1. Introduction

A familiar sight in the open markets and the streets of some African countries is a display of a wide range of pharmaceutical products intended for sale to the general public. Such medicine sales constitute a real danger to public health since the authenticity, the origin and the quality of the medicines cannot be ascertained. Although such sales are not authorized, they are tolerated by local medicine regulatory authorities. In addition, the people involved in such sales are not authorized as they are not pharmacy professionals.

What is the origin of such medicines? Why is this unauthorized trade flourishing? Could there be a link between this trade and the proliferation of counterfeit and substandard medicines? The present issue of the AFRO Pharmaceutical Newsletter attempts to examine some of these questions. In particular, it discusses the overall problem of counterfeit and substandard medicines and WHO’s contribution to the fight against the problem.

Why the “AFRO Pharmaceuticals Newsletter”?  

The WHO mission in the area of essential medicines is to help save lives and improve health. Although medicines are an essential element in the provision of health care and have a huge potential, the reality is that for millions of people, particularly the poor and disadvantaged, medicines are unavailable, unaffordable, unsafe or misused. Providing policy-makers and essential medicine managers with practical and evidence-based information is one important element of WHO’s work. Therefore, the objectives of the “AFRO Pharmaceuticals Newsletter” are:

- to share information and experiences related to essential medicines and pharmaceutical policies with WHO Member States, partners in the pharmaceutical sector, health professionals and the general public;
- to serve as a forum for the diffusion of information on the work of the WHO Regional Office for Africa in collaboration with Member States and Headquarters particularly in the following areas: medicines policy, access, quality assurance and rational use, and traditional medicine.

The newsletter welcomes contributions from Member States, pharmaceutical sector partners, health professionals as well as the general public. They should be addressed to:

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2. The problem of counterfeit medicines

The problem of counterfeit medicines is as old as medicines themselves. Information on the exact scale of the problem is difficult to determine, but with the increasing conduct of national, regional and global
studies, our understanding of the problem is improving. The problem of counterfeit medicines is real and globalization of economies is helping to ‘globalize’ the problem, which poses an increasing challenge to present day health-care delivery systems.

Contrary to popular belief, the problem of counterfeit medicines affects both developed and developing countries and both branded and generic products. However, it is more pronounced in countries or regions where the pharmaceutical sector is less regulated and enforcement of existing regulations is weak.

3. Enabling factors for counterfeiting

Counterfeiting is primarily motivated by the huge profits that can be made from the sale of such medicines. It is perpetrated by criminals who compromise peoples’ health for illegal profits. Today, there is also some evidence that counterfeiting is linked to organized crime. Factors that facilitate the production or free circulation of counterfeit medicines include lack of appropriate legislation, non-existence of laws of national medicine regulatory authorities, lack of law enforcement, sanctions, corruption, inadequate supply compared to demand, use of free trade zones, high medicine price differentials, poverty, illiteracy, and trade in medicines through numerous intermediaries.

4. Role of health-care delivery systems

It should be emphasized that the sale of medicines in the streets or in the markets may constitute an alternative source of medicines for sections of the population that are denied regular access to medicines through the normal health-care delivery system, either because the medicines are too expensive or because they are too expensive. Therefore, as long as health-care delivery systems are unable to provide these medicines on a regular basis and at an affordable cost to populations, and medicine regulatory authorities are unable or unwilling to regulate their sales, they will both be unintended accomplices to the proliferation of such medicines and will therefore be putting populations at risk of using counterfeit medicines with all the well-known consequences.

5. What are counterfeit medicines?

Counterfeit medicines are part of a larger group of substandard medicines manufactured below established quality standards and outside the purview of national medicine regulatory authorities. However, unlike other substandard medicines, counterfeit medicines are deliberately and fraudulently mislabeled to hide their identity or source. They do not comply with regulatory requirements and are manufactured by criminals whose objective is to make huge profits unlawfully.

6. Magnitude of the problem

It is difficult to obtain precise and detailed data on counterfeit medicines, but even without knowing the exact magnitude of the problem, it is nonetheless true that any single case of counterfeiting is condemnable. It is estimated that counterfeit medicines make up 1% of sales in the developed countries where sales are better regulated to well over 10% in the developing countries where the market may be less regulated. There may also be differences between regions and within countries, for example cities versus rural areas.

The foregoing underscores the difficulty and complexity of any estimation, given that the counterfeit market is by definition an illegal and informal market from where evidence may not always be obtainable. The problem is however there and is actually growing. If countries do not act decisively now, it will continue to grow and further threaten public health.

7. Impact of counterfeit medicines on public health

Counterfeit medicines can be dangerous to patients. Their use may be detrimental to health, and may lead to treatment failure or death, waste of scarce resources, and emergence of antimicrobial resistance in the case of antibiotics. As a consequence, counterfeit medicines may undermine public confidence in health-care delivery systems, health-care professionals, suppliers and sellers of genuine medicines, the pharmaceutical industry and national medicine regulatory authorities. Counterfeiting can also affect adversely the reputation and financial standing of the original and/or current manufacturer whose name is being fraudulently used.

8. Medicine regulation situation in Africa

As indicated above, all countries and regions of the world are affected to varying degrees by the problem of counterfeit medicines. Countries or regions where the pharmaceutical sector is less regulated and enforcement of existing regulations is weak are the most affected, either as production sites or as markets for counterfeit medicines produced elsewhere.

A 2004 study conducted by the WHO Regional Office for Africa revealed that 90% of the medicine regulatory authorities in the Region lacked the capacity to carry out all the medicines regulatory functions. Therefore, they could not guarantee the quality, efficacy and safety of medicines circulating within their markets. Some of the reasons for this were that the medicine regulatory authority, where it existed, was not functional due to lack of resources and legislation/regulations. Where legislation existed, it was inadequate or unenforced.

As can be seen in Figure 1, three of the functions of a medicine regulatory authority are registration (authorizing medicines to be put on the market after ascertaining that they are safe, efficacious and of good quality); inspection of pharmaceutical establishments (ensuring that they are functioning in accordance with set standards); and licensing (ensuring that only duly qualified and authorized pharmaceutical personnel can carry out pharmaceutical operations in authorized premises).

When there is no regulatory authority, or where the existing authority cannot carry out the functions above, counterfeiters tend to exploit the existing vacuum.

9. Work of WHO in controlling counterfeiting

Concern about the quality of drugs is as old as drugs themselves. As early as in 1951, three years after the creation of WHO, the WHO Executive Board adopted Resolution EB7.R79, requesting the Director-General of WHO “to consider the advantages of more uniform methods for the control of drugs in countries in the interest of health and international commerce”.

In 1985, the problem of counterfeit medicines was addressed at the Conference of Experts on Rational Use of Drugs in Nairobi, Kenya. The conference recommended that WHO and other international and nongovernmental organizations should “study the feasibility of setting up a clearing house to collect data and information on governments about the nature and extent of counterfeiting”.

In April 1992, the first international meeting on counterfeit medicines was jointly organized in Geneva by WHO and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The meeting agreed on the following definition of counterfeit medicine:

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products:

- with correct ingredient(s);
- with the wrong ingredient(s);
- without active ingredients;


In 1994, the World Health Assembly adopted Resolution WHA47.13 requesting the WHO Director-General to assist Member States in their efforts to ensure that available drugs are of good quality, and in combating the use of counterfeit drugs.

In implementing this resolution, a WHO project was created in 1995, with the objective of assisting Member States to assess the problem of counterfeit medicines and to develop measures to combat counterfeiting. One of the outputs of the project was the production in 1999 of Guidelines for the development of measures to combat counterfeit drugs.

10. Guidelines for the development of measures to combat counterfeit drugs

The guidelines provide an overview of the problem of counterfeit drugs, their impact on public health and the factors that facilitate counterfeiting. At the core of these guidelines are proposed strategies, approaches and measures to be taken by governments and other pharmaceutical sector actors in order to detect and prevent counterfeiting.

The proposed measures have to be applied after a prior assessment of the problem of counterfeiting at national level in order to have an idea of the magnitude and the nature of drug counterfeiting in a given country and to determine priorities for implementation. The measures include the following:

- Strengthening governments’ political will and commitment to improve drug control;
- Promulgating appropriate legislation in order to effectively regulate the manufacture, importation, distribution, supply and sale of drugs;
- Establishing functional national drug regulatory authorities;
- Developing standard operating procedures and guidelines;
- Enforcing drug control laws and clearly specifying the agency or agencies responsible for enforcing those laws relevant to counterfeiting;
- Ensuring comprehensive training of adequate numbers of inspectors and other regulatory officers;
- Empowering the judiciary to impose severe penalties including confiscation, forfeiture and destruction of all detected counterfeit drugs;
- Sharing responsibilities and fostering partnerships with all pharmaceutical sector actors: pharmaceutical industry, wholesalers, retailers, health professionals and consumers, with a view to curbing counterfeiting.

None of the above measures can be effective if it is applied alone. In addition to sharing responsibilities at all levels, these measures need to be implemented collectively and consistently if any success is to be expected in the fight against counterfeiting.

11. Global partnership

In February 2006, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was created. It is a global partnership comprising all 193 WHO Member States on a voluntary basis, as well as international organizations, enforcement agencies, national drug regulatory authorities, law enforcement agencies, nongovernmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients’ groups.

The partnership aims at coordinating global action to fight the counterfeiting of pharmaceutical products, and to protect public health. It operates through working groups, focusing on the areas where weaknesses have been identified and the action that needs to be taken at national and international levels:

11.1 Legislative and regulatory infrastructure: Looking at existing laws in countries and effective models countries can replicate and adapt to meet their own needs. Draft principles and elements for national legislation against counterfeit medical products were endorsed by a general meeting of IMPACT in Lisbon, Portugal, in December 2007;

11.2 Regulatory implementation and enforcement: Helping countries whose regulatory systems are weak to strengthen them by improving collaboration with those who have to deal with counterfeiters (police, customs, judiciary, investigators, prosecutors);

11.3 Technology: Facilitating technology transfer and innovative solutions to be adapted to local situations in the fight against counterfeiting;

11.4 Risk communication: Creating international information networks to monitor trafficking of goods, exchange information, issue alerts across countries and regions, and also to help investigate suspected cases.

12. Conclusion

Combating counterfeiting of medical products is a shared responsibility which must involve all relevant government agencies, pharmaceutical manufacturers, distributors, health professionals, consumers and the general public. Governments have to create the appropriate environment for the participation of all concerned partners.

Similarly, cooperation and collaboration between various government agencies such as medicine regulatory authorities, customs, police and the judiciary are essential for any success in the fight against counterfeiting. Given the international dimension of the problem, there is need to foster intercountry, subregional, regional and international cooperation. We must act now.

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