

LETTER

Time to Invest in Medicines Resilience

Ravina Barrett

University of Brighton, GB

R.Barrett2@brighton.ac.uk

Keywords: counterfeit drugs; drug-related side effects and adverse reactions; falsified medicines; Falsified Medicines Directive (Directive 2011/62/EC); pharmacists; public health; pharmacy; medicine quality; procurement; substandard medicine

The Falsified Medicines Directive (FMD 2011/62/EC) (European Commission 2011) is designed to eliminate counterfeit medication and limit potential risk of harm to the public. We know that the world has changed since this directive was conceived. While enshrined in law (Moore 2019), we risk not being able to deliver on this directive (Barrett & Al-Mousawi 2018; Barrett 2020). The UK leaves the Europe Union on the 31st of December 2020, with it access to the 'national verification system' whereby dispensed medicines get verified against a European central database for their authenticity is lost.

This makes the UK a target for flow of falsified medicines into its domestic market and as a route into Europe. Nobody wants this, except the spurious agents involved in the business of providing substandard medication. The UK also provides globally admired universal care and is responsible for securing and supplying medicines to patients via the NHS. Medicine costs have been rising (Acosta et al. 2019; Batista et al. 2019; European Medicines Agency 2018; Hughes 2019; Miljković et al. 2019) and can be linked to currency fluctuations and policy (Ewbank 2018; Kanavos et al. 2011; Kanavos et al. 2020). The concern is that there will be potential trade wars and with them, further volatility (e.g., currency, geopolitics, supply routes, and natural resources) putting medicine access at risk. Globally, we face increasingly difficult choices with concern about patients' access to medicines.

The path to regulatory approval also seems convoluted and expensive for most small-scale manufacturers. Increasingly, there are fewer large manufacturing sites and these are controlled by a few market participants. Looking at strategic, regional, and political pressures is vital when thinking about securing medicine supply across the world. Resources and research need to be dedicated to this area, as its importance is likely to grow.

Competing Interests

The author has no competing interests to declare.

References

- Acosta, A, Vanegas, EP, Rovira, J, Godman, B and Bochenek, T.** 2019. Medicine shortages: Gaps between countries and global perspectives. *Front Pharmacol*, 10: 763. DOI: <https://doi.org/10.3389/fphar.2019.00763>
- Barrett, R.** 2020. Evaluation of community pharmacists' readiness to implement the Falsified Medicines Directive (Directive 2011/62/EC): An English cross-sectional survey with geospatial analysis. *BMJ Open*, 10(1): e033405. DOI: <https://doi.org/10.1136/bmjopen-2019-033405>
- Barrett, R and Al-Mousawi, HA.** 2018. Development and initial validation of a postal survey evaluation of community pharmacists' opinion regarding falsified (counterfeit) medicines in Hampshire (UK). *J Pharm Pharmacogn Res*, 6(4): 242–249.
- Batista, A, Miljković, N, Polidori, P and Kohl, S.** 2019. Medicines shortages. *Eur J Hosp Pharm*, 26(5): 290–291. DOI: <https://doi.org/10.1136/ejhpharm-2019-001911>
- European Commission.** 2011. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified

Medicinal Products Text with EEA Relevance. Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0062> [Last accessed 27 April 2017].

European Medicines Agency. 2018. Shortages catalogue. European Medicines Agency. Available at <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue> [Last accessed 6 August 2020].

Ewbank, L, Omojomolo, D, Sullivan, K and McKenna, H. 2018. The rising cost of medicines to the NHS What's the story?

Hughes, DA. 2019. Medicines Shortages in the United Kingdom. *Clin Pharmacol Ther*, 106(4): 712. DOI: <https://doi.org/10.1002/cpt.1495>

Kanavos, P, Fontrier, A-M, Gill, J and Efthymiadou, O. 2020. Does external reference pricing deliver what it promises? Evidence on its impact at national level. *Eur J Health Econ*, 21(1): 129–151. DOI: <https://doi.org/10.1007/s10198-019-01116-4>

Kanavos, P, Vadoros, S, Irwin, R, et al. 2011. Differences in costs of and access to pharmaceutical products in the EU. Available at <http://www.europarl.europa.eu/activities/committees/studies.do?language=EN>

Miljković, N, Gibbons, N, Batista, A, Fitzpatrick, RW, Underhill, J and Horák, P. 2019. Results of EAHP's 2018 Survey on Medicines Shortages. *Eur J Hosp Pharm Sci Pract*, 26(2): 60–65. DOI: <https://doi.org/10.1136/ejhpharm-2018-001835>

Moore, T. 2019. Falsified Medicines Directive: Safety Features – MHRA Inspectorate. Available at <https://mhrainspectorate.blog.gov.uk/2019/02/08/falsified-medicines-directive-safety-features/> [Last accessed November 28, 2019].

How to cite this article: Barrett, R. 2020. Time to Invest in Medicines Resilience. *Journal of Illicit Economies and Development*, 1(2): pp. 1–2. DOI: <https://doi.org/10.31389/jied.75>

Submitted: 22 October 2020

Accepted: 18 November 2020

Published: XX Month 202X

Copyright: © 2020 The Author(s). This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International License (CC-BY 4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. See <http://creativecommons.org/licenses/by/4.0/>.



Journal of Illicit Economies and Development is a peer-reviewed open access journal published by LSE Press.

OPEN ACCESS