int/iris/bitstream/handle/10665/259492/9789241565523-eng.pdf?sequence=1>.

⁴ P.N. Newton, PN et al. (2008). A Collaborative Epidemiological Investigation into the Criminal Fake Artesunate Trade in South East Asia. *PLoS Med.* 5 (2), e32, pp. 209–219. <https://doi.org/10.1371/journal.pmed.0050032>, and P.N. Newton, et al. 2006. Manslaughter by Fake Artesunate in Asia—Will Africa Be Next? *PLoS Med.* 3 (6), e197, pp. 752–755. <https://doi.org/10.1371/journal.pmed.0030197>.

⁵ Newton, A Collaborative Epidemiological Investigation.

⁶ WHO. 2013. *Emergency Response to Artemisinin Resistance in the Greater Mekong Subregion: Regional Framework for Action 2013–2015*. Geneva. http://apps.who.int/iris/bitstream/handle/10665/79940/9789241505321_eng.pdf?sequence=1.

⁷ WHO. 2011. *Global Plan for Artemisinin Resistance Containment*. Geneva. <http://www.who.int/malaria/publications/atoz/9789241500838/en/>.

⁸ WHO. 2016. WHO’s Emergency Response to Artemisinin Resistance. *Bulletin No. 5*. Geneva. <http://www.who.int/malaria/publications/atoz/ERAR-Bulletin-5.pdf?ua=1>.

⁹ C. Riley, et al. 2015. Oral Artemisinin Monotherapy Market Still Maintains a Foothold in Myanmar. Population Services International. Presentation prepared for the 65th Annual Meeting of the American Society of Tropical Medicine and Hygiene. Atlanta. November. <https://www.psi.org/publication/oral-artemisinin-monotherapy-market-still-maintains-a-foothold-in-myanmar-2015/>.

Both the Asia Pacific Leaders Malaria Alliance (APLMA) and the Asia Pacific Regional Regulatory Partnership for Malaria Elimination (AP-RRP) have helped maintain the focus of NRAs on the importance of malaria, and how they can affect the accessibility and availability of quality-assured products. NRA post-marketing surveillance and adverse drug reaction monitoring activities have also been strengthened through WHO capacity-building initiatives, and via funding through the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund). However, these initiatives tend to focus on those products procured through The Global Fund's mechanism and there is concern whether these will be maintained as countries increasingly transition from The Global Fund grants to their own public procurement of medicines with domestic funding.

For NRAs in low-resource settings to continue their effective post-marketing surveillance with sampling and testing of suspected SF health products, it is important that there be cost-effective and affordable tools to support them. Mobile medicine quality testing devices offer one such avenue but little is known about their application in the field.

EMPOWERING REGULATORS WITH MEDICINE QUALITY SCREENING TOOLS

The medicine supply chain starts with raw material suppliers selling to international and national manufacturers, and products being sold, including across national borders, to wholesalers and distributors, who in turn sell to retailers, including pharmacies, drug stores, and other vendors. At each stage, the supply chain is threatened by the entry of SF products, and NRAs attempt to combat this threat with post-marketing surveillance, where suspect samples are identified and sent to a quality control laboratory for confirmatory testing.

Various techniques and technologies, ranging from basic to highly sophisticated, have been developed to determine the quality of medicines in the laboratory. NRAs can assess suspect medicines by identifying fake packaging, detecting the presence and quantity of the APIs, and testing the dissolution rate of a medicine. Some of these processes require highly trained technicians and bulky, very expensive equipment. However, a number of portable and handheld devices have come onto the market, or are being developed for the purpose of field screening of medicine quality.

Equipping NRAs to screen the quality of medicines despite limited resources is an important measure in order to expand

their post-marketing surveillance and reduce the presence of SF products, particularly antimalarial and antimicrobial medicines, in the market. If NRA staff can screen samples in the field, they can process a larger number of products at a given time, objectively prioritize and reduce the number of samples sent for expensive laboratory confirmatory testing, and enable timely quarantine or removal of suspect products from the market.

Suitable screening tools for field-testing must produce accurate, rapid results, and must be cost-effective. While some of the technologies behind these tools have been described, there has been no independent assessment of how suitable and accurate these devices are for medicine screening in the field.¹⁰ It was unclear where in the supply chain they are best deployed, which active ingredients they can detect, and whether they can detect both SF products. Both NRAs in low-resource settings and their technical and funding partners lacked the information needed to decide whether and where a particular device would be most useful.

FIELD TESTING IN THE LAO PEOPLE'S DEMOCRATIC REPUBLIC

To address this, and evaluate the diagnostic accuracy, ease of use, and cost-effectiveness of different medicine screening devices, in 2016 the Asian Development Bank (ADB) contracted Oxford University with the Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit (LOMWRU) based in Vientiane, Lao PDR, together with the Georgia Institute of Technology, United States and Mahidol Oxford Tropical Medicine Research Unit, based in Bangkok, Thailand, to investigate and give evidence to help NRAs decide whether these new technologies are appropriate for medicine screening in the field. The three-stage investigation entailed a review of existing knowledge, a laboratory phase to determine sensitivity (false positives rate) and specificity (false negatives rate) against up to seven different anti-infective medicines, plus suitability for field work, and a field test by inspectors of the Lao PDR NRA.¹¹

The research team first conducted a systematic review to identify the gamut of portable screening devices for SF medicines and any evidence of their accuracy and use in medicine quality screening, particularly in the field.¹² While 62 studies of 41 devices being marketed or under development were identified, only six of these devices had been field-tested and there were many key information gaps. A number of devices were selected, with at least one for each type of technology employed, for further assessment in laboratory and field tests with selected antimalarial and antimicrobial pharmaceuticals.

¹⁰ S. Kovacs, et al. 2014. Technologies for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries. *PLoS ONE* 9 (3), e90601, pp. 1–11. <https://doi.org/10.1371/journal.pone.0090601>.

¹¹ ADB. 2018. An Evaluation of Portable Screening Devices to Assess Medicines Quality for National Medicines Regulatory Authorities. Consultant's report. Manila (RETA 8763).

¹² S. Vickers, et al. 2018. Field Detection Devices for Screening the Quality of Medicines: A Systematic Review. *BMJ Global Health*. 3 (4).

Box: Technologies Used by Portable Screening Devices Assessed in the Study

Infrared and near-infrared spectroscopy. The sample is bombarded with a laser and a detector then measures the absorption or emission of infrared radiation to identify the spectrum of the compounds within the sample, as compared to a reference spectrum (e.g., 4500a FTIR, Neospectra 2.5a, NIRscan, microPHAZIR Rx).

Infrared and visible light reflection. The radiation/light of various wavelengths is shined on the packaging or tablet surface of a reference and test sample and the resulting processed pictures are compared (e.g., CD3+).

Lateral flow immunoassay. Active pharmaceutical ingredient (API)-specific antibodies interact with the API in the sample, which results in a test line that shows the absence or presence of the API (e.g., rapid diagnostic test).

Liquid chromatography. A sample solution is passed over columns of coated beads in order to separate, detect and quantify its ingredients using specific detectors (e.g., C-Vue).

Mass spectroscopy. A sample is disintegrated and ionized with the ions detected by their mass-to-charge ratio, which is then compared to a reference spectrogram (e.g., Qda MS).

Microfluidic technology. Fluids made from the sample are passed through a “lab-on-a-chip” technology with microchannels that have a suitable detector to identify the API (e.g., PharmaChk).

Paper-based colorimetry. The sample is placed on a card that has a number of embedded lanes, each with a chemical compound that interacts with a specific functional group on a molecule of the product tested, and results in a color “barcode” that can be compared to a reference (e.g., paper analytical devices).

Raman spectroscopy. A sample compound is bombarded with a laser and the scattering of light/radiation is measured by a detector to identify the spectrum of the compounds within compared to a reference spectrum (e.g., Progeny, TruScan RM).

Thin-layer chromatography (TLC). Compounds in a liquid mixture are separated by drawing them up on a coated sheet by capillary action and comparing the distance reached by each dot to a standard. (e.g., Minilab).

Source: Asian Development Bank.

Various physicochemical technologies are employed in the devices that were identified (Box). The types of devices ranged from single-use rapid diagnostic test kits able to detect single compounds, to handheld spectrometers with electronic libraries that can detect a wide range of APIs. Some were destructive in nature, requiring tablets to be removed from their packaging and crushed, while others were nondestructive and could even scan through transparent packaging. Only portable devices—those that could be transported between sites by up to two persons and requiring minimal setup or training—were included in this assessment (Tables 1 and 2).

DEVICE PERFORMANCE IN THE LABORATORY AND THE FIELD

All devices tested in this study could accurately identify falsified medicines that contained none of the stated API, and none misidentified good quality medicines as falsified (Table 1). However, when tested using simulated medicines containing 50% or 80% of the API, the devices were generally poor at detecting substandard pharmaceuticals. Only two devices, the C-Vue and PharmaChk, could do this; the C-Vue was considered suitable for use in the field while the PharmaChk is still undergoing development. The spectrometers tested could be potentially used for the quantitation of some active ingredients through additional software or tweaking of the device settings, but the initial setup process is complicated. Where spectral libraries were required, in some cases these needed to be specific to each brand due to interference from inactive excipients (substances in the medicines along with the APIs). The ease of generation and loading of

libraries for new products or APIs varied and, in one case, it would be necessary to send the data to the developer in order to create the new library. Although devices could be used for raw APIs, testing on finished medicines was limited to tablets and liquids. With nondestructive devices, tablet coatings and packaging caused interference.

Field testing followed by focus group discussions with Lao PDR medicine inspectors revealed challenges in using some devices. These included sticky buttons on devices, errors interpreting results, devices being too heavy to hold comfortably by hand, software freezes, short shelf life of consumables, and problems in maintaining the chain of custody. Paper analytic devices and Minilab took markedly longer per sample than other devices. Inspectors tended to rely on the devices and spent less time visually inspecting packaging for signs of falsification than they would have without access to the devices. Some devices, according to the inspectors, were suitable for use during inspections at medicine selling points, while others, due to their size or time taken for analysis, would be more appropriate at earlier points in the supply chain or employed at provincial or central laboratories.

COST-EFFECTIVENESS OF SCREENING MALARIA MEDICINES

The team assessed the cost-effectiveness of six portable devices for detecting falsified and substandard antimalarial artemisinin-containing combination therapies (ACTs) in the context of the Lao PDR, in scenarios of low and high prevalence of SF medicines.

Table 1: Performance Summary of Portable Screening Devices

Device	Identify Falsified+	Identify Substandard+	Destructive?	Needs Reference Library (Difficult to Create in Device System)	Range of APIs Covered	Size/Weight	Time to Test One Sample	Ease of Use and Interpretation	Supply Chain Location Where the Device Could be Useful ^a	Technology
4500a FTIR ^f	Yes	No*	Yes	Yes (medium)	Wide	Large, medium weight, requires computer	5 min	Easy but many steps	BP, M, W, L	IR/NIR
CD3+	Yes	No	No	No ^b	Wide	Small, light, handheld	5-10 min***	Easy	BP, M, W, R	IR/VIS
C-Vue	Yes	Yes	Yes	No	Medium	Large, heavy, requires computer	10 min	Difficult	L	LC
MicroPHAZIR Rx ^f	Yes	No*	No	Yes (difficult)	Wide	Medium, medium weight, handheld	2 min	Easy but long set-up	BP, M, W, (R)	IR/NIR
Minilab ^f	Yes	No*	Yes	No	Medium	Large, Heavy	34 min	Difficult	W, L	TLC
Neospectra 2.5	Yes	No*	No	Yes (difficult)	Wide	Small, light, requires computer	2 min***	Easy	M, W	IR/NIR
NIRscan ^f	Yes	No*	No	Yes (not possible**)	Wide	Small, light, requires smartphone, handheld	1.5 min	Easy	BP, M, W, (R)	IR/NIR
PADs ^f	Yes	No*	Yes	No	Medium	Very small, very light	10 min	Easy to use, difficult to interpret	BP, R	Colorimetry
PharmaChk	Yes	Yes	Yes	No	Small	Large, heavy, requires computer	10 min	Difficult	L	MF
Progeny ^f	Yes	No*	No	Yes (medium)	Wide	Medium, medium weight, handheld	4.5 min	Easy/medium	BP, M, W, (R)	Raman
RDT	Yes	No*	Yes	No	Small	Very small, very light	5 min	Medium for use (sample preparation), medium for interpretation	(W), R	LFI
TruScan RM ^f	Yes	No*	No	Yes (medium)	Wide	Small, heavy, handheld	2 min	Easy	BP, M, W, (R)	Raman

API = active pharmaceutical ingredient; BP = border post; IR = infrared; L = laboratory; LC = liquid chromatography; LFI = lateral flow immunoassay; M = manufacturer; MF = microfluidics; NIR = near-infrared; PAD = paper analytic device; R = retail; RDT = rapid diagnostic test; TLC = thin-layer chromatography; VIS = visible; W = wholesaler/distributor; items in parentheses indicate some potential usefulness.

+ NB Only 7 APIs tested; ^a context specific; ^b Genuine quality-assured medicine required for comparison.

^f Device was both laboratory- and field-tested.

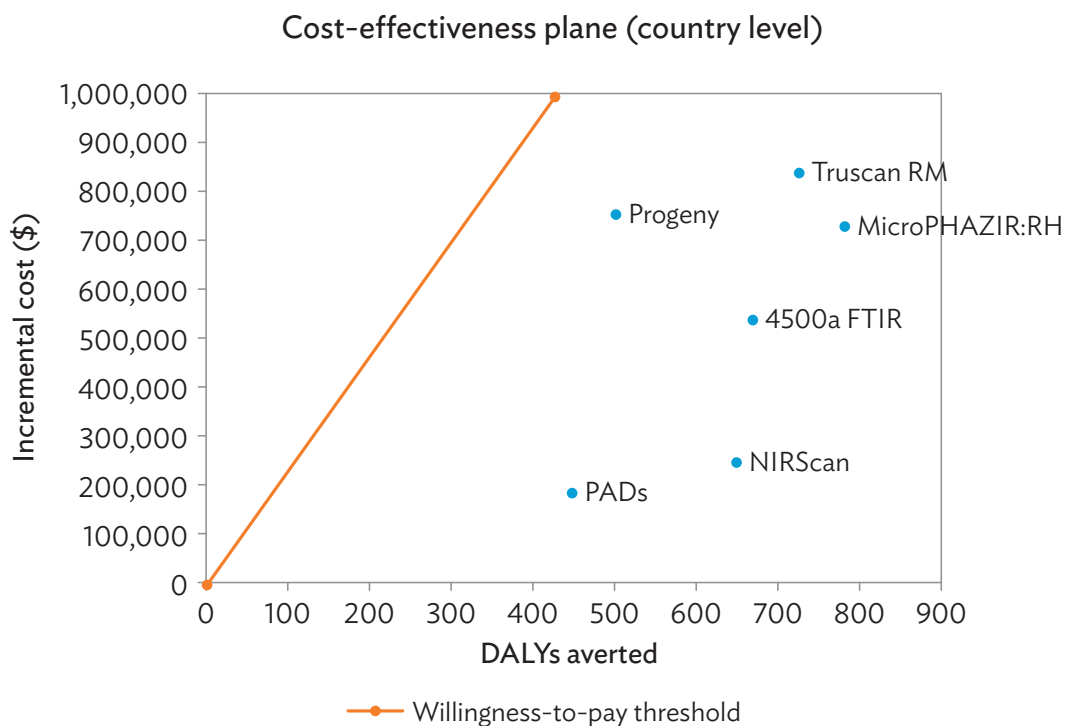
* Device was able to identify when some samples had reduced (50% or 80%) API but not with high enough sensitivity.

** The reference library cannot currently be created by the user

*** Estimation by the chemist expert.

Sources: Asian Development Bank. 2018. Results for Malaria Elimination and Control of Communicable Disease Threats in Asia and the Pacific. Consultant's report. Manila (RETA 8763); and Vickers, S., et al. 2018. Field Detection Devices for Screening the Quality of Medicines: A Systematic Review. *BMJ Global Health*. 3 (4).

Figure: Incremental Costs and Effects of Inspection with Portable Screening Devices Compared with Visual Inspection



DALYs = disability-adjusted life years; PAD = paper analytic device.

Notes: Scenario based on one device per each of the 42 malaria endemic districts using a one-sample strategy in high prevalence of substandard and falsified medicines (20% substandard and 20% falsified) compared with visual inspection alone. The diagonal line represents the willingness-to-pay threshold at \$2,353, which is the Lao People’s Democratic Republic gross domestic product per capita. Costs at 2017 values.

Source: Asian Development Bank. 2018. Results for Malaria Elimination and Control of Communicable Disease Threats in Asia and the Pacific. Consultant’s report. Manila (RETA 8763).

The incremental cost and disability-adjusted life years (DALYs) averted were measured when implementing each of these devices in the field (Figure).¹³ All six devices were found to be cost-effective in a scenario of high prevalence of SF medicines in the supply chain, compared to screening by visual inspection alone. In this scenario, the NIRscan was the most cost-effective option among the six devices as indicated by the greatest net monetary benefit, followed by MicroPHAZIR RX, 4500a FTIR, PADs, Truscan RM, and Progeny. However, these findings depended on the number of samples taken and tested for each product. In a scenario of lower prevalence of SF medicines, only four devices remained cost-effective, with the NIRscan again being the most cost-effective device followed by PADs, 4500a FTIR, and MicroPHAZIR RX.

While these findings are preliminary and very context-specific (i.e., they would have to be recalculated for each country’s current situation), it is clear that the use of most of the devices is cost-effective on a national level in terms of averting morbidity and mortality due to having less SF medicines in the supply chain, provided that they are used regularly and action is taken on their results. The analysis is considered conservative since it only considered the benefit of detecting SF ACTs, and additional benefits would accrue from detecting poor quality medicines from other pharmacological classes and disease areas.

While the devices are cost-effective from a public health perspective, this does not necessarily mean they are affordable to NRAs. While some are relatively low cost to purchase, the

¹³ Cost-effectiveness analysis parameters: one screening device per each of 42 districts compared to visual inspections alone, from a health system perspective with the benefit of removing poor quality medicines measured in disability-adjusted life years (DALYs) averted. Cost-effectiveness/willingness-to-pay threshold was based on the Lao PDR gross domestic product per capita. Assumptions included 10 pharmacies per district that would stock three ACT brands on average with 86 malaria cases per facility and five district NRA inspectors conducting two inspections per pharmacy per year with suspect samples being withdrawn and replaced by genuine products for one month until return to baseline conditions again. Costs based on 2017 values.

lowest cost being PADs (purchase price \$3 each; single use, excluding recurrent costs) and the NIRscan (\$1,200 + \$200 smartphone), both purchase and recurrent costs of the devices need to be part of any operational plan to ensure that adequate funding will be available for them to be fully utilized during their lifetime.

LESSONS LEARNED

Portable devices screening of suspected poor quality antimalarial and antimicrobial medicines is likely to be cost-effective at the country level and holds promise to improve the efficiency and capacity of NRAs in post-marketing activities. However, low-resource NRAs would need support to purchase the devices and cover running costs. While all devices tested could accurately detect falsified medicines, there was no single device that was able to detect both SF medicines in the field. While these devices could be used to support NRA post-marketing inspections, more work is required to independently assess variability, the range of medicines that can be detected, and the effects of packaging and excipients on device performance. A dialogue is needed between regulators and developers to make the devices more practicable, and solutions need to be found for the development of spectral libraries, particularly of pharmaceuticals marketed within a region in order to reduce duplication of efforts by NRAs.

NEXT STEPS

This collaboration provided basic evidence to help NRAs and technical partners determine the optimum use of portable medicine quality screening devices to suit their particular needs and situation. Together, they could develop post-marketing surveillance and screening plans, which could be used to approach funding partners and collaborate with operational research centers.

Stakeholder Engagement

A forum to bring together technical assistance partners, device developers and regulators is needed to ensure that the equipment being produced is tailored for the use of regulators in lower-resource countries. NRAs have specific needs and concerns

(e.g., chain of custody), and these must be considered to achieve the potential of these devices. Such a forum could also work at setting standards, for example, so that spectral libraries or other data could be transferred between different devices.

Independent Testing

More independent testing of devices is needed to describe their variability, accuracy over a wider range of APIs, and usability. The United States Pharmacopeial Convention (USP) has established a Technology Review Program led by an expert panel, which recently published a review of a mini Raman spectrometer for medicine quality screening.¹⁴ This may need to be supplemented with separate independent assessments directed at specific features or target compounds. Although this is operational research, development partners should support such assessments and ensure that potential low- and middle-income countries that could benefit from the findings are included in the research.

Policy Advice

WHO, together with experts and national regulators should develop policy guidance and model regulations in order to assist NRAs to meaningfully implement medicine quality screening. This would include determining an optimal screening strategy, device selection criteria, training requirements, standard procedures in the field, and advice on amending legislation to allow for prompt and appropriate regulatory action on the identification of suspected SF products. This should also be supported by donors like the the Global Fund to Fight AIDS, Tuberculosis and Malaria, to ensure the sustainability and quality assurance of malaria medicines after The Global Fund financing phases out in countries.

Regional Center of Excellence

As the number and use of these devices grows, there will be an increasing need for a regional center of excellence which can independently advise NRAs on the use of particular devices and further investigate their relative cost-effectiveness, and support them in the production of spectral libraries or, ideally, produce and distribute spectral libraries within the region in order to reduce the burden on NRAs.

¹⁴ U.S. Pharmacopeia. 2017. USP Technology Review: ID Raman Mini. Maryland: The Technology Review Program.

Table 2: Portable Screening Devices Included in This Study

Device Name	Manufacturer or Institution	Market Status	Main Technological Specification	Handheld	Purchase Cost ^a
4500a FTIR	Agilent	M	FTIR-MIR λ : 4000 cm^{-1} –650 cm^{-1}	N	\$31,000
CD3+	US FDA	D	IR and Vis Camera system with various LED sources	Y	–
Counterfeit Drug Indicator (CoDI) ^c	Centers for Disease Control and Prevention, United States	D	Laser absorption/ Fluorescence	Y	–
C-Vue	C-Vue	M ^a	Liquid chromatography	N	\$6,500
Minilab	Global Pharma Health Fund	M	TLC, colorimetry, disintegration test ^b	N	\$2,510
MicroPHAZIR RX analyzer	Thermo Scientific	M	FTIR-NIR λ : 1600 nm–2400 nm	Y	\$47,500 ^c
Neospectra 2.5	Si-Ware	M	FTIR-NIR λ : 1350 nm–2500 nm	N	\$6,000 ^c
NIRscan	Young Green Energy	M ^d	NIR - Dispersive λ : 900 nm–1700 nm	Y	\$1,200
Paper Analytical Device (PAD)	University of Notre-Dame and Veripad	D	Paper-based color test	Y (S)	\$3
PharmaChk	Boston University	D	Microfluidic device with luminescence detection	N	–
Progeny	Rigaku	M	Raman λ : 1064 nm laser	Y	\$61,500 ^c
TruScan RM	Thermo Scientific	M	Raman λ : 785 nm laser	Y	\$62,500 ^c
Rapid diagnostic test	China Agricultural University of Beijing and University of Pennsylvania	D	Lateral flow immunoassay dipsticks	Y (S)	\$2–\$3
Single-quadrupole Qda MS ^e	Waters	M	Mass spectrometry	N	\$76,000

λ = wavelength; – = no information available; cm = centimeter; D = under development; FTIR = Fourier Transform Infrared; HPLC = high performance liquid chromatography; LED = light-emitting diode; M = marketed; MS = mass spectrometry; MIR = mid-infrared; N = no; nm = nanometer; NIR = near infrared; S = single-use device; TLC = thin-layer chromatography; US FDA = US Food and Drug Administration; Y = yes.

^a Guide purchase cost excluding value-added tax, shipping, bulk discount, maintenance, consumables, add-ons.

^b Only TLC was used in this assessment (both qualitative and semi-quantitative analysis).

^c Cost may vary based on location. Ordering several devices to the manufacturer is subject to potential reduced purchase cost.

^d The device is available for purchase but has been only used as an educational tool. The near-infrared sampling unit is marketed but the smartphone application is not.

^e Technical and intellectual property issues resulted in the CoDI and Qda MS not being fully assessed.

Note: ADB recognizes “China” as the People’s Republic of China.

Source: Asian Development Bank. 2018. Results for Malaria Elimination and Control of Communicable Disease Threats in Asia and the Pacific. Consultant’s report. Manila (RETA 8763); and Vickers, S., et al. 2018. Field Detection Devices for Screening the Quality of Medicines: A Systematic Review. *BMJ Global Health*. 3 (4).

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