

# **Third Global Congress on combating counterfeiting and piracy**

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## **Statement by Dr. P. Emafo, President of the International Narcotics Control Board**

Mr Chairman, distinguished delegates,

For more than two decades, counterfeit medicines have been identified as a growing problem constituting serious health risk to the user. The World Health Organization estimates that counterfeits could account for more than 10 per cent of the global medicines market. Counterfeiting medicines is a lucrative criminal activity and the proportion of counterfeit medicines, containing narcotic drugs and psychotropic substances, is rising. According to the Centre for Medicines in the Public Interest in the United States, counterfeit drug sales will reach US\$ 75 billion globally in 2010, an increase of more than 90% from 2005.

While counterfeits can be found in all world regions, developing countries are disproportionately affected by the problems of counterfeit medicines. It is suspected that about a quarter of medicines used in developing countries are counterfeit, with even higher levels of up to 50 per cent in some countries. The International Narcotics Control Board examined the role of counterfeit drugs in its most recent annual report which will be released to the public on 1 March, 2007.

### **Counterfeit Medicines**

In addition to violating copyright provisions and constituting an economic crime, counterfeit medicines undermine national health care systems, result in loss of confidence of the systems of drug control and enforcement of drug laws because of failures in therapeutic efficacy and safety and pose serious health risks to their users. The result of their use can entail therapeutic failure and, in the worst scenario, death because the products are of doubtful quality, safety and efficacy and their sources are not guaranteed. Trafficking in counterfeit drugs should therefore be considered a potentially life-threatening crime.

Counterfeit narcotic drugs and psychotropic substances constitute additional significant risks to the users as such drugs which should normally be obtained through prescription and used exclusively under medical guidance, are subject to abuse and misuse. Counterfeit narcotic drugs and psychotropic substances are normally in demand among drug abusing populations.

An example is the illicit market for flunitrazepam (often marketed as Rohypnol), a drug

that has gained notoriety as "date-rape" drug. In Scandinavian countries, the demand for this drug used to be met by diverting the substance from the legal trade. However, after methods of diversion had been uncovered and counteracted effectively, counterfeits are now manufactured and trafficked to the countries concerned. A similar counterfeit industry has developed for fenetylline (known as Captagon) which is illegally manufactured in South-East Europe and trafficked to countries on the Arabian peninsula.

Over the past years, the Board has witnessed the rise in the abuse of some counterfeit narcotic drugs and psychotropic substances, several of them with lethal consequences for their users. The clandestine manufacture of counterfeit fentanyl and oxycodone, both potent narcotic drugs, has resulted in numerous deaths in some countries.

## **The Internet**

A major factor in the increasing distribution of counterfeit drugs has been the facilitation of contact between suppliers and consumers through the Internet, which offers almost limitless marketing opportunities for counterfeit drugs. Illegally operating Internet pharmacies are among the main suppliers of counterfeits and their number continues to rise and has long surpassed the number of licensed and accredited Internet pharmacies. Counterfeit drugs are also sent through postal and courier services.

The International Narcotics Control Board has identified the role of the Internet in the illicit distribution of narcotic drugs, psychotropic substances and counterfeit drugs. The use of the Internet to prescribe and sell medicines is fraught with health risks as the source, quality, safety and efficacy of such medicines cannot be guaranteed, and in particular when such Internet services are unregulated and unlicensed. Currently, the Board is engaged in developing guidelines for governments to counteract the spread of illegally operating Internet pharmacies. The Board will continue to alert countries with regard to specific cases and developments and stands ready to support and facilitate international cooperation efforts.

## **Laws and Regulatory Authorities**

Clandestine manufacture and trafficking is facilitated by weak drug regulations, weaknesses in enforcement of existing regulations and lenient penal sanctions for counterfeiters. However, if sanctions are not commensurate to the enormous profits that are made, they do not serve as sufficient deterrent and consequently increase the appeal to engage in such illicit activities.

Effective action also requires competent national drug regulatory authorities with a sustained resource base that will ensure control and regular inspection of entities involved in the manufacture, trade and distribution of pharmaceuticals.

These actions at the national level need to be complemented by strengthened concerted international preventive and investigative efforts. National drug regulatory authorities should cooperate effectively in interdicting counterfeit medicines in international commerce. Drug regulatory authorities, law enforcement agencies, manufacturers of

pharmaceuticals, professional associations of medical practitioners and pharmacists, as well as consumer protection groups need to work in concert to identify counterfeit medicines that are in national distribution channels and their sources, so that adequate preventive measures can be undertaken. Without cooperation of all concerned, we stand no chance to overcome this problem.

## **Unregulated Markets**

The distribution, supply and sale of medicines in unregulated and parallel markets undermine the quality, safety and efficacy of medicines. National drug laws must make counterfeiting of medicines a punishable offence and provide for severe penal sanctions. The laws should also make the sale of medicines in unregulated or parallel markets and through unlicensed Internet pharmacies a punishable offence, also, subject to severe penal sanctions.

## **Law Enforcement and Cooperation**

The Board is of the view that Governments have obligations to enforce applicable control regimes and to strengthen drug regulatory authorities, in particular, the registration and inspection of medicines and their manufacture, import, export, distribution, supply and sale, with a view to outlawing unregulated markets. In this regard, the drug regulatory authorities will need to enlist the assistance of customs, police and postal services to intercept unauthorised assignments of medicines in national and international distribution channels. The pharmaceutical industry should also cooperate by notifying national drug regulatory authorities of the existence of or attempts to manufacture and distribute counterfeit medicines.

Cooperation among national drug regulatory and enforcement authorities would help to stop or interdict shipments of counterfeit medicines and arrest of persons engaged in counterfeiting through intelligence sharing.

Meanwhile let national drug regulatory authorities cooperate with the International Medical Products Anti-Counterfeiting Task force set up during the Declaration of Rome of 18 February 2006.

## **Political Will**

Governments need to be appropriately sensitised on the safety, health and economic risks associated with counterfeiting of medicines so that appropriate laws against counterfeiting are enacted and resources and infrastructure are provided for effective enforcement purposes at national levels.

Thank you for your attention.