Fake medicines: How to spot substandard drugs and protect your patients

Written by The Life Science Feed Editorial Team · Published 24 July 2026 · Edited by William Lopes

The global pharmaceutical supply chain, while vast and complex, harbors a persistent and dangerous threat: counterfeit and substandard medicines. These products, often indistinguishable from legitimate drugs, can contain incorrect ingredients, improper dosages, or no active pharmaceutical ingredient at all, directly jeopardizing patient health and eroding trust in medical treatments.

For European GPs and specialists, understanding the scope of this problem and implementing practical safeguards is not merely good practice; it is essential to patient safety and effective clinical outcomes. The World Health Organization (WHO) estimates that one in ten medical products in low- and middle-income countries is substandard or falsified, a figure that, while lower in highly regulated markets, still represents a tangible risk.

KEY TAKEAWAYS

- The Pivot: The global prevalence of fake or substandard medicines necessitates heightened vigilance from prescribers and pharmacists.
- The Data: Up to 10% of medicines in low- and middle-income countries are substandard or falsified, with varying but present risks in regulated markets.
- The Action: Clinicians should procure medicines only from verified, licensed suppliers and counsel patients on avoiding unverified online pharmacies.

The proliferation of falsified and substandard medical products presents a silent epidemic, undermining public health systems and directly harming patients. These products range from those with no active ingredient, to those with incorrect active ingredients, or those with the correct active ingredient but in the wrong concentration. The consequences are dire: treatment failure, adverse drug reactions, drug resistance (particularly with antibiotics and antimalarials), and even death. The problem is not confined to specific therapeutic areas; it affects everything from life-saving antibiotics and cancer therapies to routine pain relievers and vaccines.

Identifying the exact prevalence of substandard and falsified (SF) medical products is challenging due to their clandestine nature. But the World Health Organization (WHO) has conducted extensive surveillance, estimating that approximately 10% of medical products circulating in low- and middle-income countries are SF. While Europe's highly regulated supply chains offer greater protection, the internet and globalized trade routes mean no region is entirely immune. The European Medicines Agency (EMA) and national regulatory bodies like the UK's Medicines and Healthcare products Regulatory Agency (MHRA) continuously monitor for such threats, but vigilance remains paramount.

Understanding the Threat Landscape

Falsified medicines are deliberately and fraudulently misrepresenting their identity, composition, or source. This includes products with no active ingredient, the wrong active ingredient, or insufficient active ingredient. Substandard medicines, by contrast, are genuine products that fail to meet quality standards or specifications due to manufacturing errors, poor storage, or degradation. Both categories pose significant risks, but the intent behind falsified products makes them a criminal enterprise.

The supply chain vulnerabilities exploited by criminals are numerous. These include unregulated online pharmacies, parallel import schemes, and diversion from legitimate supply chains. The rise of e-commerce has exacerbated the issue, allowing illicit sellers to reach consumers directly, often bypassing any regulatory oversight. Patients, seeking convenience or lower prices, may unknowingly purchase dangerous products from these sources. For clinicians, this means patients may present with treatment failure or unexpected side effects from what they believe are legitimate prescriptions.

Protecting the Supply Chain and Patients

Clinicians play a critical role in mitigating the risks associated with SF medical products. The first line of defense is ensuring that all medicines prescribed and dispensed originate from reputable, licensed suppliers. This means avoiding any procurement channels that fall outside established regulatory frameworks. Pharmacists, in particular, must maintain stringent checks on their inventory, verifying batch numbers and expiry dates, and reporting any suspicious packaging or product anomalies to national regulatory authorities.

But the responsibility extends beyond procurement. Educating patients about the dangers of purchasing medicines from unverified sources, especially online, is crucial. Patients often lack the knowledge to distinguish between legitimate and illicit online pharmacies. Advising them to only use pharmacies registered with national regulatory bodies, and to be wary of unusually low prices or offers that seem too good to be true, can prevent significant harm. A simple conversation can make a difference, reinforcing the message that convenience should never outweigh safety.

The European Union has implemented the Falsified Medicines Directive (FMD), which includes a pan-European system for verifying the authenticity of medicines. This system requires a unique identifier on each medicine pack and an anti-tampering device, allowing pharmacists to verify the product's authenticity at the point of dispense. While the UK has left the EU, the principles of supply chain integrity remain vital, and similar national verification systems are in place or under development to safeguard patients. Clinicians should familiarize themselves with these systems and advocate for their robust implementation.

Still, the FMD and similar initiatives are not foolproof. Criminals adapt, and new methods of falsification emerge. Continuous vigilance, international cooperation, and robust regulatory enforcement are essential to stay ahead of these threats. The onus is on every stakeholder in the healthcare system, from manufacturers to prescribers and patients, to contribute to a secure medicine supply. For general practitioners, a reliable clinical reference like the Oxford Handbook of General Practice can provide quick access to guidelines on safe prescribing and dispensing practices.

The Clinician's Role in Vigilance

When a patient presents with an unexpected lack of response to a prescribed medicine, or with unusual adverse effects, clinicians should consider the possibility of an SF product. While rare in highly regulated settings, it is a differential diagnosis that cannot be entirely dismissed. Reporting suspected SF products to national regulatory agencies is vital, as

this intelligence helps authorities track and intercept illicit supply chains. This proactive reporting forms a critical part of the global effort to combat medicine counterfeiting.

The complexity of modern polypharmacy also adds a layer of risk. Patients managing multiple chronic conditions may source medicines from various channels, increasing their exposure to risk. A comprehensive medication review, including a detailed history of where and how patients obtain their medicines, can uncover potential vulnerabilities. This is particularly relevant for conditions requiring long-term therapy, where patients might seek cheaper alternatives over time.

CLINICAL IMPLICATIONS

The pervasive threat of falsified and substandard medicines demands a proactive stance from every clinician. It is no longer sufficient to assume that every pill a patient takes is precisely what it purports to be, even within highly regulated markets. The globalized nature of pharmaceutical trade and the rise of unregulated online channels mean that vigilance must extend beyond the pharmacy counter.

GPs and specialists must integrate patient education on safe medicine sourcing into routine consultations. A brief, clear warning about the dangers of unverified online pharmacies or informal supply chains could prevent serious harm. This is particularly critical for patients on long-term therapies or those managing chronic conditions, who might be more susceptible to seeking cheaper, unverified alternatives.

But the responsibility does not end with patient counseling. Clinicians must also scrutinize their own procurement channels, ensuring that all medicines come from licensed, reputable distributors. Any deviation from expected drug efficacy or unusual adverse event profiles should trigger suspicion and prompt reporting to national regulatory bodies. This collective vigilance forms the strongest barrier against a threat that directly undermines both patient trust and clinical outcomes.