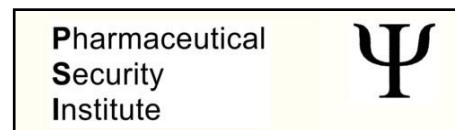


Counterfeit Medicines Toolkit

6. Key Messages

Materials developed in collaboration with:



- 1. Medicine counterfeiting is first and foremost a crime against patients.** By deliberately and deceitfully attempting to pass themselves off as something that they are not, namely, genuine approved medicines, counterfeit medicines pose a global public health risk, leading to resistance to treatment, illness, disability and even death.
- 2. Counterfeit medicines threaten the full spectrum of legitimate medicines.** They can be falsified versions of patented medicines, generic medicines or over-the-counter medicines and exist in all therapeutic areas (even traditional medicine). They range from medicines with no active ingredients to those with dangerous adulterations.
- 3. Patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents.** Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the fraudulent production of falsified versions of genuine approved medicines.

4. **All substandards are not counterfeits.** A medicine which is approved and legally manufactured but does not meet all quality criteria is substandard, and may pose a significant health risk but should not be regarded as counterfeit. However, all counterfeits are, by their nature, at high risk of being substandard.
5. **A medicine that is authorized for marketing by one regulatory authority but not by another should not be regarded as counterfeit** on these grounds alone in the latter's territory.
6. **Government regulatory and enforcement authorities must be fully vested with the proper power and adequately resourced to fight counterfeits.** While the incidence of counterfeit medicines occurs in both developed and developing countries, the problem is more prevalent in countries where regulatory oversight and enforcement are weak.

7. **Stopping the international trade in counterfeit medicines is vital.** Countries should be encouraged to adopt border measures that will stop trade in medicines that do not contain the ingredients that they purport to contain.

8. **All stakeholders across the pharmaceutical supply chain must be made aware of the health threats posed by counterfeit medicines and collaborate.** Public and private organizations; national regulatory and enforcement agencies; health professionals; patients; research-based and generic pharmaceutical manufacturers; drug distributors, wholesalers and retailers. All play a role in preventing counterfeits from reaching patients.

9. **Global cooperation is needed.** Because counterfeiting does not recognize borders, the International Medical Products Anti-Counterfeiting Task Force (IMPACT), which is the sole global initiative launched by regulators to specifically focus on combating counterfeiting of medical products, should be supported. IMPACT brings together the expertise of medicines' regulatory agencies, enforcement agencies, healthcare providers and the private sector in a unique global platform.
10. **The leadership of the World Health Organization is crucial.** Patients need to be protected worldwide. As the leader on global health matters, and particularly with respect to threats to public health in developing countries, the World Health Organization has a key role to play. The WHO is currently the home of the IMPACT secretariat.