

For potential side effects, read the patient information leaflet!

Advocating for quality-assured medicines

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Dit is de omschrijving



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Imagine falling ill with a bacterial infection for which the doctor prescribes antibiotics. You buy the medicine in the pharmacy, start taking it, and in about a week you feel better again. Now imagine you live in Kinshasa, Democratic Republic of the Congo. You get the same prescription, go to the pharmacy, take your meds... But you don't recover. The doctor accuses you of not taking the antibiotics correctly or of selling pills to someone else. You did neither – unbeknownst to you, what you have swallowed were poor-quality medicines, with insufficient active ingredients.

“Such is a common scenario in many low- and middle-income countries [LMICs],” says Dr Raffaella Ravinetto, a pharmaceutical expert at ITM. “According to the latest estimates of the World Health Organization [WHO], on average 10.5% of medicines are of poor-quality in LMICs, and in some countries the number can be much higher. For instance, a study conducted with ITM researchers in the Kinshasa area found a staggering 27%. In other words: patients living in these parts of the world may have a one in three chance of getting a medicine which will be at best ineffective, at worst, cause even greater harm, or even death.”

So what allows for such a prevalence of poor-quality medicines? On the one hand, the national regulatory bodies in LMICs often lack the resources to properly check the quality of medicines that are imported, manufactured, or distributed in their country. Secondly, the international pharmaceutical market – similarly to other markets – has become increasingly complicated and globalised in the past decades, which poses serious challenges for tracking the supply chains of medicines.

After a long period of neglect, these global developments have increasingly raised concerns for many actors in the humanitarian, development and health sectors. Some donors of humanitarian and development programmes want to ensure that funds are not used for purchasing substandard medicines that could be detrimental to people’s health. These donors, like the Global Fund, ECHO (the European Commission’s Humanitarian Aid directorate), or the Belgian Development Cooperation and others developed their own policies to ensure that medicines used with their funds were quality assured. Sadly, in reality, there is not always a mechanism in place to do that beyond medicines for HIV, malaria and tuberculosis. The cause of quality-assured medicines has been gaining political momentum in Belgium and beyond. In 2017, as a result of joint efforts by the Belgian Development Cooperation, ITM and various Belgian implementers such as Memisa and the Damien Foundation, Belgium became the first country in the world to officially make a commitment to adopt a stringent pharmaceutical quality assurance policy. Catherine Dujardin, Global Health Officer at the Belgian Development Cooperation: “Belgium has committed to purchase good-quality medicines in humanitarian and development programmes. The commitment was drafted together with Belgian implementers and ITM who provided significant input to make the document concrete and compliant with what already exists on the global level. We hope other countries will follow suit.”



ITM and the Belgian Development Cooperation have devoted themselves to prioritising universal access to quality-assured medicines over a decade ago. The QUAMED network was launched by ITM with Belgian Development Cooperation support in 2010 to improve the quality of medicines in LMICs via a network of non-profit organisations and national procurement agencies that supply medicines in or for these countries. QUAMED, now an independent entity, organises missions for humanitarian and development agencies to audit manufacturers and distributors according to international standards as well as running trainings on medicine quality issues. In addition, QUAMED closely cooperates with ITM for research, advocacy, and policy development.

Daniel Berman, board member of QUAMED explains their working mechanism with an example: “In Bangladesh where there are extensive humanitarian programmes, NGO partners of QUAMED ask to help with deciding which medicines to buy. QUAMED sends in experts to examine the local market including producers and procurement centres and by means of a very rigorous process, grades them, so NGOs know which drugs are safe to purchase. There is no black and white answer, but we provide the best possible information and assessment based on the standards of the WHO.” Berman envisions, in the long term, a type of ‘seal of approval’ system, which could steer the business to buying medicines from the best producers. A universal certification system could be of interest to manufacturers and procurement centres and could positively shape the market.

Others share his sentiment in the humanitarian and development world. Various organisations such as Médecins Sans Frontières (MSF), ECHO, or the US Pharmacopoeias (USP) developed their own assessment systems, but a global one is lacking. In 2001, the Prequalification of Medicines Programme (PQP) was initiated at WHO to facilitate access to medicines that meet unified international standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. Dr Deus Mubangizi, the head of the PQP team welcomes the idea to expand the scope of prequalification: “At this moment only 26% of the 194 UN-member countries have the capacity to enforce adequate quality assurance systems for pharmaceuticals. We work to strengthen these regulatory systems but we also need an international, harmonised quality assurance system, which can facilitate free movement of products for emergencies and also for routine use. Especially in global emergencies the different systems may become a barrier.”

What is the most pressing issue today? According to Dr Ravinotto, poor-quality medicines not only represent a threat for individual and public health by causing therapeutic failure, including deaths, or direct toxicity, but they contribute to the emergence of resistance, and erode trust in health systems. “It’s proven by now that poor-quality antimalarials have contributed to the resistance to malaria-drugs. If we don’t act fast, the global effect of the poor-quality antibiotics can be colossal.”

To further advocate for quality-assured medicines, ITM has joined the global #MedsWeCanTrust campaign to raise awareness of the scope and impact of the problem and inspire collective worldwide action.

WHAT’S IN A NAME? FALSIFIED, SUBSTANDARD OR POOR-QUALITY MEDICINES

The turn of the century saw some highly publicised cases such as the contaminated cough syrup in Panama that caused hundreds of deaths, or the many cases of under-dosed malaria medicines detected in many low-income settings. In the first case we are talking about falsification – industrial diethylene glycol was put in the syrup instead of glycerine, whether on purpose or by negligence. In the second case, these were substandard products: bad manufacturing practices were the probable cause, but bad storage practices were also perhaps a factor. The term ‘falsified medicines’ implies criminal activity, where manufacturers or distributors have falsified a product on purpose. Repressive measures may help fight these kinds of ‘medicines’, but they will do little to stop the circulation of ‘substandard medicines’. Substandard medicines are of poor-quality despite being produced by licensed manufacturers and approved by the national regulators. Fighting them requires sustained capacity strengthening of national regulators, improved surveillance on international supply chains, and increased awareness of purchasers including international donors. Substandard implies that the medicine was ‘part of the system’, yet it caused therapeutic failure or toxicity. The failure may be due to a great variety of factors, such as insufficient amount of active ingredient, presence of unwanted impurities, lack of sterility, or inadequate ways of storage or transport. In our text falsified and substandard medicines are brought together under the wording ‘poor quality’.