

Investment is key to tacking the ongoing threat of fake medicines

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From Vienna to the Democratic Republic of Congo, fake medicines have threatened citizens across the board – and borders – in wartime as well as peacetime.

Falsified medicines have sadly probably been with us since the first manufacture of medicines and their producers may be the world's third oldest profession after prostitution and spying. Last year falsified ampicillin was discovered circulating in the Democratic Republic of the Congo, in bottles of 1,000 capsules and containing no detectable ampicillin.

The post Second World War trade of fake <u>penicillin</u> inspired The Third Man, a fascinating film written by Graham Greene and set in Vienna. Many of the characters, including the protagonist, fake penicillin smuggler Harry Lime, were inspired by real spies and criminals who used penicillin – both falsified and genuine – to bribe, lure and get rich in the chaos of post-war Germany and Austria. Greene later turned the script into a novel.

Unfortunately, the problem is not yet consigned to history. There are probably thousands of Third Men hidden in today's world, for example, a Parisian who 'manufactured' falsified antimalarials containing laxatives, international trade in falsified medicines especially from Asia into Africa, and emergency contraceptives containing antimalarials in South America.



But falsification is not the only problem. There are also severe issues with substandard medicines, poor quality medicines produced due to negligence, sometimes gross, in the manufacturing processes, but not deliberately to defraud patients and health systems. Their consequences are also very harmful; they are likely to be under-recognised drivers of antimicrobial resistance, as they often contain less than the stated amount of active ingredient.

For both falsified and substandard medicines objective prevalence data are few and poor quality, as there has been remarkably little research or surveillance. The data are insufficient to reliably estimate the extent of the problem. Much more investment is needed to understand the epidemiology of poor quality medicines and guide interventions.

Considered a 'miracle' medicine, penicillin was highly effective to treat gonorrhoea and syphilis, common venereal diseases among soldiers. During the Second World War and shortly after, the drug supply was controlled by the authorities and primarily reserved for the Army, but as often happens with prohibitions, the illegal trade flourished.

Penicillin was so scarce but so sought after, as an innovative cure of many important bacterial infections, that it became a currency in postwar Europe.

The drug was also at the centre of Operation Claptrap, conducted by US Major Peter Chambers in the first years of the Cold War in Vienna. He offered genuine penicillin to Russian soldiers, in exchange for secrets and defection. It was an attractive offer, as venereal diseases were a court-martial offence in the Red Army.

Austria and France cooperated in 1946 to manufacture penicillin in the Alps to facilitate availability. In 1951, they developed the first oral version of the drug, as Penicillin V. The V referred to vertraulich, the



German word for confidential.

In the 21st century, government action remains key to fighting both falsified and substandard medicines. Although there has been an enormous increase in global pharmaceutical manufacturing, there has been a grossly inadequate parallel investment in support for national medicine regulatory authorities (MRAs) in many countries. A key intervention to protect the drug supply in Low- and Middle-Income Countries will be investment in MRAs, the national keystones of medicine regulation.

IDDO works to strengthen knowledge of the scale of the problem of poor quality medicines and the most affected areas, and raise awareness among key stakeholders by sharing global expertise and collating information. The Antimalarial Quality Literature Surveyor, available through the WorldWide Antimalarial Resistance Network (WWARN), is an interactive tool that visualises summaries of published reports of antimalarial medicine quality, displaying their geographical distribution across regions and over time.

The full article, 'Fake Penicillin, The Third Man and Operation Claptrap', can be read in the *BMJ*.

More information: Paul N Newton et al. Fake penicillin, and Operation Claptrap, *BMJ* (2016). DOI: 10.1136/bmj.i6494

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