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REPORT OF THE INTERNATIONAL WORKSHOP ON
COUNTERFEIT DRUGS

Geneva, 26-28 November 1997

Division of Drug Management and Policies
and
Action Programme on Essential Drugs

World Health Organization, Geneva, Switzerland

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SUMMARY REPORT
INTERNATIONAL WORKSHOP ON
COUNTERFEIT DRUGS

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- To the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), for their contribution to this International Workshop

Welcome and Introduction

**Dr F.S. Antezana, Deputy Director-General ad interim
World Health Organization**

(In the absence of Dr Antezana the speech was presented by
Dr J. Idänpään-Heikkilä, Director, Division of Drug Management
and Policies.)

“Ladies and gentlemen,

It is a great pleasure for me to welcome you to Geneva to participate in the second workshop on counterfeit drugs. I am pleased that we have been able to interest so many representatives from regulatory authorities, in particular from the developing world, where as we know the problem of counterfeit pharmaceuticals is most important. Many international organizations are present here, both from within the UN family and from without, too many to mention them individually, but you may be assured that we appreciate your interest.

The pharmaceutical industry is quite well represented, signifying that they take the issue seriously, and demonstrating that they are willing to collaborate with us in this important pharmaceutical area. Their support is instrumental in making this meeting possible, and I hope that our collaboration will continue.

I would like to introduce the work of this meeting giving you a short overview of the history of WHO's activities in the area of counterfeit pharmaceuticals. In 1985 a conference was held in Nairobi, which had as a major subject for discussion the rational use of drugs and how to develop a revised drug strategy. Among many other

achievements, the conference recommended that "WHO, with other international and nongovernmental organizations, should study the feasibility of setting up a clearing-house to collect data and inform governments about the nature and extent of counterfeiting". In 1988, the World Health Assembly adopted a resolution requesting the Director-General "to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations". Four years later, in 1992, WHO organized the first International Workshop on Counterfeit Drugs, in a joint effort with the pharmaceutical industry, represented by the IFPMA.

This workshop was the first international conference devoted exclusively to the problem of counterfeit pharmaceuticals. Before this meeting WHO's activities had been necessarily restricted, due to budgetary constraints, to the collection of data, resulting in the first version of the database that was to be further developed at a later stage.

The workshop broke new grounds in several aspects. A major result was that awareness was created of a problem that had only been realized in a few expert circles: that of fake pharmaceuticals. An important outcome of the workshop was the definition of a counterfeit pharmaceutical that was formulated during the meeting, a definition that has been subsequently quoted in many publications and studies. Another important aspect of this meeting was that the main thrust was on the consequences of drug counterfeiting for public health.

A few years after this workshop, WHO received considerable financial support from the Government of Japan. This resulted in a project on counterfeit drugs organized jointly by the Division of Drug Management and Policies, and the Action Programme on Essential

Drugs. In the framework of this project a database was set up, containing information derived from anecdotal reports in published literature, and on reports received directly from Drug Regulatory Authorities and industry.

At an early stage it was felt that quantitative information on the size of the problem of counterfeit drugs was needed. Two country studies were carried out, one in Viet Nam, and another in Myanmar. The preliminary results will be discussed later during this meeting.

The last few years the project included the organization of several consultations. These consultations have resulted in a number of guidelines: for pharmaceutical inspection, for subsequent examination of suspected samples, and on training programmes. One consultation formulated guidelines to assist Governments to develop a programme for combating counterfeit pharmaceuticals. A model training course for combating counterfeit pharmaceuticals has recently been held in Japan to assist drug inspectors. A workshop for decision-makers has also been held in Viet Nam

This brings me to one of your assignments of this meeting. At a consultation in March this year it was concluded that the various guidelines produced would gain in understandability and applicability if they were combined into one Manual on the Combatting of Counterfeit Drugs. You have been sent a copy of the draft of this document, and we would be very grateful if you would give us your comments on this text.

I would like to come back briefly to the report of the 1992 Workshop. As I said, several recommendations were formulated. However varied they may look at first sight, they have one important common point: There is a great need to increase awareness, in all

parties, without exception. This can only be achieved if all parties work together. Awareness and concern about counterfeiting can only be raised if all concerned know what is going on in this area. The most important recommendation of the 1992 Workshop therefore was to establish a network for the exchange of information on counterfeit pharmaceuticals.

At the 8th International Conference of Drug Regulatory Authorities in 1996 in Bahrain it was decided that WHO should set up a network of officers in Ministries of Health to deal with such matters. This matches quite well with the recommendations of the previous workshop, stating that an improved system of information exchange was needed between parties concerned.

But these parties include not only drug regulatory authorities, but also other international institutes dealing with this subject, including the pharmaceutical industry. Only if all of us work together can we succeed. The development of an efficient system of exchange of information is your other assignment for this meeting. I realize that information may be of a confidential nature, but this should not prevent us from active collaboration.

In conclusion, apart from general discussions on the problem of counterfeit pharmaceuticals and approaches to combat them, two major issues for this meeting are:

1. To discuss the draft Manual on combating counterfeit pharmaceuticals; and
2. To establish and develop a network for exchange of information.

One final issue I need to mention: this Project was made possible through the generous support of the Government of Japan. This support was intended for a three years period, which is now coming to an end. The problem of counterfeit pharmaceuticals has not been solved, far from that. Probably it will never be solved completely, but we have to continue our fight. We would need more training courses, in other areas of the world, such as Africa and Latin America. We need to develop our network, and collect information. We need human and financial resources to do that. I hope that there will be other sponsors standing up to help WHO continue this important activity, and enable us to continue to help in particular those countries that suffer most.

I wish you a very successful meeting."

* * *

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. (From: "Counterfeit Drugs". Report of a Joint WHO/IFPMA Workshop, 1-3 April 1992, ref. WHO/DMP/CFD/92; and the Draft Report of an Internal Consultation which took place from 11 to 13 September 1995 in Geneva.) 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 incorrect quantity of active ingredient or with fake packaging.

* * *

Officers for the Workshop were nominated as follows:

Chairperson	Dr F. Rosenberg, Brazil
Vice-chairpersons	Dr S. Keitel, Germany and Dr V. Lepakhin, Russia
Rapporteur	Dr G. Munro, United Kingdom

An overview of the activities of the Division of Drug Management and Policies (DMP) was presented by Dr Idänpään-Heikkilä, who focused briefly on its history, moving rapidly into its role on anti-counterfeiting. He mentioned the documents, guidelines and studies relating to quality and effectiveness for pharmaceutical products and biologicals, including the International Pharmacopoeia, the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and the WHO Good Manufacturing Practices for Pharmaceutical Products, many of which now accommodated those derived from the International Conference on Harmonization.

Dr J.D. Quick, Director, Action Programme on Essential Drugs (DAP), presented an overview on the activities of the Programme, setting out the three main issues it addresses as the programme working at country level to ensure:

- equity of access to essential drugs
- rational use of drugs
- drug quality

The Programme tries to reach its aims by linking policy and technical direction in country programme development through partnership and collaboration..

Session 1 Surveillance of Counterfeit Pharmaceuticals

Dr K. Kimura, DMP, introduced the WHO Data Base on Counterfeit Pharmaceuticals, which included the following facts:

- 751 cases of counterfeiting had been received between 1982 and October 1997
- 25% of cases were found in developed countries and 65% in developing countries
- the majority of counterfeit products are discovered by visual detection
- reports embraced virtually all classes of products, but antibiotics appeared to be the most common.

However, some caveats needed to be stated. These were:

- that the cases were not validated as this could only be done by painstaking research into each individual case
- some regions did not respond as well as others

It was noticed that in over 90% of countries which responded to WHO questionnaires, pharmacists, pharmacies, and other drug outlets were regulated. However, GMP and licensing of importers was only regulated in 70% and 78%, respectively of those countries responding. The essential problem appeared to be that counterfeit products escape quality control.

Mr E. Wondemagegnehu, DAP, then reported on the WHO country studies on counterfeit pharmaceuticals, carried out in Viet Nam and Myanmar. Questionnaires had been sent out to these countries relating to the drug supply systems, regulatory capability and performance and counterfeit drug problems.

Results were presented indicating problems with substandard products in both countries, some of which appeared to implicate counterfeiting. Out of 212 samples tested in Myanmar: 34 were found to be substandard, but genuine; six samples were found to be mislabelled with respect to their source, but had passed laboratory testing; and one sample contained wrong ingredients.

The Pharmaceutical Security Institute (PSI) was presented by Dr F.G. Madsen, who first described the history of this Institute. He emphasized the increasing role of organized crime and the

opportunities presented by parallel importation to the counterfeiter. He indicated that the Workshop should remember that the gap between the cost of manufacture and the sales price of research and development based pharmaceuticals, in particular, would continue to present a major opportunity for criminals who did not bear the heavy research and development costs of the products which they counterfeited. He went on to provide summary information on investigations into counterfeiting activities in the Philippines and China, and on counterfeited starting materials which had been proven to have caused a number of deaths in children in several countries. He concluded that counterfeiting posed a major challenge due to the international aspects of the manufacture and supply of pharmaceuticals. This rendered its control multi-jurisdictional, presenting a major opportunity for criminals to exploit the lack of multi-jurisdictional enforcement around the world.

Miss C. Bruneton responded on recent studies of counterfeit pharmaceuticals carried out by RéMed in Cambodia, Chad and Burkina Faso. The drugs studied were those most commonly used in Cambodia and generic antituberculosis drugs in Chad where the focus was also on temperature and control of storage and transportation and its impact on the quality of drugs. In Cambodia, two cases of under-dosing and five of substitution were detected, while in Chad, the products from eight different manufacturers, all of whom were overseas appeared inconsistent in respect to content of active ingredients.

In the general discussion, the issue of substandard versus counterfeit product emerged more clearly. The Workshop concluded that substandard products were a very important issue, and suggested that they should be treated as a separate topic.

The current definition of counterfeit was also challenged partly due to its tight legal definition and also because of the inclusion of the word deliberate.

More information was provided on the report from PSI on counterfeiting in Indonesia, supporting the view that estimates of the level of counterfeiting in any one country were very unreliable. More specifically the WHO Data Base is not validated as only national authorities can validate such information on a case by case basis. However, as a general pointer it was stated that various international organizations have reached the conclusion that approximately five percent of all branded products moving in international trade are counterfeit. Therefore we have to accept that a problem exists.

The issue of "lookalikes" was also raised. Although this is not counterfeiting in the strict sense of the word, measures are needed to prevent packages being printed that are too close to the branded products.

The need for collaboration between regulatory authorities, medical and pharmaceutical professions, and the industry, was also emphasized. However, it needs to be borne in mind that criminal investigation is not part of the remit of WHO.

Session 2 Combating Counterfeiting - A Shared Responsibility

Mr S. Howells opened the session by sharing experiences and counter-measures in Australia in counterfeit pharmaceuticals. He gave a short history of the Australian medicine legislation, which since 1991 has covered on a federal basis, all pharmaceutical products and medical devices, and has rendered the import and export of

unapproved drugs a criminal offence. To enforce all criminal aspects of the Australian legislation, a unit had been established comprised of criminal investigators and analysts. These staff were not trained as pharmacists, doctors of medicines or scientists or technologists, but were ex-police or criminal investigators. Even though a dedicated resource had been established, prioritization of activities was still necessary. Counterfeiting is high on the list. Mr Howells stressed the difference between counterfeit and substandard products, and that his group worked with other agencies as the crime of counterfeiting was international.

A major part of the Australian strategy has been to focus on the place of importation, and as a result the number of detected offences in this area has increased. This has resulted in larger seizures of drugs entering Australia and as a consequence, a significant decrease in the reports of illegal supply of pharmaceutical products in Australia.

Mr B.R. Wadhawan presented the experiences and counter-measures in India on counterfeit pharmaceuticals. In India, the definition of counterfeit was divided into three categories: misbranded (mislabelled); adulterated; and spurious drugs, for which stringent penalties have also been laid down in the statutes. In recent surveys on drug testing by the laboratories, 10% to 12% of pharmaceutical products were reported to be substandard on analysis, whereas 0.02% spurious/adulterated products were detected. He also raised the issue of phonetically-lookalike drugs.

Professor G.E. Osuide presented the Nigerian experiences and counter-measures. He emphasized that fake medicines create real hazards to public health and are seen in almost all therapeutic classes. Substitution of a cheaper product for one with a higher sales price,

but which looked the same as the higher one, was a relatively common form of counterfeiting. In an even more extreme case, wheat flour might be used as a substitute for antibiotics.

The response of the Nigerian Government has been very positive since its awareness was heightened and the regulatory rules were strengthened in 1989 and further in 1993 when the National Agency for Food and Drugs was established. As a consequence, unregistered products are not allowed to be sold, factories are inspected, and samples are analysed, including imported products. The Government intended to completely eradicate counterfeiting. He made a strong plea for other countries to control exports to make the task of developing countries with scarce resources easier.

Mr T. Vermillion gave some indications of the work of the FDA's Enforcement Unit, which had a similar role to that described by Mr Howells in Australia. The Unit works under statutory laws relating to medicines and other similar statutes involving money laundering, fraud and trademark protection. Staff included criminal investigators, intelligence and technical specialists. Cooperation with other institutions both nationally and internationally was being developed as there was evidence that counterfeiting involved international crime. He believed that the Internet may provide an additional dimension.

Dr H.E. Bale presented the IFPMA perspective, by stressing that industry had raised the profile of counterfeiting pharmaceuticals, and taken practical steps towards its prevention. These included anti-counterfeiting measures such as holograms, methods of detection for counterfeits, and an organized effort through the Pharmaceutical Security Institute to coordinate investigations and internal training in detecting counterfeiting within the research-based industry. The main

concerns of IFPMA are the need for stronger promotion of national and international conventions to strengthen intellectual property, to raise awareness and to resist such measures as parallel trading. The over-riding concern, however, was with protecting health, profits for research, and damage to the confidence of patients in medicines they were taking. He maintained that because medicines are low bulk/high value commodities, they continued to be a target for counterfeiting, particularly where penalties were not severe enough. He cited three key factors which contributed to allowing counterfeits to thrive: the trade through brokers outside of the regulated supply chain; parallel trade; and in some countries a lack of adequate control of manufacture, wholesale dealing, and the pharmacists. Major tasks were to raise awareness of both the health hazards and economic consequences to obtain national government support. He wished to see legislation introduced to ensure quality by more adequate trademark protection against counterfeiting through article 61 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, being implemented nationally.

Mr J.-Y. Videau presented the experiences of Pharmaciens sans Frontières, who had started their activities as a purchasing centre. In the course of sampling from the field, they had identified a number of counterfeit products in Guinea, Haiti, Niger, Cameroon and Uganda.

Mr R. Khalid presented experiences in Pakistan. His views on the WHO Draft Manual were very positive. However, he saw a number of issues which needed to be addressed, such as a continuing lack of determination and efforts worldwide to combat the menace, inadequate resource of manpower and materials, and scarcity of networking and intelligence information. Consequently he believed that there needed to be action to get the attention of governments

worldwide and to encourage manufacturers to disclose any information which they had on counterfeiting. He recommended the nomination of a focal point within each national drug regulatory authority and reduction of disparity in drug prices, and increase in collaboration amongst the governmental and nongovernmental organizations. Mr Khalid also emphasized on the need to increase checks to stop the export of expired or almost expired finished drugs and raw materials. He proposed that WHO give due priority to this vital issue, the adverse implications and extent of which are grossly under estimated.

Panel Discussion

Dr Kimura gave a short presentation on the WHO Draft Manual explaining that its scope and objective was to consolidate the various WHO documents for combating counterfeits into one manual to be used mainly by the governments of Member States. It was structured around three key concepts: grasping the situation; preparing the tools; and implementation and review. These three key concepts were structured in the draft Manual into sections on National Implementation Guidelines, How to Assess the Counterfeit Problem at the National Level, Inspection and Examination of Drug Samples to Detect Counterfeiting, Testing Methods, and Guidance for Developing Training Programmes in Inspection and Examination of Counterfeit Pharmaceuticals.

Dr G. Küsters (GPHF), gave a short summary of the technology for detection of counterfeits which they had developed, known as the Mini-lab. They had selected frequently counterfeited drugs and chosen validated methods which had been incorporated into a manual, and later tested in the field. A network of users had been developed in developing countries where the thin-layer

chromatography and colour reaction based approach was now in use. The total cost of the package was about US\$2200.

Questions were raised about when information should be exchanged relating to counterfeits. The general response from the regulators was that this should be prioritized on the basis of potential risk to patients, which if severe enough should over-ride any concerns about damaging the ability to build a criminal case later. In response to the same question, the PSI indicated that they might buy back products from the market to protect patient health while still trying to build a case against the counterfeiters. In addition, it was stressed that investigative activities often carried a high risk to the agents involved and that care had to be taken to ensure that such investigators were protected as much as possible.

In response to a specific question relating to how the Australian Regulatory Authority could prosecute outside Australia, they explained that while their jurisdiction was national, they could and would collect evidence wherever it was necessary, perhaps in liaison with other agencies. PSI indicated that they did provide advice to their members on identifying counterfeits and prevention of counterfeiting. Furthermore, they were considering opening up their proposed training course for representatives from industry early next year to allow participation by other interested parties.

During the remaining question and answer session the need to share information was identified and stressed. The question was posed as to whether there should be a legal obligation on manufacturers, wholesale dealers and brokers, to tell regulatory agencies of any counterfeiting problems of which they became aware. One barrier to good communication was identified as the lack of

definition of who was responsible for anti-counterfeiting in the various countries around the world. A possible connection between free trade zones and counterfeiting was pointed out.

The need to successfully control the destruction of excess products, raw materials, packaging components and expired products was stressed by a number of delegates. A request for model legislation for drug regulation to be supplied by WHO was believed to be already met in the Report of the Thirty-fifth Expert Committee on Specifications for Pharmaceutical Preparations. This Report would be published in the WHO Technical Report Series. A recurring theme in the discussions was that anti-counterfeiting was a shared responsibility between Member States and that drug regulation should include pharmaceutical products intended for export.

Session 3 Prevention and Detection of Counterfeit Pharmaceuticals

Ms F-Cabanlas briefly described the situation before 1995 in the Philippines. Since then action had been strengthened against counterfeit pharmaceuticals. A technical working group had been created with representatives from industry and the government, who had drafted revisions to their existing drug regulations. These introduced specific new charges including possession of counterfeit materials, printing, packaging and other materials without authority, and spelt out stronger punishments. While using the WHO definition they have added some country specific requirements. Training of inspectors, investigators, those who test drugs, and those involved in enforcing the new provisions of the law had been undertaken. In conclusion, Ms F-Cabanlas said that the key question which was

posed whenever they brought cases to court was "Is this a public health case, or one for the protection of industrial intellectual property".

Dr G. Munro introduced his talk on the experiences of the Enforcement Group in the U.K. on sophisticated counterfeit products by summarizing the legal framework and methods of inspection and enforcement. He indicated that anything which might make money could be counterfeited. He particularly called attention to the "suitcase trade" where thousands of pounds worth of goods could be shipped by one person in personal baggage, moving on ordinary commercial transport. While the incidence of counterfeiting in the U.K. is very low, a number of cases of diversion have been detected, mainly of products destined for overseas markets. Detection of sophisticated counterfeits is becoming more difficult and more advanced techniques are required. Despite the presence of a well structured licensing, and medicines control system, it is still possible for determined criminals to try to introduce products into the supply chain. Hazards to health from sophisticated products are essentially the same as those of all counterfeit pharmaceuticals ranging from lack of purity and potency to inability to perform effective recalls. In the United Kingdom, the Medicines Act carries criminal penalties, including failure to provide product of the appropriate quality. However, additional charges through the Theft and Forgery Acts have also been brought against counterfeiting. Alongside these, a policy of disrupt and destroy was also employed, when legally enforceable. In conclusion, he said that the keys to success were good intelligence, cooperation, hard work and diligence all supported by strong government policy and skilled legal and criminal law specialists.

Mr S. Mahoney introduced his presentation on international enforcement actions against counterfeit pharmaceuticals, a brief history of Interpol stressing its role in communications between police forces and supporting cooperation. However, there was currently little information with Interpol on counterfeit pharmaceuticals. He

stressed that combating organized international crime needs international police cooperation. In addition, drug cartels employ skilled lawyers and technical staff who will make every effort to foil efforts to detect and prevent crime.

Interpol could be regarded as a central repository for information. In the last year 1.6 million messages between its members had been processed. He indicated that their data bases could be relatively easily modified to carry information on pharmaceutical counterfeits if there was a desire to do so.

In the discussion which followed the particular challenges faced in some developing countries were highlighted, such as the problems which sometimes appeared when attempts were made to strengthen regulations and the lack of such fundamentals as operational quality control laboratories. The view was expressed that counterfeiting represented a different problem in different countries, emphasizing the need to work together to find and improve the means of combating the problem. WHO was asked to provide education and training, since they were key factors, and also to promote the fact that people should take pharmaceutical products from the controlled supply chain. The Philippine approach to matching penalties to the gravity of the offence was generally applauded.

Session 4 Working Group Discussions

The meeting were divided into three working groups to discuss the draft Manual to combat counterfeit pharmaceuticals (Working Group 1, chaired by Ms F-Cabanlas and Working Group 2, chaired by Mr Tsuda) and information exchange, database and indicators for counterfeit pharmaceuticals (Working Group 3, chaired by Mr Howells). Feedback from Working Groups 1 and 2 suggested some changes to the draft Manual, while Working Group 3 commended measures to strengthen the information network and international databases.

Conclusions from the Working Groups discussions are included in the Recommendations.

Closure

The workshop was closed by Dr Quick, who highlighted the magnitude of anti-counterfeit measures developed since the previous international workshop on counterfeit drugs held in 1992, and emphasized shared responsibility among related parties such as Member States, UN agencies, nongovernmental organizations, health-care professionals, police and Interpol. He also stressed collaboration at country level in communication between counterparts, information exchange and training. He concluded that the termination of the WHO Project on counterfeit drugs does not necessarily mean the completion of work but rather the beginning of further work.

Recommendations

International level

1. WHO should collaborate with other international organizations such as Interpol, UNICEF and UNIDO, with a view to eliminating international trading in counterfeit pharmaceuticals.
2. WHO should continue to support regional/subregional/national training programmes, in particular, for trainers on detection of counterfeit pharmaceuticals.
3. WHO should emphasize to Member States that they give high priority to measures aimed at combating the menace of counterfeit pharmaceuticals, and also to mobilizing resources of man power and materials.
4. WHO and Member States should take necessary measures to ensure the quality of raw materials by avoiding the undue existence of inactive isomeric forms, no shelf life or no indication of manufacturers, which can directly affect the quality of final products.
5. The WHO anti-counterfeit programmes should continue, focusing principally on
 - (a) exchanging necessary information
 - (b) maintaining and co-ordinating the network of liaison officers
 - (c) monitoring the factors facilitating pharmaceutical counterfeiting throughout the world

- (d) providing guidelines for organoleptic detection
 - (e) controlling exports
 - (f) evaluating progress
6. WHO should make information available in a database and also develop and standardize information relating to the local definition of a pharmaceutical product and counterfeit. The database should contain:
- (a) an up-dated list of liaison officers for the anti-counterfeit pharmaceuticals network
 - (b) the policy and health risk including financial consequences
 - (c) case reports, including useful information such as products involved, course of events and detecting processes.
7. Member States, international organizations, nongovernmental organizations and other related parties should take the necessary measures to detect and prevent substandard, look-alike and other spurious drugs which cause a similar menace to that of counterfeit pharmaceuticals to public health.
8. Member States and international organizations should endeavour to make technical documents available in the official languages.

National level

9. Member States should collect information and assess the actual situation of the counterfeit pharmaceutical problems in their country, as well as to introduce anti-counterfeiting measures by utilising the factors facilitating pharmaceutical counterfeiting which are set out in the Manual .
10. Member States should put the guidelines, guidances and other tools in the Manual on combating counterfeit pharmaceuticals into actual use, in accordance with the nature of the counterfeit problems in their country, and that WHO and other international organizations should provide the necessary assistance for their implementation.
11. The liaison officers for the anti-counterfeit pharmaceuticals network should:
 - (a) ensure timely exchange of information, both on cases of counterfeit as well as on countermeasures with counterparts in other countries.
 - (b) develop and coordinate national liaison network with other regulatory agencies, professional bodies, manufacturers and distributors
 - (c) be responsible to compile and report significant completed criminal investigations to WHO for further dissemination

WHO should provide the liaison officers for the anti-counterfeit pharmaceuticals network with terms of reference relating to their tasks.

12. Member States should organize training courses on detection of counterfeit pharmaceuticals for inspectors, examiners, health-care professionals and other related personnel.
13. Member States should ensure that effective mechanisms exist to conduct criminal investigation and prosecution in relation to counterfeit pharmaceuticals, as well as to have the authority to enforce anti-counterfeit pharmaceutical legislation nationally.
14. Member States should collaborate with industry to prevent their products being counterfeited.
15. Pharmaceutical manufacturers should be encouraged to collaborate with National Drug Regulatory Authorities in providing information and materials, where appropriate, on the physical attributes of their products.

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