Commentary

Poor-quality medicines: from knowledge to control and prevention

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Invited Commentary on 'Mind the gaps – the epidemiology of poor-quality anti-malarials in the malarious world – analysis of the WorldWide Antimalarial Resistance Network database' (Mal J. 2014;13:19) by P. Taberner et al.

The impressive globalization of the pharmaceutical market that characterized the last two decades has led to a situation of multiple standards, where the quality of medicines largely depends on the countries' level of income and regulation.¹ Low-income countries are particularly exposed to poor-quality medicines, including falsified products (manufactured without regulatory approval and with the criminal intent to mislead), sub-standard products (manufactured with regulatory approval but not compliant with appropriate quality specifications) and products degraded due to inappropriate storage/transport conditions.² Poor-quality medicines have serious consequences for individual and public health, i.e. direct toxicity, lack of therapeutic efficacy and emergence of resistances, but their effects are often undetected and still generally underestimated by health staff and policy makers. In the malaria world, conversely, there is a strong awareness that poor-quality medicines may have contributed to the spectacular increase in resistance to antimalarials. In an unprecedented attempt to organize and analyze the available evidence, the WorldWide Antimalarial Resistance Network (WWARN; www.wwarn.org) has established the Antimalarial Quality (AQ) Surveyor. This is the first freely available global repository compiling the existing quality reports, which were scattered across regulators' websites, policy documents, peer-reviewed medical journals and lay press.

Taberner et al. recently published in the *Malaria Journal* an in-depth analysis of this

database,³ showing that 30.1% of more than 9300 samples tested between 1946 and 2013 failed to pass the quality tests. Their paper also revealed significant gaps in the existing reports. First, no data are available for 60% of the endemic countries. Second, the sampling methodologies are often inaccurate (many studies do not even state the number of samples collected, and randomization is very rare). Third, the tests and analytical techniques were often not adequate or insufficient for a complete quality assessment, e.g. the important but relatively expensive dissolution test is not included in most studies.

Despite the gaps in the source data, the WWARN findings surely constitute an alarming confirmation of the widespread presence of poor-quality antimalarials in endemic countries. They also show that there is an urgent need to develop more accurate and standardized methods for mapping their distribution and characteristics. The knowledge generated by well-designed surveys will in turn inform national regulators for identifying and correcting the vulnerabilities of the pharmaceutical supply chain.

Noteworthy, the AQ surveyor currently includes data on medicines only, but it could be interesting to broaden its scope to rapid diagnostic tests, since poor-quality tests⁴ may also cause avoidable morbidity and increase resistance rates, due to under or over diagnosis.

To our knowledge the AQ Surveyor is still a unique initiative. However, poor-quality medicines are not limited to the malaria field, and also apparently 'simple' products (e.g. anti-cough or antifebrile syrups) have caused a heavy toll of suffering and deaths in recent years due to poor-quality formulations.⁵ It is therefore hoped that this model may be replicated for other essential medicines, especially for all those for which purchasers cannot count on the guidance of the WHO pre-qualification program (<http://apps.who.int/prequal/default.htm>) for selecting and procuring quality-assured products.

References

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