Clinical pharmacology in leishmaniasis: treatment optimization of a neglected disease

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Universal access to quality medicines: prioritisation of *a priori* solutions

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In the June issue of *The Lancet Infectious Diseases*, Michael Seear discusses the extent and consequences of poor pharmaceutical quality [1]. We fully agree that sustainable actions are urgently needed to address the scourge of poor-quality medicines, which disproportionately hits developing countries, where drug regulation is often inadequate or insufficiently enforced - even in middle-income countries [2]. The 20-year-old political controversy about the various non-mutually-exclusive definitions of *counterfeit* and *substandard* continues. However, since the 65th World Health Assembly, which approved a new member-state mechanism proposing international collaboration on so-called “substandard, spurious, falsely-labeled, falsified or counterfeit medical products”, momentum to shift prime considerations from intellectual property rights to public health is building. Seear appropriately points out that, despite the absence of accurate estimates, counterfeits are probably only a small proportion of all the poor-quality medicines worldwide.

These observations should lead to the right choice of remedial measures. For instance, if the bulk of poor-quality medicines are from legitimate manufacturers who occasionally or systematically neglect quality standards (which is often the case in low-income countries), priority should be given to *a priori* actions to prevent the production and distribution of substandard drugs. *A posteriori* detection would spot some bad medicines, but would not address the root problem. Validated field detection methods are useful for research purposes (to estimate the extent and distribution of the problem) and very basic random quality control, but they cannot systematically prevent poor-quality medicines from reaching patients. The role of technology, such as radiofrequency tags, seems limited to tracing and detection of illegal production of counterfeits; effects on so-called “legitimate” substandard medicines are negligible.

Structural investments, supported by a strong political commitment are needed to develop and enforce an efficient regulatory oversight of pharmaceutical products in low-income and middle-income countries. Furthermore, stringent repercussions, such as temporary or definitive withdrawal of manufacturing or import licenses, need to be enforced for manufacturers that do not implement corrective actions to adhere to quality assurance standards. If such actions are not taken, the problem of multiple (and variable) quality standards [3] will not be redressed. In a 2012 Editorial, *The Lancet* provided a stark example of this problem: in India, nine officers staff the national drug regulatory authority headquarters and have to deal with 20 000 new applications per year [4]. As long as regulatory oversight is not equally enforced everywhere, detection technologies can help to monitor the problem but not make any substantial changes to the current *status quo* in which the most vulnerable patients remain exposed to the serious and often fatal consequences of substandard medicines.
References


