



Pharmaceutical Manufacturers' Association of South Africa

POSITION PAPER

COUNTERFEIT MEDICINES

Counterfeit prescription medicines are a growing problem in the pharmaceutical industry especially with the importation of products from foreign suppliers located in less regulated foreign countries.

DEFINITION

The WHO describes counterfeit pharmaceuticals as: Medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

The term *counterfeit*, as applied to medicines, can be used to cover many different circumstances, including:

- ◆ a medicine which contains the right active ingredient, but in insufficient quantity (*could make it ineffective and dangerous to the patient*);
- ◆ a medicine which contains no active ingredient (*would be ineffective and therefore potentially dangerous to the patient who would not be treated correctly*);
- ◆ a medicine which contains *another* [wrong] active ingredient to the one on the label (*possibly toxic and therefore directly harmful to patients; this could also trigger allergic reactions and may cause harmful interactions with other drugs*);
- ◆ medicines which contain the right amount of active ingredient but from an unapproved source or
- ◆ A genuine medicine manufactured by the original manufacturer but which has been repackaged or redated [expiry date extended unofficially and which could therefore be substandard] e.g. could be from stock which has been stolen, or parallel imported.

Commonly counterfeited medicines: In wealthier countries the most frequently counterfeited medicines are new, expensive lifestyle medicines, such as hormones, steroids, sexual dysfunction medicine and antihistamines. In developing countries the most counterfeited medicines are those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. A fairly recent phenomenon is the appearance of counterfeit herbal and complementary medicines particularly in Asia where patients have been harmed by counterfeits.

Where and How? Counterfeit medicines come from national or international sources, organised crime and unscrupulous and greedy import-export agents. It is mostly found in countries with inadequate resources, lack of adequate regulatory controls and countries which allow parallel importation.

Medicines are an attractive target for counterfeiting because they are a high-value item, in relation to their bulk and a fake can be made relatively cheaply. A complicated distribution chain involving several wholesalers and brokers and, in particular, parallel trade in pharmaceuticals, all provide opportunities for the insertion of counterfeit products into the distribution chain. It is often virtually impossible to tell the difference between real and fake medicines from a visual inspection.

Consequences of substandard and counterfeit medicines: The harm to patients from counterfeit medicines which are ineffective and/or positively dangerous results in costs both in human suffering and an increased burden on health services. At best, the regular use of substandard or counterfeit medicines leads to therapeutic failure or drug resistance; and in many cases it can lead to death.

- Counterfeit or substandard vaccines and antibiotics may have a deleterious effect on a wide section of the population. Injuries and harm from counterfeits include death, blindness, headache, swelling, illness and rash, failure to recover from illness, burns, hospital admissions and other adverse reactions.

GLOBAL SITUATION AND THE EXTEND OF THE PROBLEM

Trade in counterfeit medicines is known to be widespread, affect both developing and developed countries and is on the increase. A World Health Organisation (WHO) survey of counterfeit medicine reports from 20 countries, between January 1999 to October 2000, found that 60% of counterfeit medicine cases occurred in poor countries and 40% in industrialised countries. According to WHO estimates, counterfeit medicines comprise 6% of the world market, higher in some areas, and including developed countries. The FDA estimates that 10% of pharmaceuticals worldwide are counterfeits and 25% of medicines in developing countries are fake or substandard.

Pharmaceutical companies in the US have recently reminded US wholesalers not to purchase products from 3rd parties as counterfeit or adulterated medicines have entered the US prescription drug supply. The goal is to tighten up the distribution system thereby ensuring the integrity of products and thus to assure the safety of patients. The American companies have also taken a zero tolerance policy on the issue of wholesalers purchasing medicine from illegal or 3rd party sources.

POSITION IN SOUTH AFRICA

In South Africa theft and counterfeit medicines result in an estimated loss of R2 Billion p.a.

In the South African legal case of Adlam and partners [pharmacists], investigators found deblistering equipment, printers to redate labels, cartons for relabelling and repackaging of State Stock. The special markings "For state use only" on State packs were also removed.

The amendments to Act 90 of 1997 by which wholesalers may only buy medicines from the primary manufacturer or importer is also designed to tighten controls in the distribution chain and therefore restrict the entry of stolen or counterfeit medicines to that chain. However other proposals in the same amending legislation permitting the purchase of medicines by the State by means of international tendering, and possible parallel importing, could open the door to the entry of stolen and counterfeit medicines.

HOW DOES IT IMPACT ON HEALTHCARE

Counterfeiting results in a waste of public and private money and affects the ability of the State to deliver quality health care.

To the pharmaceutical industry, counterfeit medicines are of significant concern, not only because of the potential safety hazards and the substantial financial loss to the companies concerned, but also because of the risk of damage to the company's reputation if its products are perceived as ineffective or harmful, as a result of counterfeiting. The trademark could also suffer enormous harm from the public. Not all members of the public are aware of the company's name but usually know the trademark.

For the patient they pose serious quality and safety issues. It erases public confidence in public health care systems, health care professionals, products and the pharmaceutical industry.

WHAT IS BEING DONE?

The international pharmaceutical industry has taken measures to address this issue by establishing The Pharmaceutical Security Institute (PSI) a not-for-profit corporation based in Washington, USA in late 2001. Its member companies mainly monitor their own products in industrialized countries where fake medicines are entering the market. However, there is not sufficient capacity and information available for the pharmaceutical industry to do the same in developing countries.

IFPMA (International Federation of Pharmaceutical Manufacturers Associations) is a partner with WHO in efforts to improve drug quality and fight counterfeiting around the world. The Counterfeiting and Drug Quality Working Group is composed not only of WHO and IFPMA, but also the International Generic Pharmaceutical Alliance (IGPA), the World Self-Medication Industry (WSMI) and Centrale Humanitaire Medico-Pharmaceutique (CHMP), an NGO of pharmacists committed to improving drug quality in developing countries.

The WHO launched an action plan against substandard and counterfeit drugs on 11 November 2003.

Intergovernmental co-operation on international pharmaceutical crime, involving medicines regulatory authorities, police, departments of justice, customs etc are continuously trying to address this problem.

Special markings, holograms on packaging materials, different colours used for tablets and capsules sold to the State or for aid programmes and other measures for tracking the movement of pharmaceuticals from manufacture to final selling point have been introduced by industry, but experience has shown that counterfeiters soon develop the technology to cope with such measures.

HOW DO WE SEE THE FUTURE

There is no simple or standard solution against the growing number of sophisticated counterfeiters. A multi-pronged anti-counterfeiting strategy is necessary to protect consumers by preventing the introduction of counterfeit drugs, minimizing the risk and exposure of consumers to counterfeit drugs, and identifying, prosecuting, and punishing those responsible for counterfeit drugs.

Key factors in preventing counterfeiting include:

- **Partnerships and co-ordination between the various parties involved** – government, regulatory, police, customs, justice, private industry and WHO – at national and international level;
- **Stronger and more specific legislation** to take action against counterfeiters of medicines
- **Enforcement of legislation to prosecute** and demand severe penalties since the selling of illegal unregistered medicines, stolen medicines or counterfeit medicines are **serious** crimes resulting in harm to consumers /patients and the economy
- Regulation of and self-regulation by, pharmacists and wholesalers in the distribution chain.
- Regulatory requirements and secure business practices;
- Rapid alert and response systems;
- Use of modern technologies to make it more difficult to distribute counterfeit drugs.
- Education and public awareness;
- International collaboration; and
- the timely and appropriate exchange of information and the harmonisation of measures to prevent the spread of these phenomena.

Legislation forms the basis for drug regulation. Medicines need to be safe, effective and of optimum quality in order to produce the desired effect. Ensuring these properties requires the maintenance of a competent national drug regulatory authority with the necessary human and other resources to control the manufacture, importation, distribution and sale of medicines.

ROLE OF INDUSTRY

- Consistent **standards** for products
- **Labelling** to meet regulatory requirements
- Constant **monitoring** of products in market
- **Alerting consumers and health care professionals** to the dangers of counterfeit or substandard medicines
- Batch tracking **records**
- Tight security measures by companies to ensure that products, and especially packaging material, are not diverted from legitimate distribution channels;
- Proper control systems in place
- Proper tracking of all products throughout the manufacturing and packing process, warehousing and distribution
- Monitoring sales versus purchases of certain final sellers (refer Robert Courtney case in US regarding overdiluted oncolytic drugs in 2003)
- Proper audit trail to be in place in case of recalls
- Systems in place for speedy response to any reports of stolen or counterfeit products found on the market
- Consider possibility of special marking of products or packaging for State or special aid projects for regulatory authority

None of the security, enforcement, education, compliance, inspection, regulatory, or other actions being considered can guarantee that counterfeiting will not occur. However, our efforts are aimed at significantly reducing this phenomenon.

ROLE OF REGULATORY AUTHORITIES

- Effective registration process to cover ALL medicines available on the market
- Effective inspectorate to
 - control and
 - monitor medicines in the market
- Effective training to develop expertise within the regulatory authority
- Effective training of police and customs police
- Source of all medicines must be known and inspected to ensure consistent quality
- Adequate resources, human and financial
- Political will
- Education of health care professionals and the public
 - To assist in spotting illegal, stolen, substandard or counterfeit medicines
 - Ensure an effective reporting system for patients to report lack of efficacy or unexpected adverse events
- Educate all in distribution chain:
 - to purchase from legitimate, authorised and validated sources only
 - to maintain an audit trail of medicines bought

ROLE OF PROFESSIONALS

- To be alert to counterfeits
 - by monitoring own stock
 - to track and follow up consumer complaints
 - to inform drug companies and authorities of suspect products
 - to be on alert for treatment failure

ROLE OF INTERNATIONAL ORGANISATIONS

- To track counterfeit medicines around the world
- To investigate each case and co-operate with Interpol and local police
- To keep WHO, local regulatory authorities and the industry informed of problems

OTHER FACTORS

- Statutory councils
 - to impose severe sanctions on members found guilty of manufacturing, distributing supplying or selling stolen or counterfeit medicines
- New provisions of Act 101 of 1965 should assist in combating theft and counterfeits
 - Wholesalers to purchase from primary manufacturers or importers only
 - All health professionals and institutions to obtain a license
 - Licensing dispensing doctors
- Medicine providers will need to exercise care regarding purchase from authorised and validated suppliers only.

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