

Substandard and Falsified Antibiotics Seized in Belgium: quality deficiencies observed in seized PDE-5 Inhibitors, Ivermectin, and Antibiotics

Celine Vanhee

Sciensano, Belgium

Illegal, substandard, and falsified medicines represent a growing public health threat worldwide, and Official Medicines Control Laboratories (OMCLs) play a central role in addressing this challenge. This work outlines the multifaceted contribution of OMCLs to the detection and control of illegal medicinal products. A core activity of OMCLs is the analytical testing of suspected samples submitted by various stakeholders, including law enforcement and customs authorities. Additionally, the Belgian OMCL, in collaboration with the Federal Agency for Medicines and Health Products (FAMHP), has recently launched a series of themed action projects designed to assess the risks associated with the use of illegal medicines, extending beyond the already well-recognized issue of self-medication with prescription drugs.

To date, three such projects have been completed, focusing respectively on PDE-5 inhibitors, ivermectin seized during the COVID-19 pandemic, and illegal antibiotics. The initial study on 32 seized PDE-5 inhibitor samples (2021–2022) revealed that approximately 38% of the samples were chemically non-compliant, and 50% displayed significant microbiological contamination. The ivermectin project, conducted on 23 seized samples, yielded even more concerning results: only 4% of samples met quality requirements, 65% were underdosed, and nearly half exceeded bioburden limits, with some samples contaminated by toxin-producing bacteria. More recently, a 2024–2025 project on seized antibiotics further highlighted the persistent risks posed by illegal medicines circulating outside regulated supply chains: 29% of samples demonstrated dissolution issues, and 43% were non-compliant overall with the quality criteria tested.

These findings have been, and will continue to be, communicated by the FAMHP and the OMCL to the broader public in order to raise awareness of the risks associated with illegal medicines.