

# IFPMA'S 10 PRINCIPLES ON COUNTERFEIT MEDICINES



## 1 COUNTERFEITING IS A CRIME!

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 that can lead to resistance to treatment, illness, disability and even death.



## 2 COUNTERFEITERS DO NOT DISCRIMINATE BETWEEN 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 FAKE MEDICINES

Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the production of falsified versions of genuine approved medicines.



## 4 COUNTERFEIT AND SUBSTANDARD MEDICINES ARE NOT THE SAME

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, illegal and therefore substandard.



## 5 FAKE AND ILLEGAL MEDICINES ARE NOT THE SAME

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 EMPOWER REGULATORS

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 COUNTERFEIT MEDICINES TRADE MUST BE STOPPED

Countries should be encouraged to adopt measures that will stop trade in medicines that do not contain the ingredients that they purport to contain.



## 8 COUNTERFEIT MEDICINES ARE EVERYBODY'S BUSINESS

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, new mechanisms that bring together the expertise of medicines regulatory agencies, enforcement agencies, healthcare providers and the private sector in a unique global platform should be supported.



## 10 WHO GLOBAL COORDINATION IS NECESSARY

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. Strong coordination among international organizations is needed to ensure that all aspects of this problem are adequately addressed.

