VOLUME 00 NO 00

Editorial

Editorial: Medicines pricing, access and safety in Morocco

Chloe Tuck[1], Abdellatif Maamri[2], Amy Hai Yan Chan[1,3] and Zaheer-Ud-Din Babar[4]

1 *Commonwealth Pharmacists' Association, London, UK*
2 *Université Mohammed Premier Oujda, Oujda, Morocco*
3 *University College London School of Pharmacy, London, UK*
4 *University of Huddersfield, HD1 3DH, UK*

Summary Unregulated supply of medicines compromises quality assurance and risks patient safety. The emergence of illegal medicines trafficking in Morocco presents a major health threat, which highlights the need for region-wide alignment in policies to drive stringent regulatory enforcement and robust health systems that ensure population- wide access to safe medicines. Herein, we draw on insights from a situational analysis in Morocco, as a lower- middle income setting, to present access to medicines through regulated supply procedures as a vital prerequisite for quality assurance and patient safety.

keywords medicines safety, quality assurance, medicines pricing, Morocco, falsified and substandard medicines, universal healthcare coverage, health systems, North Africa

Introduction

Falsified medicines are those intentionally developed to be fraudulent and misrepresent their identity, composition or source, whereas substandard medicines (also called "out of specification") are authorised medical products that fail to meet either their quality standards or specifications, or both. This includes those containing insufficient amounts of active ingredient, either through poor manufacturing processes or issues with storage leading to drug degradation [1, 2]. It is estimated by WHO that 1 in 10 medicines in low and middle income countries are either falsified or substandard [1]. In some instances, prevalence may be as high as 88% of cases, such as was reported in a post-marketing surveillance study in Malawi [3] . The full extent of this issue is unknown, but it is estimated that the cost burden of illegal medical drugs trade is greater than illegal recreational drugs [4]. Falsified and substandard medicines not only impede health outcomes, but can also lead to adverse effects. They impose additional out-of-pocket costs to patients. Moreover, substandard antimicrobials contribute to antimicrobial resistance – one of the greatest health challenges facing this century – by exposing microbes to subtherapeutic antimicrobial levels [1, 5–7].

Although the issue of falsified and substandard medicines exists in all social economic settings, low and middle income countries are affected disproportionately. This greater burden can largely be attributed to a lack of robust health systems providing affordable quality assured medicines and governance to ensure medicines regulations are enforced [8].

Medicines pricing, quality and safety in Morocco

Providing universal healthcare coverage (UHC), which aligns to the United Nations Sustainable Development Goal 3 (SDG 3), is at the core of Morocco's 2011 constitutional reforms, and the WHO strategic plan for Morocco [9–11]. Fundamental to this is providing medicines that are both safe and quality assured.

To this end, Morocco was the first country in the Middle East and North African region to sign the Council of Europe Convention on the counterfeiting of medical products (MediCrime) in 2012 [12, 13]. Counterfeit medicines refers to those copied without the author's permission, which may be falsified or hazardous to health [14]. Morocco has also played a leading role in advocating for a cooperative approach to counteract falsified medicines, and this was a major theme at the 2nd National Conference of Medicine and Health Products in Skhirat in February 2018, which led to the *Rabat Resolution* to fight against falsified medicines in Africa [15], with bilateral agreements being made between Morocco and Benin, Cape Verde, Burkina Faso and The Central African Republic [16, 17].

However, concerns over medicines quality are growing in Morocco, particularly due to reports of substandard/falsified drugs, which have recently received media attention [18, 19]. Morocco's quality control and pharmacovigilance procedures meet WHO guidelines [20, 21] and from 2012 to 2016, strengthening national health information reporting systems was a priority of the health ministry [10]. Morocco's pharmacovigilance is centralised in Rabat, covering all 12 regions in the country [22, 23]. However, there are limitations to its pharmacovigilance abilities due to under-reporting by health professionals and incomplete information [24]. A collaboration between the Global Fund and Moroccan Tuberculosis Control Program has looked to strengthen adverse event reporting, in particular to improve Tuberculous treatment outcomes [25, 26]. However, for regulatory quality control and supply procedures to be effective at ensuring patient safety, medicines need to be accessed only through governed supply routes. In Morocco, concerns over falsified and substandard medicines have been caused by increasing unregulated medicines use through informal networks. Trafficked medicines that lack quality assurance are being offered at lower prices in souks and markets [27, 28].

In the North-Eastern city of Oujda, situated at the Algerian border, medicines are easily available at souks at prices reported to be typically four times cheaper than in regulated pharmacy stores. During field observations at a Souk in Oujda, several stands stocking common over-the-counter and prescription medicines including antibiotics have been found. These are suspected to have come from Algeria and have been trafficked over the country borders.

In such settings, optimal medicines storage conditions are not regarded and cannot be followed. Many medicines are often out-of-date, posing further risk of degradation. As these medicines provide no quality assurance, either through barcode tracking or quality checks, the risk of infiltration of falsified medicines, or reduced quality due to inappropriate storage and transport, is high [27].

This illegal trade puts patients' health and safety at risk, yet local reports suggest it is flourishing in response to patient demand, as otherwise patients simply cannot afford medicines. Although the government health reforms focus on providing healthcare to all citizens, the high proportion of out-of-pocket costs is a major challenge [10].

In Morocco, medicines supplied through the public sector, such as through primary healthcare centres, can be obtained freely [29]. However, reports suggest availability through the public sector is poor. In a survey of 20 public health facilities, 35% (12/34) medicines surveyed were not available in any of the facilities. These included several on the Moroccan essential medicines list [29].

Sources have suggested medicines mismanagement, leading to significant losses, as well as delays in setting up contracts to provide medical services and staffing [30], lasting several years, impede the cost-efficiency of the health services. Such supply chain issues can contribute to low medicines availability in the public sector [31].

Indeed, 58% of healthcare financing was estimated to be out-of-pocket in 2013 [10]. Prices of medicines in Morocco are notably high when compared to other countries. Medicines purchased in the private sector have been found to be a median of 11 and 12 times higher than international reference prices for generic or originator products, respectively, with some as high as 215-fold [29, 32]. The cost of typical medicines for prevalent non-communicable diseases is substantial when considered in respect to living costs. For example, the cost for one month's treatment with the lowest priced generic of atenolol to treat hypertension was estimated to cost almost 5-days' wages in 2008, with originator brands for some treatments costing nearly 8 days' wages [29]. Sources in 2018 suggest that an average consultation and prescription could account to one-third of a typical income.

There are several factors that may contribute to the high costs of medicines in Morocco. Firstly, medicines prices include value added tax (VAT) of 7%, as well as up to 40% custom duties on imported medicines, or on the imported raw materials for medicines made locally [29]. For example, 16 × 1 g doses of the antibiotic amoxicillin (equivalent to roughly a 10 day course at usual dosing) costs 168Dh (15€ in July 2018), with 7% VAT. Secondly, the Moroccan pharmaceutical industry, although the second largest in Africa, with several large scale investments in recent years [10], is dominated by a few companies. Such monopoly counteracts the healthy business competition required to drive down prices. Moreover, for many medicines, there is no generic available in the private sector, despite being common in other markets [29]. High costs, and the requirement to pay upfront in cash, have been indicated to be major barriers that render medicines unaffordable.

Lack of access to affordable medicines, drives patients to seek medicines through unregulated informal routes, which are not subjected to regulatory procedures, and where quality cannot be assured. When seeking medicines, patient behaviour is limited by their ability to pay. Therefore, when costs through their regulated formal health system are a barrier, the public will likely be driven to acquire medicines through informal routes. In such

cases, they may or may not be aware of the risks they are subjecting themselves to.

Conversely, in Algeria, where health sector spending per capita has increased significantly above other countries in the Eastern Mediterranean Region from 2000 to 2015 [33], medicines are increasingly accessible [34]. This has meant trafficking and re-sale to feed medicine demand in neighbouring Morocco is a lucrative industry. Trafficking continues to occur despite multiple attempts to control this by police enforcement at markets and at borders. Thus, whilst high demand for low price medicines continues, efforts by authorities alone will likely have limited impact on overcoming the issue. Traffickers will seek and obtain routes to circumnavigate authorities' control attempts and feed patient demand. Similarly, patient education on the risks of medicines purchases through informal supply routes is also unlikely to be sufficient to tackle the issue when demand remains high.

To this end, a re-evaluation of medicines pricing and healthcare financing models is imperative and required in tandem with stringent regulatory processes, to assure medicines safety in Morocco. Financing and pricing strategies that ensure population-wide access are also crucial to assure adherence to regulations, and thus medicines quality. Morocco's health sector strategy outlines the need to foster strong governance and collaborations with the pharmaceutical sector, factors which are key for defining an affordable pricing model to facilitate universal access. Recently, the need to decrease medicine prices has been brought to light, with government schemes to reduce out-of-pocket costs of some vital medicines [35].

Increasing medicines affordability can be achieved by multiple approaches. Lowering or exemption from VAT is one approach suggested by WHO [36], as taxation is a key access barrier and is higher in low and middle income countries. Given prices in Morocco have been found to be substantially higher than international reference prices, benchmarking prices against other countries is an approach that could be beneficial. Incorporating health technology assessment models, and regulation of supply chain mark-up (currently retail and wholesale mark-up are set at 30% and 10%, respectively) [29], should also be considered. However, there is no universal pricing model solution and an effective pricing model should most likely incorporate several strategies, considering the local context and ensure process transparency [36].

Conclusion

There is increasing global recognition of the threat that falsified and substandard medicines pose to patient safety and health outcomes. This paper, discusses insights from field observations in Morocco which demonstrate that medicines governance and financing policy are required in tandem to ensure patients access medicines exclusively through regulated supply routes, where quality is assured. In Morocco as well as in other settings, tackling falsified and substandard medicines first requires patients being able to access and afford medicines through formal routes, where supply can be governed, and medicines quality monitored. Acknowledging this is vital to ensure patient safety and for achievement of optimal health outcomes.

References

1. Nayyar GML, Breman JG, Herrington JE. The global pandemic of falsified medicines: laboratory and field innovations and policy perspectives. *Am J Trop Med Hyg* 2015: **92** (Suppl 6): 2–7.
2. WHO Definitions of Substandard and Falsified (SF) Medical Products [Internet]. WHO. (Available from: http://www.who.int/medicines/regulation/ssffc/definitions/en/) [23 Jul 2018]
3. Chikowe I, Osei-Safo D, Harrison JJ, Konadu DY, Addae-Mensah I. Post-marketing surveillance of anti-malarial medicines used in Malawi. *Malar J* 2015: **14**: 127.
4. Ensuring the Safety and Integrity of the World's Drug, Vaccine, and Medicines Supply [Internet]. Council on Foreign Relations. (Available from: https://www.cfr.org/report/ensuring-safety-and-integrity-worlds-drug-vaccine-and-medicines-supply) [24 Jun 2018]
5. Substandard and falsified medical products [Internet]. World Health Organization. (Available from: http://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products) [19 May 2018]
6. Kyriacos S, Mroueh M, Chahine RP, Khouzam O. Quality of amoxicillin formulations in some Arab countries. *J Clin Pharm Ther* 2008: **33**: 375–379.
7. Johnston A, Holt DW. Substandard drugs: a potential crisis for public health. *Br J Clin Pharmacol* 2014: **78**: 218–243.
8. World Health Organization. *Effective Medicines Regulation: Ensuring Safety, Efficacy and Quality*. Geneva: World Health Organization; 2003. Available: http://apps.who.int/iris/bitstream/handle/10665/68391/WHO_EDM_2003.2.pdf;jsessionid=14DDE7298832F997868D142EC2A23817?sequence=1
9. Organisation mondiale de la Santé. Stratégie de coopération OMS-MAROC 2017-2021. Bureau régional de la Méditerranée orientale; 2016.
10. World Health Organization. Regional Office for the Eastern Mediterranean. Morocco health profile 2015. Regional Office for the Eastern Mediterranean; 2016.
11. Sustainable development goals – United Nations [Internet]. United Nations Sustainable Development. (Available from: http://www.un.org/sustainabledevelopment/sustainable-development-goals/) [22 Mar 2018].
12. Council of Europe. Morocco profile [Internet]. Office of the Directorate General of Programmes. (Available from: https://www.coe.int/en/web/programmes/morocco) [5 Aug 2018]

13. Council of Europe. Chart of signatures and ratifications of Treaty 211: Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health [Internet]. Council of Europe. (Available from: https://www.coe.int/en/web/conventions/full-list) [5 Aug 2018]
14. The Institute of Research Against Counterfeit Medicines (IRACM). Definition of drug falsification [Internet]. (Available from: https://www.iracm.com/en/fake-drugs/definition/) [25 Nov 2018]
15. Doukkali A. Discours de Monsieur le Ministre de la Sante. In Rabat- Skhirate; 2018.
16. Médicaments contrefaits: La lutte s'organise [Internet]. L'Economiste; 2018. (Available from: https://www.leconomiste.com/article/1024539-medicaments-contrefaits-la-lutte-s-organise) [5 Aug 2018].
17. The Institute of Research Against Counterfeit Medicines (IRACM). Africa: African countries sign resolution against falsified medicines in Rabat – [Internet]. (Available from: https://www.iracm.com/en/2018/03/africa-african-countries-sign-resolution-falsified-medicines-rabat/) [5 Aug 2018]
18. Counterfeit Medicines Cause 15,000 Poison Cases in Morocco Annually [Internet]. Morocco World News; 2018. (Available from: https://www.moroccoworldnews.com/2018/02/241278/counterfeit-medicines-cause-15000-poison-cases-morocco-annually/) [13 Jun 2018]
19. Dangerous, counterfeit drugs kill thousands of Moroccan patients] (in Arabic). Alakhbar News. 25 February, 2018. Available online: http://www.alakhbar.press.ma/%D8%AE%D8%B7%D9%8A%D8%B1-%D8%AA%D8%B1%D9%88%D9%8A%D8%AC-%D8%A3%D8%AF%D9%88%D9%8A%D8%A9-%D9%85%D8%BA%D8%B4%D9%88%D8%B4%D8%A9-%D9%88%D9%85%D8%B2%D9%8A%D9%81%D8%A9-%D9%8A%D8%AD%D8%B5%D8%AF-%D8%A3%D8%B1-48409.html
20. Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines regulation in Africa: current state and opportunities. *Pharm Med* 2017: **31**: 383–397.
21. Ampadu HH, Hoekman J, de Bruin ML *et al.* Adverse drug reaction reporting in Africa and a comparison of individual case safety report characteristics between Africa and the rest of the world: analyses of spontaneous reports in VigiBase®. *Drug Saf* 2016: **39**: 335–345.
22. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS. Specific features of medicines safety and pharmacovigilance in Africa. *Ther Adv Drug Saf*. 2012: **3**: 25–34.
23. Missions – CAPM Platform [Internet]. (Available from: http://www.capm.ma/missions) [27 Jul 2018].
24. Alj L, Touzani MDW, Benkirane R, Edwards IR, Soulaymani R. Detecting medication errors in pharmacovigilance database: capacities and limits. *Int J Risk Saf Med* 2007: **19**: 187–194.
25. Soussi Tanani D, Tebaa A, Benkirane R *et al.* Pharmacovigilance and moroccan tuberculosis public program: current situation. *Tuberc Res Treat* 2014: **2014**: 626797.
26. Tanani DS, Serragui S, Hammi S *et al.* National strategy for the integration of pharmacovigilance in the Moroccan TB Control Program. *Pan Afr Med J* 2017: **26**: 48.
27. The Institute of Research Against Counterfeit Medicines (IRACM). Morocco: The pharmacy is supposed to be the unique place where we can buy medicines… [Internet]; 2013. (Available from: http://www.iracm.com/en/2013/07/morocco-the-pharmacy-is-supposed-to-be-the-unique-place-where-we-can-buy-medicines-but-grocers-souks-ferrachas-are-selling-them-too-with-no-standard-legality/) [13 Jun 2018]
28. The Institute of Research Against Counterfeit Medicines (IRACM). Morocco is not spared from manufacture of illicit drug products [Internet]; 2015. (Available from: https://www.iracm.com/en/2015/02/morocco-is-not-spared-from-the-sale-and-manufacture-of-illicit-drug-products/) [28 Jun 2018]
29. Essential medicines and pharmceutical policy unit, Regional office for the eastern mediterranean. Morocco: medicines prices, availability, affordability and price components [Internet]. World Health Organization; 2008. (Available from: www.haiweb.org/medicinesprices/surveys)
30. [Health unions Ben Ahmed to clarify the reality of the sector and sound the alarm]. (in Arabic). Alakhbar News. 18 November, 2018. Available online: http://www.alakhbar.press.ma/%D9%86%D9%82%D8%A7%D8%A8%D8%A7%D8%AA-%D8%A7%D9%84%D8%B5%D8%AD%D8%A9-%D8%A8%D8%A7%D8%A8%D9%86-%D8%A7%D8%AD%D9%85%D8%AF-%D8%AA%D8%B9%D8%B1%D9%8A-%D9%88%D8%A7%D9%82%D8%B9-%D8%A7%D9%84%D9%82%D8%B7%D8%A7-63220.html
31. Seidman G, Atun R. Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceuticals, vaccines or health products? A systematic review of evidence from low-income and middle-income countries. *BMJ Glob Health* 2017: **2**(2): e000243.
32. Srivastava D, McGuire A. Analysis of prices paid by low-income countries - how price sensitive is government demand for medicines? *BMC Public Health* 2014: **14**: 767.
33. World Health Organization. Algeria: WHO statistical profile [Internet]. World Health Organization; 2015. (Available from: http://www.who.int/gho/countries/dza.pdf?ua=1)
34. World Health Organization. Stratégie de coopération entre l'OMS et l'Algérie. World Health Organization; 2018.
35. Morocco Slashes Drug Prices of Chronic Diseases [Internet]. Morocco World News; 2018. (Available from: https://www.moroccoworldnews.com/2018/03/243439/morocco-slashes-drug-prices-chronic-diseases/) [22 Jul 2018]
36. WHO Guideline on Country Pharmaceutical Pricing Policies [Internet]. (Available from: http://apps.who.int/medicinedocs/en/d/Js21016en/) [20 Jul 2018].

Corresponding Author **Chloe Tuck**, Commonwealth Pharmacists' Association, 66-68 East Smithfield, London, E1W 1AW, UK. Tel.: +44 7402110248; E-mail chloeztuck@gmail.com