



WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

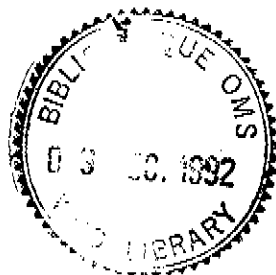
WHO/DMP/CFD/92
DISTR: GENERAL
ENGLISH ONLY

42858

Counterfeit drugs

report of a WHO/IFPMA Workshop

1-3 April 1992



Division of Drug Management & Policies
World Health Organization, Geneva, Switzerland

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. The document may, however, be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

The views expressed in documents by named authors are solely the responsibility of those authors.

SUMMARY REPORT

JOINT WHO/IFPMA WORKSHOP ON COUNTERFEIT DRUGS

1-3 April 1992, Geneva

Contents	Page
Introduction	1
Welcome Speech by Dr Hu Ching-Li, Assistant Director-General, WHO	2
Counterfeiting in perspective/IFPMA	5
Workshop	9
Observations	11
Recommendations	14
ANNEX 1	Resolution WHA 41.16: Rational Use of Drugs
ANNEX 2	List of Participants
ANNEX 3	Bibliography

INTRODUCTION

The counterfeiting of any product is a crime. Counterfeiting of pharmaceuticals is a particularly serious criminal offence and handling such counterfeits is an unethical practice because it endangers human health.

Counterfeiting of pharmaceuticals occurs worldwide. It has increased substantially in recent years, and international trading conditions are coming into place which could lead to a further rapid increase in this criminal activity.

The health hazards resulting from the use of counterfeit products vary in severity according to the nature of the counterfeit. In cases where the counterfeit product contains wrong, inadequate or toxic active ingredients or excipients, it can be responsible for lack of effectiveness, serious damage to health or even death. There is no such thing as a "good" counterfeit. Any counterfeiting of medicines is unacceptable since such products are manufactured and/or packaged outside properly-controlled channels and are not subject to the established safeguards provided by drug regulation, quality assurance, GMP and inspection.

Definitions

A **counterfeit medicine** is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.

For the purpose of this report the terms **drug**, **medicine** and **pharmaceutical product** are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use.

WELCOME SPEECH

Dr Hu Ching-Li, Assistant Director-General World Health Organization

Ladies and Gentlemen,

It is my pleasure to welcome you on behalf of Dr Hiroshi Nakajima, Director-General of the World Health Organization, to this meeting on counterfeit drugs. I am particularly pleased to see representatives of so many other international organizations: the International Federation of Pharmaceuticals Manufacturers Associations, who are WHO's partners in the organization of this meeting, the International Chamber of Commerce, Interpol, the Customs Co-operation Council, the International Narcotics Control Board, the International Organization of Consumers Unions, the European Association of Industries of Branded Products and the General Agreement on Tariffs and Trade. Representatives of regulatory authorities will play a key role in the discussions and I welcome them. Representatives of the pharmaceutical industry, international pharmaceutical organizations, and an expert in legal matters are equally welcome.

You have been invited in your personal capacity, in view of your own experience with the matter under discussion, and we invite you to speak freely. This meeting is rather exceptional. The problem of counterfeit products in general has been discussed before in many different settings. For the most part, however, consideration has been largely confined to economic aspects. Some meetings specifically concerned with drugs have focussed on pharmaceutical interests and, as such, have mainly involved pharmacists, regulators and representatives of pharmaceutical companies. This meeting, in contrast, brings together participants from many backgrounds. Each of them, from their different professional perspectives, has been confronted with the problem of counterfeiting, but they have not yet been given opportunity to interrelate effectively.

During the last decade the number of reports of counterfeit medicines has increased considerably. Indeed, the money involved is estimated to run into billions of dollars each year. However, it is the associated health risk that is of most immediate concern to WHO. Pharmaceutical products that are marketed without having passed the regulatory channels may not meet required standards. They may contain little or no active constituent. A patient suffering from a serious disease such as malaria or diabetes who receives such a product will be deprived of proper treatment. In these circumstances lack of therapeutic activity can be lethal. Counterfeit medicines may also contain unauthorized substances and excipients, different from those in the genuine product and sometimes toxic. Cases have been reported where patients – among them children receiving treatment for the most trivial of reasons – have died or suffered permanent injury as a result of exposure to inadmissibly toxic ingredients.

WHO's governing bodies have long realized the importance of the problem. In 1988 the World Health Assembly adopted resolution WHA 41.16 (Annex 1) requesting "governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations". I am very happy that we are convened here today to discuss this important subject and I should acknowledge the support we have received from a number of contributors that has enabled us to organize this workshop in response to the World Health Assembly resolution.

Throughout the meeting we must make the most of the varied competence and experience of the participants. You will note from the draft agenda that each of you is requested to give a brief presentation on your individual involvement in the problem. Ample time is reserved for discussion. We want the meeting to be informal and you should feel free to contribute constructively in the way that you consider appropriate.

If this meeting is to achieve everything we expect from it, it must invoke commitment that will assist both WHO and its partners in the fight against counterfeiting. Basic objectives will be to explore the possibility and potential of intensified collaboration between all those concerned, and to share information. World Health Assembly resolution WHA 41.16 calls on governments and pharmaceutical manufacturers to take action, and we

believe WHO may be able to play an important supporting role in this effort, but it is for you to decide to what extent a central clearing house of information is feasible.

We are acutely aware, of course, that any initiative intended to facilitate sharing of relevant information should enhance and not compromise the confidence of the public in the quality of pharmaceutical products that have met the proper standards for marketing. Ultimately, the solution must surely reside in preventive measures rather than deterrents. Effective regulation must be complemented by effective enforcement through competent inspection and control. Without reliable assurance of drug quality, the public health infrastructure and the vital confidence of the public in the medical establishment is dangerously eroded.

If we all work together — industry, WHO, drug regulators, police, and customs — we must, and will, succeed.

I thank you for your attention, and wish you a successful meeting.

COUNTERFEITING IN PERSPECTIVE

Dr R. Arnold, International Federation of Pharmaceutical Manufacturers Associations

In making a few general remarks about the counterfeiting of medicines, I would like to emphasize two fundamental points which I believe we should keep in mind throughout this meeting. These are, firstly, that counterfeiting is a criminal activity and, secondly, that counterfeiting of medicines is doubly criminal as it creates a threat to health which has caused and continues to cause injury and even death in many countries in the world. As such, its elimination necessitates special measures.

The purpose of counterfeiting is to deceive. In some cases a product may resemble the original not only in superficial appearance and packaging, but also by containing the correct ingredients. It is still, however, a "deceitful product" and is a potential hazard because its source, history and level of quality assurance is unknown. In addition, as we all know, there are many counterfeit products which do not contain any of the correct active ingredient, and may even include a completely different active ingredient.

Counterfeiting of any type of goods is a crime because it is theft and thus deprives the authentic manufacturer of his just rewards. As such, the main answer to the control and — hopefully — elimination of counterfeiting must be the application of the due processes of the law. But if this is to be effective, four elements must each operate successfully:

detection; prosecution; judgement; punishment.

Detection necessitates the existence of an effective system of monitoring and inspection. Because we are talking about high technology products the inspectors will need to be technically competent and professionally trained.

Prosecution, in order to be initiated, means that a comprehensive system of laws must be in place so that counterfeiting, especially the sort of counterfeiting that we are considering, is clearly regarded as a criminal rather than a civil offence. The law should be sufficiently comprehensive to ensure that handling as well as trading and manufacture of counterfeits is also treated as a criminal offence. Furthermore, because of the nature of the traffic in counterfeit products — often involving offshore operations — international cooperation agreements should ensure that there are no gaps between the laws in place in the countries involved, and that witnesses and evidence will be mutually acceptable.

To ensure that prosecutions can succeed and that appropriate **judgements** are handed down, convincing evidence must be provided. Companies marketing legitimate products must collaborate fully in investigations by national or international authorities. This collaboration may well include investigations carried out on behalf of the companies themselves, the results of which will need to be made available to national authorities. Furthermore, companies will need to collaborate among themselves to make information, and possibly evidence, which they acquire about the counterfeiting of other companies' products available to the companies concerned. It is, however, very important that the reaction of authorities to the discovery of counterfeit goods does not penalize the legitimate manufacturer and retailer as well as the criminal. Not only is this inequitable but it will also inhibit the collection and submission of evidence to the authorities.

Another aspect which needs to be addressed is that of assuring the security and integrity of evidence. We have all heard of cases where evidence seized from alleged counterfeiters or handlers of counterfeit goods has 'disappeared' mysteriously and where evidence has been discredited because of doubts about the provenance of the samples.

Finally, the **punishments** handed out to those convicted of counterfeiting must be sufficiently severe to serve as a real deterrent and to ensure that local plants producing counterfeit material cannot continue to operate by simply regarding any penalty as an easily affordable tax on their business.

These general observations apply to all types of counterfeiting but, because it represents a threat to health, the counterfeiting of medicines involves the consideration of many additional factors.

The members of IFPMA are the manufacturers of prescription medicines, by which I mean products which are, or should be, taken on professional advice by medical, pharmaceutical or suitably qualified paramedical personnel. Whilst I cannot speak for my colleagues who are concerned with the manufacture, sale and distribution of products intended for sale 'over-the-counter', I feel that my first point is equally relevant to both OTC and to prescription medicines.

It is extremely difficult to establish whether medicinal products on the market are legitimate or not if there is no effective system of registration and licensing of products. The efforts of WHO to define guidelines for small regulatory agencies in those countries presently without should be given practical implementation with greater emphasis and help in actually creating these agencies. Registration should be a requirement for all products whether they are procured and made available within the private or the public sector. Registration of a product should require the identification of the manufacturer as well as the marking of the package with the appropriate licence number. It is preferable, but may not be always practicable, that the patient receives the medicine in the form of a manufacturer's original pack. But even if the prescription is dispensed from bulk, the original pack should be clearly labelled with the necessary information.

My second point is that the distribution and sale of 'prescription medicines' should be confined to duly registered and competent outlets. Recognising that in some (but not all) of the poorer countries the availability of professionally qualified people is limited, it may be necessary to permit non-professionals to sell such medicines. But they should only be registered as a legitimate seller if they can demonstrate certain basic competence and skills. Recognizing that manufacturers of counterfeits will be frustrated in their objectives if their products are not distributed and sold, distribution and selling of counterfeits must be regarded as a criminal activity and removal of the right to handle medicines must be part of the punishment. The insertion of counterfeit products in the regular market obviously involves the active compliance of one or more individuals in the

distribution chain. Incidentally, it is worth bearing in mind that it does not require a particularly high level of skills on the part of those responsible for inspection of the market to determine if medicines are or are not on sale. It is another matter to decide if the products are what they purport to be.

This meeting has a lot of ground to cover in discussing counterfeits *per se* and I suggest that we do not get sidetracked into a lengthy consideration of "passing off", by which I mean legitimately marketed products which have packaging designed to resemble better known brands in order to benefit from the credulity of the consumer. In drafting the conclusions and recommendations of this meeting, we may well wish to include a request to regulatory agencies to decline to register products which, inadvertently or by intent, may be confused with established products based on the superficial appearance of the trademark and the pack.

In these general remarks I have mentioned what we see as some of the responsibilities of governments and legitimate manufacturers. But if the scourge of counterfeiting is to be overcome it requires help from the ultimate user. Patients themselves should not only take precautions to avoid purchasing counterfeit products but they also have a responsibility to draw examples to the attention of the authorities and, possibly, the manufacturer. To do this, the public obviously needs guidance and education on how to identify the more obvious fakes. Such guidance and education I see as the responsibility not only of governments but also of consumer organizations. It is a responsibility which needs to be handled with care, however, since it would be quite counterproductive if the attempt to increase awareness about the possibility of fake medicines simply discouraged the patient from taking the medicine which was needed.

A balanced and constructive approach is therefore needed and one which recognizes the interests and concerns of all parties. Measures to contain the spread of counterfeit medicines in the interests of health should not be taken at the expense of the legitimate use of the authentic products. Cooperation between all those involved in the distribution chain from the producer to the patient will be needed and I am confident that this Workshop, which brings together a wide spectrum of different interests, will be able to offer valuable advice and recommendations on ways to build and strengthen such cooperation.

THE WORKSHOP

For a long time now, WHO's governing bodies have realized the importance of the problem of counterfeiting. In 1988, the World Health Assembly adopted resolution WHA41.16 (Annex 1) requesting "governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations".

This is the background against which WHO and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) have convened this workshop; bringing together representatives of various international and national organizations in an attempt to help to improve or at least to prevent, further degradation of what appears to be a rapidly worsening situation.

Each of the four sessions addressed a different aspect of the issue.

In the introductory session on "Counterfeiting in perspective", the Workshop received reports on the types of counterfeiting which occur in both developing and developed countries. The spectrum of illegal activities which needed to be considered by the meeting was outlined. They ranged from the highly sophisticated production of counterfeit branded products which are almost indistinguishable from the authentic product, to poor-quality substitutes of authentic generic products.

In the second session on "The role of legislation and enforcement" an overview was provided of the different types of legislation which need to be implemented and enforced in order to control counterfeiting. The role and use of the WHO Certification Scheme was reviewed, and examples were provided of legislative measures adopted in a developing country (Thailand) and in a developed country (Italy). A discussion was held on the GATT proposals for the protection of intellectual property rights and for control of all types of counterfeiting, and the potential application of these proposals

for the control of counterfeit pharmaceuticals at an international level. The need for cooperation between the different enforcement agencies was emphasized in the presentation given by the representative from customs control. Because of the parallels between the illicit trade in counterfeit medicines and trafficking in drugs of abuse, a report was received on the implementation of controls under the international treaties on narcotic drugs and on psychotropic substances.

The third session on "Professional responsibility and education" addressed the role of the pharmaceutical industry, the pharmacist, the wholesale dealer and the consumer in ensuring that established professional standards are maintained and that adequate precautions are taken to minimize the possibilities of medicines being diverted and of counterfeit medicines being introduced into the legitimate drug distribution chain. There was a discussion of measures needed to protect consumers from counterfeit products. It was stressed that health education is needed to increase awareness amongst health workers, retailers and patients of the health implications of using counterfeit medicines and the importance of purchasing medicines only from authorized sources.

The discussion on "Information exchange" in the fourth session reviewed some of the systems currently in place for sharing information on instances of counterfeiting. They include the Counterfeiting Intelligence Bureau of the International Chamber of Commerce, the Interpol network, the Customs Cooperation Council Central Information System and the exchange of information between regulatory agencies through WHO. The experiences and views of two regulatory agencies (USA and Brazil) and a Commonwealth Secretariat report on experiences in West African countries also provided background to the discussions on ways to increase mutual confidence and willingness to cooperate in information exchange.

OBSERVATIONS

1. Society and all innocent parties in the healthcare chain are "victims" when counterfeiting occurs and it is important that they work together in an atmosphere of mutual cooperation and trust, rather than criticism, in order to combat the menace.

- Patients are the primary victims because it is their health and even lives which are put at risk when they take medicines without the safeguards which they are entitled to expect from legitimate pharmaceutical production and regulatory control.
 - Legitimate manufacturers are victims not only because of direct loss of revenue but because confidence in their products is undermined, leading to loss of sales. The reputation of the company and image of the products are both damaged.
 - Governments are victims because funds are used to purchase medicines of unknown reliability and safety and they are therefore failing in their objective to protect the public health. Governments are also victims because of fiscal revenue losses.
 - Healthcare professionals are the victims through loss of patient confidence in their services. When the professional is also the supplier (e.g. the pharmacist) financial losses may be incurred through the purchase of fake products.
2. There is evidence that trade in counterfeit products is facilitated where:
- there is weak drug regulatory control and enforcement;
 - there is a scarcity and/or erratic supply of basic medicines;
 - there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems;

- price differentials create an incentive for drug diversion within and between established channels;
- there is lack of effective intellectual property protection;
- due regard is not paid to quality assurance.

3. There is inadequate information about the scale of pharmaceutical counterfeiting. The Counterfeiting Intelligence Bureau estimates that 5% of all world trade in 1991 was counterfeit. This is likely to be greater for pharmaceuticals which are in high demand and easily transportable. Estimates from a wide spectrum of countries range from 0% to over 60% in sectors of the market that are inadequately controlled.

4. There is little consistent information on the source of counterfeits. It was noted, however, that there appears to be a clear correlation between the source of counterfeits and the absence of a strong intellectual property system.

5. Although the exchange of information on counterfeit pharmaceuticals has improved:

- there is a perceived inadequacy on the part of certain regulatory authorities in both developing and developed countries to acknowledge and manage the problem, perhaps because this admits to a failure in their control systems, perhaps because they are unable or unwilling to commit adequate resources to address the issue, or perhaps owing to other priorities.
- there is also a perceived reluctance on the part of authentic manufacturers to share information available to them, perhaps because of the lack of confidence in the way in which regulatory authorities address the problem, and in concern about the damage to the legitimate product which may result.

6. Counterfeiting varies from small "cottage industries" in some countries, to large international consortia, including some elements of organized crime. Often, those dealing in counterfeit medicines are also involved in counterfeiting of other products such as spirits, tobacco, perfume, etc. There are signs of generalized corruption including bribery or threats to politicians, officials, pharmacists and other groups.

7. Evidence is emerging of links between pharmaceutical counterfeiting and international narcotics rings. There are highly developed laws to address the distribution of narcotic drugs and psychotropic substances, in contrast with the lack of laws or adequate systems to cope with counterfeit drugs. Lessons can therefore be learned from the experience of the International Narcotics Control Board (INCB) and United Nations International Drug Control Programme (UNDCP) in trying to combat the illicit trafficking of narcotic drugs and psychotropic substances, through international controls.

8. There is a general lack of effective regulation and an appropriate legal infrastructure to manage the counterfeiting problem in both developed and developing countries, leading to surprising loopholes in the most sophisticated of systems.

9. Conditions are being created for a greater flow of counterfeits as border controls are relaxed or are abolished between countries.

10. While there is a need to avoid unnecessary public alarm, the principle of openness is, in the long-term, in the best interest of all parties.

11. Consumer-generated demand for inappropriate products, in a situation where they are misused or abused can encourage the availability of counterfeits.

12. Often there are insufficient official resources dedicated to prevention and prosecution in instances of the distribution and sale of counterfeit products.

13. Also in many countries there are insufficient channels available to pharmaceutical companies to pursue effective remedial action.

RECOMMENDATIONS

At International Level

1. There is a need for greater international awareness and acknowledgement of the hazards to health of counterfeit medicines. Political will is needed to mobilize resources for implementation of effective counter measures. Without political will and effective regulation, counterfeiting will continue to thrive.
2. Counterfeiting is an international problem which needs to be addressed by the implementation of international laws. A sound legal framework is provided by the proposed anti-counterfeiting provisions in the draft GATT-TRIPS Agreement (General Agreement on Tariffs and Trade-Aspects of Intellectual Property Rights including Trade in Counterfeit Goods), which is based on effective international trademark protection and supported by enforceable sanctions and penalties (including imprisonment). The workshop looks forward to a speedy conclusion of the current negotiations on this matter.
3. Governments should implement appropriate legislation that identifies the import, national transit and export of counterfeit goods into, across and out of their customs territories as a customs offence and should confer upon their customs services the necessary legal powers to seize the goods with a view to forfeiture if they are subsequently found to be counterfeit. Such legislation should provide for customs acting on an *ex officio* basis, and not only on application by the trademark owner.
4. A mechanism should be established through which organizations with an interest in tackling the counterfeit problem can exchange information about the nature and extent of counterfeiting, the movement of counterfeit products and concluded investigations into counterfeit operations. To be fully effective, this information network should include manufacturers, distributors, professional bodies and regulatory agencies.

5. A databank of cases should be established within a clearing house, that maintains a directory of interested organizations and the contact points concerned. The medium should also provide technical support for training those involved in the detection of counterfeiting activity.

6. Since investigation of an enquiry may be frustrated by leakage of information it was recognized that, until a given case is concluded, relevant information should be disclosed only to organizations and agencies in a position to assist in its investigation.

At National Level

1. A legal and administrative framework needs to be in place to define and control the legitimate drug market and the drug distribution system before effective controls can be applied to illicit trade and counterfeiting.

The establishment of a drug regulatory agency, with a registration procedure for all products is a prerequisite and the workshop endorsed the recommendations of the WHO Guidelines for Small Drug Regulatory Authorities. Full use should also be made of the WHO Certification Scheme for Pharmaceutical Products moving in International Commerce to establish the true origin of products. Counterfeiting of medicines should be an explicit criminal offence with appropriately severe penalties.

2. Adequate resources must be made available for inspection and enforcement of controls at all stages in the drug distribution chain. Laboratory facilities for carrying out analytical tests on products should be available everywhere, preferably on a national basis or, failing this, through regional or international cooperation.

3. The points through which pharmaceutical products can be imported or exported should be designated. Customs staff at these designated points should be alerted to the significance of pharmaceutical counterfeiting and trained to identify suspect counterfeit material.

There should be targeted inspection of pharmaceutical goods at border points and samples should be taken for analysis where appropriate.

4. Procedures should be established to ensure cooperation and exchange of information between the different branches of law enforcement: police, customs and the national drug inspectorate.

5. A critical examination of the whole legal framework should be made in both developed and developing countries in order to ensure that there are no 'loopholes' which allow pharmaceutical products to be manufactured, imported, exported or distributed outside the controls of Good Manufacturing Practices, product licensing and other regulatory requirements.

6. Pharmaceutical manufacturers, distributors and health-care professionals should notify their national customs service of any information which comes into their possession concerning possible import/export shipments of pharmaceutical products suspected to be counterfeit. Whenever possible, specific details should be provided of carrier, likely point of entry/departure, consignor/consignee, probable date of arrival, description of goods involved, details of packaging/labelling to assist customs to target the goods for interception.

7. National laws should provide rights of private action by companies to enforce their trademark rights through seizure of clearly suspected counterfeit shipments. Such rights, which are exemplified by the U.S. 1984 Anti-counterfeiting Act, can provide additional protection to patients and manufacturers if:

- confidentiality in associated legal proceedings is protected, and
- penalties for their infringement constitute a serious deterrent.

8. Developing countries should study, in particular, the countermeasures adopted in some countries of West Africa, and consider the adoption of a similar strategy.

The Pharmaceutical Industry

1. The national industry associations and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) should encourage pharmaceutical companies to share information both with drug regulatory agencies and among themselves when instances of counterfeiting are detected. The development of guidelines should be considered.

2. The industry should continue to develop anti-counterfeiting measures such as packaging and labelling (e.g. use of holograms) which are hard to copy.

This includes the use of both covert and overt devices that are made known to reliable enforcement agencies to facilitate identification.

3. Manufacturers should ensure that they establish suitable security measures to detect and prevent diversion of ingredients, products and packaging material for illegal purposes.

4. The industry, through the IFPMA, should collaborate with the Customs Co-operation Council (CCC) over the preparation of guides and training material for customs officials and inspectors.

5. Industry should be prepared to contribute its expert knowledge on both packaging and the active ingredient profile of its products in undertaking or assisting in the inspection and analysis of suspected counterfeit products.

6. Pharmacists, wholesalers and manufacturers should cooperate with each other and with enforcement authorities to assure regular sampling and analysis of pharmaceutical products in circulation as a means to identify and deter counterfeiting activities.

Pharmacists

1. The professional bodies should exhort pharmacists to purchase stocks from reputable sources; to report to them any suspicion that they have been offered or have acquired counterfeit products; to isolate and withhold from sale any suspect products and to cooperate with enforcement agencies.

2. The professional bodies should also establish effective channels for communication and cooperation with enforcement agencies and legitimate manufacturers, and should act to disseminate information about suspected counterfeiting activity to their members.

Wholesalers

1. Products should reach the end user by the most direct route that is practicable. Distribution of products through a large number of intermediaries and complex transactions should be discouraged. Each facility within the distribution chain must be registered, licensed, inspected, and required to maintain complete records of the source from which the consignment was purchased.

2. Ideally the dispensing pharmacist should obtain medicines directly from a reputable manufacturer. In practice, a legitimate role exists for the responsible wholesaler. However there should not normally be more than one transaction between manufacturer and wholesaler, and wholesaler and dispensing pharmacist. Batch documentation should provide details of all transactions to which a given consignment has been subjected throughout the distribution chain.

3. As a condition of licensing, distributors should employ a suitably qualified person, preferably a pharmacist to assure responsibility for documentation and analysis.

4. To facilitate the investigation of suspected counterfeit products and their origin, acquisition and sales records should be available to authorized persons.

Consumers and Educators

1. The public should be sensitized about the existence of counterfeit products in order to mobilize the "political will" to assure implementation of effective countermeasures. In those countries where medicines are sold outside normal pharmaceutical channels, the public should be encouraged to purchase medicines only from reliable vendors.

2. A programme of education of community leaders, teachers, the media, the police, traditional healers and local health personnel about counterfeit medicines should be developed having regard to national circumstances.

3. The industry, professional bodies, regulatory authorities and the international community should ensure that consumers are given appropriate and timely information on the availability of counterfeit products, recognizing the complementary needs to provide relevant consumer information, without engendering unwarranted public alarm.

Next Meeting

It is recommended that a further workshop be convened in one year to review the situation and/or any progress made towards dealing with the problem of counterfeit medicines.

ANNEX 1

RATIONAL USE OF DRUGS WHA 41.16

The Forty-first World Health Assembly,

Recalling resolutions WHA37.33 and WHA39.27 on the rational use of drugs;

Having reviewed the report of the Executive Board on the implementation of WHO's revised drug strategy, aimed at ensuring the rational use of drugs;

1. NOTES with satisfaction that, in spite of severe financial constraints, the revised drug strategy is being carried out almost in its entirety, the implementation of the remaining components having been delayed solely due to lack of resources;

2. CONGRATULATES all parties concerned that have fulfilled their responsibilities in compliance with resolution WHA39.27, and encourages them to continue to do so;

3. INVITES bilateral agencies, multilateral agencies inside and outside the United Nations system, and voluntary organizations, to support developing countries in setting up and carrying out programmes aimed at ensuring the rational use of drugs, particularly essential drugs programmes, and thanks those that are already doing so;

4. REQUESTS the Director-General:

(1) to implement the remaining components of the revised drug strategy, seeking extrabudgetary resources in addition to those in the regular budget to this end;

(2) to include in his biennial reports to the Health Assembly information on the implementation of the revised drug strategy, and to provide reports thereon to the Executive Board from time to time, as necessary;

(3) to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations, and to cooperate with the Secretary-General of the United Nations in such cases when the provisions of the international drug treaties are violated.

13 May 1988

ANNEX 2

LIST OF PARTICIPANTS

Dr H. Bale, Jr. Senior Vice President, International, Pharmaceutical Manufacturers Association, Washington, D.C. 20005, USA

Dr W. Bannenberg, Public Health Consultant, Health Action International, International Organization of Consumer Unions, c/o Brederodestraat 5, 1054 MP Amsterdam, The Netherlands

Dr G. Battaglino, Director Chemist Coordinator, Pharmaceutical Division, Ministry of Health, 00144 Rome, Italy

Dr J. Y. Binka, Pharmaceutical Consultant, P.O. Box 8885, Accra-North, Ghana

Mr A. Cox, Trade Marks Manager, The Wellcome Foundation Ltd., 160 Euston Road, London NW1 2BP, United Kingdom

Mr W. Goetz, President, International Federation of Pharmaceutical Wholesalers, P. O. Box 117-E38, Alexandria, Virginia 22323, USA.

Mr R. Harper, representing AIM Brussels and Anti-Counterfeiting Group, c/o Smith Kline Beecham plc., Brentford, Middlesex, United Kingdom

Mr D. Hartridge, Director, GNG & Policy Affairs Division, General Agreement on Tariffs and Trade, Rue de Lausanne 154, 1211 Geneva 21, Switzerland

Dr D.C. Jayasuriya, Attorney-at-Law, G 2 NY Court, 67 Soi Chaern Chan, Soi 55 Sukhumvit, Bangkok 10110, Thailand

Mrs C. J. Kimmons, Head of Industry and External Affairs, Glaxo Pharmaceuticals UK Ltd, Stockley Park West, Uxbridge, Middlesex, United Kingdom

Dr J. Lakeman, Director, Quality Assurance, Organon International BV, Postbus 20, 5340 BH Oss, The Netherlands

Dr J. Leuchtner, External Relations Manager, Hoffmann-La Roche Ltd., Grenzachstr. 124, 4002 Basel, Switzerland

Mr Peter Lowe, Assistant Director, Counterfeiting Intelligence Bureau, Maritime House, 1 Linton Road, Barking, Essex IG11 8HG, United Kingdom

Mr D. L. Michels, Director, Office of Compliance/CDER, U.S. Food and Drug Administration, 5600 Fishers Lane (HFD-300) Rockville, MD 20855, USA.

Mr P. Morgese, Specialist Offices, ICPO Interpol, Secretariat General, 50 Quai Achille Lignon, 69006 Lyon, France

Mr P. Pachta, Officer-in Charge, Psychotropics Control Unit, International Narcotics Control Board Secretariat, UNDCP, Vienna, Austria

Mr L. B. Rowsell, Head, National Drug Monitoring Centre, Bureau of Pharmaceutical Surveillance, Ministry of Health and Welfare, Ottawa, Ontario, Canada

Dr Murtada M. Sesay, Assistant Project Officer, UNICEF Freetown, POBO 1011, Freetown, Sierra Leone (representing the Commonwealth Pharmaceutical Association — CPA)

Mrs S. Marsh-Sharpe, Head, Law Department, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN, United Kingdom (representing the International Pharmaceutical Federation — FIP)

Mr N. Sheffield, Technical Officer (Enforcement), Customs Co-operation Council, 1040 Brussels, Belgium

Mr Viroj Sumyai, Chief, Standards Control Sub-Division, Narcotic Control Division, Food and Drug Administration, Ministry of Public Health, Bangkok 10200, Thailand

Professor Antonio C. Zanini, Department of Therapeutics, Faculdade de Medicina, University of Sao Paulo, SP-Brazil

**International Federation of Pharmaceutical
Manufacturers Associations (IFPMA),
1211 Geneva 11, Switzerland**

Dr R. Arnold, Executive Vice-President,
Ms M. Cone
Mr J-F. Gaulis
Mr D. George

World Health Organization

Mr H. Benaziza, Health Education
Dr J.F. Dunne, Director, Drug Management & Policies
Dr M. ten Ham, Drug Safety (Secretary)
Dr Hu Ching-Li, Assistant Director-General
Mrs A.H. Mazur, Legal Counsel
Ms A. Wehrli, Drug Regulatory Support

BIBLIOGRAPHY

- PHA/CFD/91.1 The Brazilian Situation. Dr A.C. Zanini
- PHA/CFD/91.2 Customs Co-operation Council's action to combat counterfeiting.
- PHA/CFD/91.3 Professional responsibility in combatting counterfeiting of medicines/fake drugs — a new threat to health-care. Mr Murtada M. Sesay
- PHA/CFD/91.4 Italian activity on the control of medicaments.
- PHA/CFD/91.5 Counterfeit drugs: some policy and legal aspects. Dr D.C. Jayasuriya
- PHA/CFD/91.6 Counterfeit drugs: implications for health. Dr M. ten Ham
- PHA/CFD/91.7 Study on spurious drugs in some West African countries — Nigeria, Ghana and Sierra Leone/Control Training Programme (West Africa). Dr J.Y. Binka
- PHA/CFD/91.8 How to protect consumers against counterfeited drugs. Dr W. Bannenberg
- PHA/CFD/91.9 Counterfeit drugs and information exchange. Mr P. Lowe
- PHA/CFD/91.10 WHO support to national drug regulatory authorities with special emphasis on the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. Ms A. Wehrli
- PHA/CFD/91.11 Situation of counterfeit drugs in Thailand. Viroj Sumyai
- PHA/CFD/91.12 Counterfeit Medicines — the responsibilities of manufacturers. Mrs C. Kimmons
- PHA/CFD/91.13 Parallels with control of psychotropic substances. Mr P. Pachta
- PHA/CFD/91.14 Workshop on counterfeit drugs. Dr J. Leuchtner
- PHA/CFD/91.15 Counterfeit drugs/data and information relating to counterfeit drugs or medicinal preparations. Mr P. Morgese