

## POSITION STATEMENT ON QUALITY AND COUNTERFEITING<sup>1</sup>

<p><b>Trade in counterfeit drugs is widespread and affects both developing and developed countries. All medicines are subject to counterfeiting, both branded and generic. Counterfeit drugs are found under different forms, including:</b></p> <ul style="list-style-type: none"> <li>▪ Products with the correct ingredients (but often with incorrect quantities of active ingredients, or time-expired resistance. The product may also have been relabelled, which can lead to allergic reactions and harmful interactions with other drugs);</li> <li>▪ Products with the wrong ingredients (possibly toxic and therefore directly harmful to patients);</li> <li>▪ Products without active ingredient (leaving patients at risk as their disease is left without treatment) active ingredients, creating an increased risk of drug</li> </ul> <p>It is virtually impossible to tell the difference between real and fake medicines. Taking for granted that the drugs can be trusted, patients, doctors and other medical staff often do not even suspect that there is anything wrong with their medicines. However, not only is it in most cases hard to detect suspicious products, but there is also a lack of public awareness about counterfeit drugs and their seemingly uncontrolled presence on the market. As a consequence, medicines that do not work or cause unusual side-effects are rarely even reported, since symptoms (including deaths) are usually attributed to the disease. From a judicial perspective, prosecution is complicated by the fact that the evidence of counterfeiting is consumed.</p> <p>Because the public health risk of counterfeit medicines recognizes no national boundaries, companies have created the Pharmaceutical Security Institute (PSI) and developed global security strategies to ensure public safety and product integrity. The pharmaceutical industry works closely with law enforcement and regulatory agencies in both developed and developing countries to implement a multilayered security strategy focused on both prevention and enforcement. The IFPMA's Director General serves as President of the PSI.</p> <p>The IFPMA also works in close partnership with the WHO to improve drug quality and fight counterfeiting around the world. The Pharmaceutical Industry has endorsed the recent WHO Declaration of Rome on Counterfeiting Medicines (insert link) and is committed to participate in the WHO's new International Medical Products Anti-counterfeiting Task force (IMPACT). The IFPMA, the health professions and other pharmaceutical manufactures associations are all active partners against this crime.</p>	<p><b>Quick Facts</b></p> <ul style="list-style-type: none"> <li>▪ Counterfeiting is growing in scale and geographical scope. The PSI has documented a 40% growth in the number of counterfeiting incidents reported between 2004 and 2005. It recorded counterfeiting incidents in 67 countries in 2004 and in 89 in 2005, a 32% increase.</li> <li>▪ However, attempts to estimate the scale of the problem at a global level are misleading, as counterfeiting is above all a health issue in developing countries (the incidence in developed countries is certainly much lower).</li> <li>▪ Parallel trade in medicines is legal, for example within the EU, but re-labeling of products by wholesalers to allow them to be sold in another country creates opportunities for counterfeit products to enter the supply chain.</li> </ul>
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<sup>1</sup> International Federation of Pharmaceutical Manufacturers & Associations, [http://www.ifpma.org/Issues/issues\\_quality.aspx](http://www.ifpma.org/Issues/issues_quality.aspx)