

## *International Principles for Drug Safety*

Counterfeit drugs, whose origin, manufacturer and quality is disguised, hidden or unknown, are intrinsically unsafe and put patients around the world at risk.

Sellers of counterfeit drugs defraud patients and deny ill patients therapies that can alleviate suffering and save lives. The harm and fatalities from contraband and counterfeit medicines must stop.

The Partnership for Safe Medicines is a group of organizations and individuals that have international policies, procedures, or programs to protect patients from contraband and counterfeit medicines.

To join us in our stand against counterfeit drugs, please visit [SafeMedicines.org](http://SafeMedicines.org).

Patient safety is being compromised due to counterfeit drugs. Around the world, patients are encountering fake medicines. The packaging seems right, the tablets or capsules look the same—but these fakes are really imitations of government-approved drugs created in unsanitary or unsterile conditions with unsafe manufacturing practices. Counterfeit drugs may be too strong or too weak, missing key ingredients or made with dangerous, even toxic substances. Drug safety can also be compromised improperly labeled, stored or handled the drugs, as well as taking medications past the expiration date.

The Partnership for Safe Medicines has developed the following international principles to support quality assurance programs and establish a drug distribution system that is without compromise so people in every corner of the globe can feel secure that the medicines they receive are legitimate, safe pharmaceuticals approved by their country's regulators.

### *Secure and Protect the Supply Chain*

- There is strong need for strict, rigorous oversight when pharmaceuticals are transported between countries, including the regulation of its storage throughout the distribution system of imported pharmaceuticals.
- Distribution facilities should be subject to inspection and government agencies should have sufficient funding to inspect all the facilities that manufacture drug products or components of drug products for foreign or domestic use.
- Field offices staffed with both inspectors and criminal investigators should be established to inspect facilities in key exporting areas.
- The public and private sectors should continue to work together to standardize drug pedigrees and documentation.

### *Regulate Online Drug Sellers*

- Online drug sellers and pharmacies should be to the same rigorous oversight and high standards as traditional pharmacies.
- There should be mandatory Internet accreditation programs created by a country's pharmacy board protect patients from rogue online drug sellers.
- All Internet drug sellers, regardless of which state, territory or country they are based, must comply with the pharmaceutical licensing and survey requirements for every area in which they sell pharmaceuticals.
- No one should be able to purchase prescription drugs, including controlled substances, over the Internet without a valid prescription and physician oversight.

### *Unify the Fight Against Counterfeit Drugs*

- Counterfeit drugs, tainted medicines, and rogue online drug sellers are global public health problems that require an international solution.
- International cooperation must occur between government agencies, legislatures, law enforcement, and diplomatic corps to prosecute drug counterfeiters.
- Criminal penalties against the manufacturers, seller, distributors, and purveyors of counterfeit medicines must be increased to reflect the gravity of their offenses.
- Government authorities should be granted the power to destroy unapproved, unlicensed, tainted, and/or counterfeit drugs entering a country's border rather than returning them to the criminals who sent them.

8100 Boone Blvd., Ste. 220  
Vienna, VA 22182  
USA

Phone: +1-866-300-1077  
Fax: +1-703-848-0164  
[info@safemedicines.org](mailto:info@safemedicines.org)  
[www.safemedicines.org](http://www.safemedicines.org)