

# **REPORT OF PRE ELEVENTH ICDRA SATELLITE WORKSHOP ON COUNTERFEIT DRUGS**

13 and 14 February 2004, Madrid, Spain

## **1. INTRODUCTION**

The workshop was organised in cooperation with the Spanish Medicines Agency and it took place in their premises. It was attended by approximately 100 participants, consisting of national drug regulatory authorities, international organizations, nongovernmental organizations, industry associations, media and others.

Invited speakers representing national drug regulatory authorities (NDRAs), international organizations, associations of pharmaceutical industries and nongovernmental organizations made presentations reflecting their experiences in combating counterfeit drugs. The main topics of presentation were:

- Combating counterfeit drugs: national experiences
- Investigations and actions against counterfeit medicines: industry perspective
- E-commerce: challenges of controlling pharmaceutical trade
- Combating counterfeit medicines: international organizations' perspective

The workshop also discussed a draft concept paper prepared by WHO entitled "An international framework convention for combating counterfeit drugs and related strategies."

The WHO data base on counterfeit drugs was also presented and copies of CD-ROMs were distributed.

## **2. SUMMARY REPORT OF THE WORKSHOP**

### **SESSION 1: COMBATING COUNTERFEIT MEDICINES: NATIONAL EXPERIENCE**

*Dr James Makumbi, Moderator*

*Mr Peter Lowe, Rapporteur*

#### **1) Mr Steve Howells, Head, Surveillance Unit, Therapeutic Goods Administration, Australia**

Mr Howells mentioned that counterfeiting is a crime in Australia. He said that the crimes of counterfeiting include the import, export, manufacture and supply of counterfeit goods and mentioned that there were four separate distinct criminal offences, all of which could be prosecuted. Counterfeit imports and exports can also be seized and destroyed without prosecution.

The penalties for counterfeiting in Australia if committed by an individual include a fine of AUD\$ 220,000 and 5 years imprisonment. If committed by a cooperation the fine is AUD\$ 1,100,000.

Mr Howells gave a number of different examples of counterfeit pharmaceuticals, including: the bulk substitution of unapproved products, counterfeits with wrong ingredients, counterfeits where overlabelling had taken place on a competitive product, counterfeits where veterinary products had been sold for human use, and examples of counterfeit packs and processes. He said that counterfeiters would copy anything for money including herbal tea.

Regarding current trends, Mr Howells gave an example where a Certificate of Pharmaceutical Product (CPP) had been forged and used to gain registration of a counterfeit good in an importing country. This had required the introduction of a new law to criminalize copying CPP documents. Other recent trends included counterfeit goods being imported in the same container as other counterfeit goods such as clothing and footwear. Mr Howells indicated that the essentials of an effective anti-counterfeiting programme included:

- The adoption of WHO Guidelines on Developing Measures for Combating Counterfeit Drugs
- Making counterfeiting pharmaceuticals a specific crime with appropriate severe sanctions
- Having an effective licensing and registration system
- Effective regulation of pharmaceuticals including export controls - product registration, inspection and licensing
- Assigning drug regulatory authority investigators
- Increasing local and international cooperation between NDRAs, nongovernmental organizations (NGOs), law enforcement agencies and industry
- Raising public and decision-makers awareness that counterfeiting of pharmaceuticals is a serious public health risk
- Support of industry

**2) *Mr Xu Chen, Division Director, Department of Market Compliance, State Food and Drug Administration (SFDA), China***

Mr Xu Chen mentioned that the Chinese Government is fully committed to a drug safety programme to combat counterfeit medicines proactively. In 2003 the Chinese Government established the SFDA.

Mr Xu Chen described the legal system for combating counterfeit medicine and gave some general information about how the Chinese Government had implemented this in recent years.

In 2003, the Chinese Drug Administrative Authorities (CDAs), in conjunction with the Ministry of Public Security, launched a joint action to crack down on the illegal counterfeit medicines marketed in China. In 2004 the CDAs will continue their regulatory activities by collaborating with other agencies to tackle the ongoing problem with a number of different initiatives.

Mr Xu Chen concluded his presentation by summarising the measures put in place to combat the spread of counterfeit medicines in China. These include:

- Strengthening the drug inspection system
- Implementing the “Five don’t-let-it-pass” principles
- Working with different levels of government to ensure effective cooperation between departments
- Carrying out regular drug sampling exercises to identify the incidence of counterfeits
- Implementing new working methods to ensure effective control and supervision
- Working effectively with consumers to ensure effective drug supervision

**3) Mrs Ta Thi Phuc Chan, Head, Drug & Cosmetic Quality Management Division, Drug Administration of Viet Nam (DAV), Viet Nam**

Mrs Chan discussed measures taken to fight counterfeit drugs and implement good manufacturing practice (GMP) in Viet Nam. She began by giving an overview of the situation in Viet Nam and the network for monitoring the quality of drugs. She also mentioned the Government's Drug Quality Assurance Policy, the legislation that covered Public Health in the country, technical guidelines and the system of pre-market approval of pharmaceutical products. Mrs Chan displayed several graphs that indicated the presence of substandard and counterfeit drugs in Viet Nam, for example, one graph showed that more than 40,000 drug samples had been tested each year between 1997 and 2002. Another graph showed that a total of 70 batches of substandard drugs had been recalled in 2002 of which 51 were foreign imported products and 19 batches were locally produced. A further graph showed a number of counterfeit drugs detected between 2000 and 2002. The categories of products detected were: antibiotics, anti-inflammatory drugs, traditional and herbal medicines and others. The graph also showed that the incidence of counterfeit traditional and herbal medicines is on the increase.

Looking at the difficulties, which contributed to the counterfeit pharmaceutical problem, Mrs Chan mentioned that there are a number of factors involved including:

- Poor state of the economy and low income per capita
- Drug smuggling across the border
- Lack of drug retail outlets in the countryside and some of the mountainous areas
- Lack of education about the danger of counterfeit drugs
- Lack of awareness by consumers of the legislation relating to counterfeit drugs
- Corruption

Mrs Chan emphasised the importance of post-marketing surveillance in tackling counterfeit drugs and also mentioned the need to organise workshops and publicise the problem of fake pharmaceuticals in the marketplace. She also stated that there is a need to share information on detected cases and measures taken against counterfeiters of drugs.

#### **4) Mr Aphichai Hoonchamlong, Pharmaceutical Inspector, Thai FDA**

Mr Hoonchamlong began by providing an overview of the Thai FDA and its activities. With regard to counterfeit drugs these include surveillance of illegal drugs in the market place, taking samples and analysing these and carrying out investigations where necessary. Mr Hoonchamlong mentioned that law enforcement had significant powers to tackle counterfeit drug dealers, the maximum penalty being from 3 years to life imprisonment as well as a fine of between Baht 10,000-50,000 (Euros 200-1,000 approx). He mentioned also that there was close cooperation between the police, customs, the private sector, NGOs, international agencies and neighbouring countries.

Mr Hoonchamlong said that there is regular training for Thai FDA officers, local surveillance officers and other enforcement officers on the issue. The Thai authorities also provide information and warnings about counterfeit drugs through the media, newspapers, television and lectures on the subject. There is also information to be obtained from government web sites and CD-ROMs, which are distributed to enforcement officers carrying out the surveillance.

Mr Hoonchamlong gave some examples of counterfeit drugs found in Thailand between 2002 and 2003 and concluded by summarising the main problems encountered in regulating counterfeit pharmaceuticals:

- Lack of collaboration and cooperation between different regulatory agencies both at national and international level
- The economics of supply and demand – the issue of poverty/low purchasing power compared with the high price of drugs
- Lack of human and financial resources in the NDRA
- Insufficient exchange of information about the problem.

#### **5) Dr Justine A Molzon, Asso. Director for International Programme, USA FDA**

Dr Molzon gave a brief overview of the drug-counterfeiting problem in the USA and the way in which the FDA was trying to combat it with the Counterfeit Drug Task Force. She provided a chart to show the increasing level of counterfeit drug cases, which numbered 22 last year. Dr Molzon illustrated the sophistication of the counterfeits coming into the US by giving examples of different drugs with the counterfeit side by side with the genuine. In one of these illustrations, the only difference was the absence of a degree symbol in the counterfeit. She covered the public health concerns arising from the availability of counterfeit pharmaceuticals and outlined the work of the FDA Counterfeit Drug Task Force, which was convened in July 2003. The Counterfeit Drug Task Force has produced an interim report and is about to publish its final report within the coming weeks.

Dr Molzon mentioned that the interim report had discussed the implementation of overt and covert anti-counterfeiting technologies as well as track and trace solutions. Other potential options include strengthening wholesaler licensure requirements, updating FDA regulations where necessary, developing voluntary secure business practices and installing anti-counterfeiting/security teams within businesses. In addition, other

measures suggested included enhancing MedWatch, creating a counterfeit alert network and increasing the educational efforts for stakeholders. She also stressed the importance of developing global standards to cover: packaging, tamper evident, product pedigree, anti-counterfeit measures and track and trace technologies.

Dr Molzon also addressed the issue of what consumers could do to protect themselves from counterfeit drugs and recommended that consumers should only purchase from US state-licensed pharmacies and if buying over the internet they should ensure that the web site has the Verified Internet Pharmacy Practice Sites (VIPPS). She also suggested that consumers should be vigilant when taking pharmaceuticals and check the packaging, labelling, colour, taste and shape of a pill, as well as noting unanticipated side effects.

On the international front, Dr Molzon called for improved cooperation between law enforcement, identification of counterfeits, and use of anti-counterfeit measures.

#### **6) *Mr Hashim Ubale Yusuf, National Authority of Food and Drug Administration and Control (NAFDAC), Nigeria***

Mr Yusuf gave a history of the Nigerian health care system from the 1980's to the present day. He highlighted that the Nigerian health care system was dependent on imports and that the wealth Nigeria derived from the crude oil industry resulted in good quality drugs being readily available. The disfunction of this affluence was that corruption became rife and for many years counterfeiting, as a result, became prevalent. The extent of this corruption overwhelmed the ability of the NDRA to regulate. However, in 1993 a new agency was formed with autonomy and extra powers. This new agency, the National Authority of Drug Administration and Control (NAFDAC) is now attacking the counterfeit drug problem, which he described as a social problem worse than hard drugs, which in his country had serious implications resulting in illness and death. He identified factors that had facilitated drug counterfeiting in Nigeria as being: Corruption, poor drug controls systems, poor interagency cooperation. He also identified factors that were successful in combating counterfeit drugs in Nigeria. These are:

- Better laws and enforcement
- The restructuring of the DRA
- A public enlightenment campaign
- The implementation of GMP requirements
- Defining the points of entry for medicines
- Surveillance at points of entry

Mr Yusuf recommended that:

- WHO and international agencies need to take a more proactive approach to combating the trade in counterfeit drugs
- There should be harmonised regulation of pharmaceuticals moving in international commerce
- Counterfeit drug laws should be severe enough to serve as a deterrent

- Products for export should be subject to the same standards as those for domestic use
- Importing countries should adopt regulatory measures to prevent dumping of counterfeits
- An international convention against counterfeiting of pharmaceuticals such as applied for narcotics and psychotropics should be applied
- Eradication of counterfeit drugs should be treated as an international health emergency programme
- DRAs must maintain anti-corruption practices within their agency
- Cooperation between industry, regulators and health care practitioners is essential to combating trade in counterfeit drugs

In conclusion Mr Yusuf highlighted that the trade in counterfeit drugs is trans-national and as countries have come together to combat major health care problems such as HIV/AIDS, TB, Malaria etc, similar cooperation is required to combat this significant health crisis.

## **SESSION 2: INVESTIGATION AND ACTION AGAINST COUNTERFEIT MEDICINES: INDUSTRY PERSPECTIVE**

*Mrs Gugu Mahlangu, Moderator*

*Mr Steve Howells, Rapporteur*

### **1) Mr Jim Christian, Novartis International**

Mr Christian said that counterfeiting is the crime of the century. Organised crime is moving into counterfeiting because it is easy to do and penalties are low. Counterfeit drugs endanger health, threaten the reputation of drug companies and damage the impression that the regulatory officials can regulate or control counterfeiting. Counterfeiting is moving to the west, specifically the US and EU. He said, medicines supply in Europe is at risk because of expansion in the EU. He highlighted that counterfeits are manufactured in conditions of poor GMP. Their detections now disclose that counterfeit drugs are now mixed with genuine products, even in the same pack. Mr Christian showed examples of counterfeit medicines that have been detected and stated that security technology may not be the answer. He also displayed several examples of counterfeit drugs.

### **2) Mr Geoff Power, Director, Packaging Security, GlaxoSmithKline, UK**

Mr Power provided several examples of counterfeit cases that satisfied the WHO definition of counterfeit drugs. He also gave examples of other issues including diversions, Internet sales, falsification of expiry dates, substitution and adulteration. He highlighted the breach of trust that counterfeits pose to the public health system with both hospitals and patients accepting products at face value.

He endorsed internal company strategies to combat counterfeiting, including formal investigation procedures, anti-counterfeiting features in packaging, secure manufacturing and supply sources, and the conduct of market surveys. He endorsed

external strategies including consumer education, tougher laws, strengthened enforcement and stricter penalties. He compared both covert and overt measures that companies may adopt to combat counterfeiting. Covert measures must be kept secret, may not be difficult to copy, may be used in combination, easy to incorporate, do not require regulatory approval and are very cost effective. Whereas, overt measures require user education, must be very difficult to copy, must be applied in a way that prevents reuse, may be a deterrent to counterfeiters and are more expensive than covert options. In conclusion, Mr Power said that there is no such thing as a good (or safe) counterfeit.

### **3) *Mr Thomas Kubic, Executive Director, Pharmaceutical Security Institute (PSI)***

Mr Kubic mentioned that the PSI has an intelligent mission to collect, collate and disseminate information and a training mission to identify and satisfy training needs. He observed that counterfeit drug investigations by law enforcement agencies are often under resourced due to other crime problems. PSI key findings in 2003 included that there were 327 incidents of crime involving pharmaceuticals. 81% of these were counterfeits. Most incidents occurred in the US, followed by India and China. Key trends identified in 2003 were that there were more female offenders detected and that organizations involved in counterfeiting are small sized. 363 people were arrested and the average value of seizures was \$3 million. A significant key finding was that most arrests, 53%, were made at the point of sale; 13% were manufacturers and only 5% were at borders. He made the point that these statistics indicate that further education of customs officials is required based on these statistics. Mr Kubic made predictions for 2004 - the US market would become a target for counterfeit medicines and drug diversion would re-emerge as a problem. He provided the results of a survey of international parcels entering the US both in mid and late 2003. On both occasions 88% of the parcels contained unapproved drugs, thus highlighting international mail as a distribution corridor exploited by medicine traffickers. He also gave an example of illicit Internet pharmacy sites purporting to be based in Canada. 432 Canadian sites were reviewed, he summarised 3 of those in detail, all 3 were investigated and found to be actually located in the US.

### **4) *Mr Hector Bolanos, Director General of ILAR & Vice Chairman, World Self-Medication Industry (WSMI) for Latin America***

Mr Bolanos provided statistical information in relation to the prevalence of counterfeits in Latin America and globally and argued that such statistics are unreliable. He stated that counterfeit drugs pose a significant public health risk. Mr Bolanos said drug counterfeiting involves established, sophisticated, regional, criminal organisations and international organised crime. He identified factors that make counterfeiting a wide spread activity as being:

- Lack of access to many drugs makes low-priced counterfeit products attractive
- Counterfeit drugs don't have to be sold from regulated outlets only
- The sale of prescription products without a physician's prescription facilitates the selling of fake or counterfeit products

- Pharmacy clerks do not possess the ability to detect counterfeit products as pharmacists do.
- Counterfeiting is not a specific crime
- There are inadequate penalties applying to drug counterfeiting
- Lack of intellectual property protection
- Existence of free trade zones
- Internet facilitating cross-border trade in counterfeits

He also highlighted factors that are successful in combating counterfeiting. These were:

- Interagency cooperation
- Categorising counterfeiting as a specific crime
- Establishment of stiffer penalties
- Monitoring of wholesalers and pharmacies
- The development of best practice manuals regarding distribution, dispensing of medicines
- Consumer education

Mr Bolanos also put forward other activities to consider in combating counterfeit medicines. These are:

- The implementation of anti-counterfeiting technologies
- Regional cooperation between agencies
- DRAs should publish and provide information on drugs to consumers, retailers, professionals
- Anyone suspecting counterfeit drugs should report this to the DRA, who should publish and disseminate the information
- Government should mandate the reporting of the discovery of counterfeit drugs

He also highlighted the essential benefits of the active participation of the pharmaceutical industry with regulators, as this would allow for the development of a more complete programme and ensure the achievement of better outcomes.

In conclusion he highlighted that measures against counterfeiting should have the ultimate goal of protecting consumers/patients.

### **SESSION 3: E-COMMERCE: CHALLENGES OF CONTROLLING PHARMACEUTICAL TRADE**

*Dr David Weber, Moderator*

*Maryam Hinds, Barbados, Rapporteur*

#### **1) Mr Marcel Moester, Senior Inspector, Healthcare Inspectorate Ministry of Health Sports and Welfare (MoHSW), The Netherlands**

Mr Moester pointed out that the Internet is a virtual product not a physical one. He said that the Internet plays an important role in the distribution of medicinal products that are being used without prescription. Where normal safeguards are

bypassed, consumers are put at risk. The greatest areas of risk in The Netherlands were identified as lifestyle and embarrassment drugs. Examples were given as anabolic steroids, drugs used for weight loss and drugs used for hair loss. To maintain public confidence in the Health Care System it is necessary to prevent unreliable products from entering into this system. He said the Internet is by definition a highly volatile medium on a massive scale which facilitates cross-border trade. Therefore it is impossible to police. Still, some things can be done to counter the negative effects of Internet trade in medicinal products.

The situation in The Netherlands has been analyzed. Although certain medicines are available on a very large scale, the actual use seems quite limited. This is probably due to the present Dutch reimbursement system. The lesson from this is that reimbursement offers some protection against illegal use. Furthermore, we find that the regular distribution chain for medicinal products needs to be closely watched for any introduction of unreliable products, especially those coming through the Internet. Because of the supranational nature of the medium, international co-operation is also needed.

In the Netherlands, it was indicated that, the existing legislation was sufficient, particularly as sentencing was raised from 6 months to six years, there was no need for new legislation. Improved flow of information among the various agencies would be useful.

## **2) *Mr Apchichai Hoonchamlong, Pharmaceutical Inspector, FDA, Thailand***

Mr Hoonchamlong described the purchasing and controlling procedures for pharmaceutical trade via e-commerce in Thailand. Web sites offering pharmaceuticals for sale via e-commerce provide detailed information on products, as well as order procedure, order form and price. Payment could be using Credit Card or through bank transfer. They also provide information on delivery date and route of delivery. In Thailand 3 main organisations are involved: FDA, Customs and the IT department and there are laws to enforce web sites and cooperation to trace the offenders. The control procedure includes: check of the web site for illegal electronic advertisement and sale of product, follow up on complaints received from individuals in the form of letter, telephone, email and random spot check. If the web site is located in Thailand an e-mail message is sent to the advertised web site ordering them to stop the illegal advertisement and distribution. In addition, investigation and inspection of the company and the storage site is carried out using the information given on the web site - the name of the company, telephone number, and the name of the person who opened the bank account. Thai FDA personnel also check mail parcels at the Central Post Office randomly. There is cooperation with Customs Dept., the Post Office Organization.

Mr Hoonchamlong gave examples of products seized in 2002 and 2003. He mentioned the following as problems in controlling trade of pharmaceuticals via the Internet:

- Servers located in other countries
- Use of incorrect company name or address

- Clandestine pharmaceutical storage/unlicensed drug stores
- Limited resources
- Not enough cooperation and collaboration among government agencies
- Sites close and open easily.

**3) *Dr. Justina A Molzon, Associate Director for International Programme, FDA, USA***

Dr Molzon said that the sale of drugs on the Internet has both positive and negative aspects. Prescription drug sales on the Internet can provide benefits to consumers, especially to the disabled or homebound patients who cannot move easily. It is convenient for shopping 24 hours a day and gives privacy and anonymity for those who do not want to discuss their medical condition in a public place. The negative aspects include: sale of unapproved new drugs, absence of doctor/patient relationship, dispensing of prescription drugs without prescription, and marketing products with fraudulent claims. She said, to address these and other challenges posed by the Internet, the FDA has developed an Action Plan, the goals of which are: insuring that consumers are receiving FDA approved products, consumers are afforded the same protections that are available when a consumer shops at a pharmacy and to encourage consumers to involve their health care professionals in their treatment.

She remarked that in order to achieve these goals FDA has customized and expanded its enforcement efforts by setting its enforcement priorities, improving data acquisition, coordinating case assessment. This has resulted in the evaluation of over 400 websites and an increased number of civil and criminal actions, improved collaboration with international regulatory officials and the issuance of cyber letters. Hard copies of each cyber letter are sent to the website operator, the U.S. Customs Service and the regulatory authority officials in the country in which the operator is based. Other strategies used to control the sale of drugs on the Internet include, collaboration with other law enforcements and regulatory partners, professional organizations, public outreach-media campaign, public education.

Following the presentations there were questions from the floor on how criminal activities were handled and it was indicated by the presenters that there was no general routine method. Cases were dealt with on individual basis and depending on the type of problem, individual approaches were used. The issue of legislation was also raised and it was agreed that cooperation between the different agencies would be needed.

There was also a comment from the floor that even though regulatory agencies are responsible for combating the counterfeiting of drugs, industries do have responsibility to report if they know who should be trading their product and in which country. Therefore, if they notice a significant drop in sales then they should notify the regulatory agencies. It was also agreed that international cooperation is needed for the control of trade on Internet.

## **SESSION 4: COMBATING COUNTERFEIT MEDICINES: INTERNATIONAL ORGANIZATIONS' PERSPECTIVE**

*Mr Marcel Moester, Moderator*

### **1) Mr Erik Madsen, Criminal Intelligence Officer, INTERPOL**

Mr Madsen informed the meeting about the creation of the Interpol Intellectual Property Crime Action Group (IIPCAG). He said that IIPCAG is a multi-agency Action Group consisting of different organizations such as the European Union, World Customs Organization, World Intellectual Property Organization, REACT UK and law enforcement agencies, customs from USA, Ireland, Canada, China, Finland, Northern Ireland, Italy and Europol. IIPCAG is involved in training and best practices, information and intelligence sharing/databases, promoting public awareness activities. The Action Group has carried out several successful investigations based on intelligence received from industry and law enforcement agencies, they have developed leaflet and reporting form to report on seizures and intelligence, they train national authorities, and have developed a guide on best practices. He also said that 5-7 % of the global trade is counterfeit and diversion. The scale up of Intellectual Property (IP) crime is proof of organized crime and organized criminal activity. An emerging body of evidence shows IP crime is linked to terrorism and terrorist organization.

He mentioned that the role of the Interpol Crime Unit is to develop strategies and programmes to combat international criminal activity linked to IP crime, establish central IP crime databases to facilitate timely exchange of information about enforcement actions, emerging trends and strategic assessment, develop best practice and deliver training, raise law enforcement and public awareness of IP crime, collect, collate and analyse non-police cross-industry information about IP crimes, etc.

The role of Regional Liaison Officers is to develop and maintain contacts with law enforcement agencies investigating IP crime, deliver training on IP crime, facilitate and coordinate IP crime enforcement action in partnership with the private sector, and proactive collection of police information about IP crime enforcement activity.

### **2) Ms Danielle Maiano, Technical Officer, World Customs Organization**

Ms Maiano made a presentation on the mission, role and function of the World Customs Organization and particularly on combating counterfeit drugs. She said the WCO has 162 Members and its mission is to enhance the effectiveness of customs administration in matters concerning the application of commercial legislation, protection of society and recovering of tax revenues. It assists Members to respond to new challenges and encourages communication and cooperation which favours customs ethics, improvement of working methods and promotes best practices.

WCO's work is based on a strategic plan that aims at combating fraud or any other form of transnational criminal activity, in particular counterfeiting and piracy. It has a partnership with international and regional organizations as well as with the private sector in order to provide an effective response to the problems encountered.

WCO has set up a Strategic Working Group in 1999 bringing together Customs administrations and the private sector (business). They have developed a strong working relationship, which benefits from the combined and complementary skills of Customs and business and particularly a model legislation to help countries in drafting, or revising their existing Customs legislation. A specific web site has also been created to provide WCO member administrations and WCO business sponsors with a full range of IPR services: a world directory of Customs Legislation; On-line applications for Customs protection; you can down-load the appropriate forms and follow our guidance on how to apply; a full listing of contact points; relevant presentations and published articles; a hyperlink to the "REACT" internet sites which helps front-line officers to identify infringing goods. Technical assistance, including training, fellowship programmes, practical exercises, IPR management consultant services, are offered to WCO Member Administration through the "**WCO IPR Technical Assistance Group**". Business partners fully support this approach and fully fund the programme.

Some of the problems encountered by WCO are limited resources, well organized criminal networks, lack of information and appropriate training in the identification of counterfeit medicines, absence or lack of contact with pharmaceutical laboratories and national health authorities.

Ms Maiano also presented the result of a recent survey carried out by WCO. She said that out of 40 countries that responded to a questionnaire, 15 reported that they have seized illegal medicines. 13 of them reported the medicines seized were counterfeit. The regions concerned were Europe, West Africa and East Asia. Some of the medicines seized included the following: in Europe (10 countries) Amoksiklav, Amoxyl, Ampiclox, Anabolisant, Analgin, Bornchlytin, Carlis, Halfa, Viagra, in West Africa (1 country) Paracetamo, Ibuprofen, Amoxicillin, Tetracycline and Amphetamine and in East Asia (2 countries) Panadol, Travid, Proasca, Viagra, Centrum and Mycogynon.

### **3) *Mr Peter Lowe, Ass. Director, International Chamber of Commerce (ICC) Counterfeiting Intelligence Bureau***

Mr Lowe opened his presentation by giving examples of incidences that occurred in different countries - Nigeria, Bangladesh, Haiti, Niger and United States of America as a result of consumption of counterfeit medicines. The problem of counterfeit drugs, he said, is largely unseen and is perceived by many to affect developing countries only. It is difficult to solve the problem due to the culture of denial, lack of resources and corruption. Counterfeiting of drugs involves both backstreet and more advanced production facilities and increasingly it involves organized criminals. It affects both developed and developing countries. He said in some developing countries such as Argentina, Mexico and Columbia 40% of the drugs on the market are counterfeit and in parts of West Africa up to 70% of the market is a wash with counterfeits.

He said that recent trends show an influx of fakes into the western market particularly the US. Over the past two years there has been 1000% increase in pharmaceuticals entering the US by mail and the US Customs officials estimate that 14% of drugs coming through the mail have something wrong with them. Growth of Internet trade in pharmaceuticals is also becoming a medium for selling counterfeit medicines. The Internet is attractive for counterfeiters because of its anonymity, the difficulty of apprehending, the ease of setting up and provide convincing shop windows.

Mr Lowe also explained to the participants the objective of Counterfeit Pharmaceutical Initiative (CPI). CPI is non-profit making organization launched by the International Chamber of Commerce (ICC) at the beginning of 2003. Its objectives are collecting information, disseminating information confidentially and publicly, educating and creating awareness. It publishes a Counterfeit Pharmaceutical Digest. Constructing a dedicated CPI web site, compiling a list of international contact points in governments, law enforcement and customs who can assist in tracking pharmaceutical and liaising with regulators and international bodies are also some of its objectives. Mr Lowe concluded his presentation by saying that we need a war against counterfeit drugs. To win the war, information sharing is vital and there should be greater public awareness, and political will. Action must be mobilized and firm and decisive action against counterfeiters and their distributors is crucial.

**4) Ms. Louise van Greunen Vuagnat, Deputy Director, Enforcement and Special Projects Division, World Intellectual Property Organization (WIPO)**

Following a general introduction, Ms. Van Greunen Vuagnat said that the WIPO Convention mandates the protection and promotion of intellectual property throughout the world and collaboration with other intergovernmental organizations (IGO's). The activities of the Enforcement Division include, *inter alia*, giving legislative assistance to Member States particularly in the implementation of obligations under the TRIPS Agreement and other conventions administered by WIPO, cooperation with other organizations at the international level, assisting Member States in formulating effective national enforcement strategies, training, education and awareness raising.

Ms. Van Greunen Vuagnat also explained the various articles of TRIPS pertinent to enforcement, including to the issue of criminal sanctions in the event of wilful trademark counterfeiting on a commercial scale and the remedies and measures to be taken against counterfeiters, namely imprisonment and/or monetary fines, and pointed out that remedies may also include seizures, forfeiture and destruction of counterfeited goods and implements. She said the TRIPS Agreement, in footnote 14 to Article 51, defines counterfeit goods as goods including packaging materials bearing an unauthorized trademark which is identical to the registered trademark or which cannot be distinguished in its essential aspects and which thereby infringes rights in the country of importation. In order to define "counterfeit pharmaceuticals," she contended that reference could be made to the WHO definition of counterfeit medicines and/or to other suitable formulations.

WIPO has, since 1998, established a number of committees dealing with enforcement issues, such as an Advisory Committee on Enforcement of Industrial Property Rights. In 2002 it held a Consultation Meeting on Enforcement subsequent to which the WIPO General Assembly has established an Advisory Committee on Enforcement in charge of global enforcement issues, the objectives of which includes coordination with certain organizations and the private sector to combat counterfeiting and piracy; public education; assistance; coordination of national and regional training; and the exchange of information. She indicated that the next session of this Committee will take place

from 28–30 June, 2004, and will consider “the role of the judiciary and quasi-judicial authorities, as well as of the prosecution, in enforcement activities.”

WIPO's global approach to address counterfeiting includes: coordination at the international level with inter-governmental and nongovernmental organizations, also training, awareness, and information exchange. At the national level they assist Member States in concluding effective public/private partnerships, educate consumers and help develop judicial infrastructures under which counterfeiters will receive deterrent sanctions and right holders will obtain adequate relief and/or compensation.

#### **5) *Dr Lembit Rägo, Coordinator, QSM/WHO***

Dr Rago explained to participants WHO's mandate in the area of pharmaceuticals. He said the mandate of WHO includes: development of global norms, standards and procedures for pharmaceuticals and biologicals which could be used by countries to ensure the safety, efficacy and quality of medicines, and to provide technical advice and administrative support to countries to strengthen national drug regulatory capacity to enable them to implement the tools and control their markets. In addition, WHO has been/and is very active in supporting countries to combat counterfeit drugs. Guidelines on combating counterfeit drugs have been developed and training on detection and investigation of counterfeit drugs had been carried out in several countries. WHO has also established a working group with pharmaceutical industry associations and nongovernmental organizations. The working group has carried out advocacy and awareness activities. At present WHO is supporting six countries in the Greater Mekong Sub-Region. Activities include promoting awareness of the public and decision makers, surveillance of the quality of medicines, training of inspectors in detection and investigation of counterfeit medicines, promoting cooperation between drug regulatory authorities and other law enforcement agencies such as the police and customs and prosecutors.

Participants of the session discussed a number of issues raised during the presentations and suggested that awareness must be raised of the link between counterfeiting of drugs and organised crime and that the exchange of data between DRAs, law enforcement agencies, international organisations, industry and all stakeholders should take place. They also suggested that the culture of denial needs to be addressed more urgently than a lack of legal possibilities. For instance, national police and justice organisations must be made aware of the need to regard counterfeit medicines as a serious problem (“Weapon of Mass Destruction”). Existing activities and initiatives need to be supported. Customs are already active in detecting counterfeit products at the borders but they need expert support from local DRA's. The obligation in TRIPS to implement and enforce anti-counterfeiting legislation must be fully used.

## **SESSION 5: COMBATING COUNTERFEIT DRUG: A DRAFT CONCEPT PAPER FOR AN INTERNATIONAL FRAMEWORK CONVENTION AND RELATED STRATEGIES**

*Moderator: Dr Stewart Sinclair Jessamine*

*Rapporteur: Mr. Rutendo Kuwana*

***Panelists: Ms. Michele Forzley, Mr. Lembit Rago, Mr. Thomas Kubic, and Prof. Henk de Jong***

Mr. Lembit Rago opened the session by stressing that the document “Combating counterfeit drugs: Concept paper for an international framework convention and related strategies” is a preliminary draft and is intended to stimulate discussion. It is by no means a final document and participants are urged to review it carefully.

Ms Michele Forzley, WHO Consultant, then took delegates through the draft document. She explained the intentions of the document and the meaning of a framework at international law. She indicated that the document comprised of the skeletal elements for an international agreement – which was the main impetus for the draft document. She also pointed out the values and roles of treaties and frameworks, as well as their advantages. She said that such a framework could encourage the possibility of the application of the concept of universal jurisdiction in which criminals could be prosecuted where they are found, rather than where they had committed the crime. Conventions as proposed could also be used to form international organizations as well as promote uniformity of sanctions. She reiterated that drug regulatory authorities (DRAs) have important roles in the process of developing the framework as they have the expertise in drug control. Ordinary citizens and the pharmaceutical industry could also be involved.

Following Ms Forzley’s presentation, the Moderator stressed that the convention should clearly state that medicines are not items of ordinary commerce but public health goods. He said that there is more moral imperative than intellectual property rights and commercial concerns at stake. The convention has to concentrate on regional differences and underlying causes which have relevance to concerns on public health. He reminded participants that most member states are more concerned about public access to good quality, safe and effective medicines than intellectual property rights.

Mr. Kubic suggested that the international starting point of the proposal could be difficult as international agreements were usually difficult to achieve and could be controversial.

Prof. Henk stressed that the key success factors for the exercise are cooperation and the operational use of positive forces. He was more concerned with the controls on excipients and suggested the need for risk analysis on the different possibilities where material could be used in, for example, food vs. pharmaceuticals or in oil drilling vs. pharmaceuticals.

Mr. Lambit Rago again stressed the direction in which discussions should focus, i.e. to determine whether the proposed convention is an appropriate concept or not.

From the floor, Mr Davi Rumel (Brazil) raised his concern that the paper did not adequately address the worrying scenario where legitimate pharmaceutical manufacturers opted to acquire raw material from dubious sources that did not meet pharmaceutical requirements. There was also need to stress the matter of public health in the legal framework.

Ms Maryam Hinds (Barbados) disagreed with Mr. Rumel. She was of the opinion that the paper was acceptable and in fact was actually reflecting what had been discussed in the previous sessions. She suggested that since it will take a long time until ratification of such conventions, it was essential to expedite the adoption of the concept. Adoption of the convention would also assist those member states that did not have legal frameworks in place already.

Ms Louise van Greunen Vuagnat (WIPO) supported the concept and reiterated the need for clarity on definitions. She conceded that the paper was obviously not on intellectual property rights but that did not suggest that this was to be ignored particularly when an element of unauthorized use of intellectual property rights was clearly evident.

Dr Nazira Nazimovna Bakhramova (Uzbekistan) pointed out that such noble conventions would increase the influence of international agreements on national authorities to get them to act on non-compliance of their own industry. It is also useful in combating international crime.

Mr. Lembit Rago suggested that there is also need to identify certain activities that could be implemented before a possible convention became effective.

Ms Michele Forzley reminded delegates of the need for each country to have a good basket of laws to protect public health with adequate links to other aspects such as IPR. Lack of such laws had resulted in counterfeiting.

Dr Jessamine (New Zealand) reiterated the importance of the global rather than local nature in applicability of the convention. If the outcomes of its implementation resulted in protection of public health then that was most encouraging. He sought comments on who would however meet the costs of the initiative.

Dr Molzon (USA) supported the concept framework. She stressed the need for DRAs to remain engaged in the further development of the convention until its possible finalisation.

Ms Raffaella Ravinetto (MSF, Spain) was concerned that the disparities in sophistication between regions would make centralized discussions difficult for less prominent countries.

Ms Forzley suggested that there were several ways in which such disadvantaged members could be assisted. They could be part of sub-committees, technical advice groups or common interest country blocs. A separate procedure through use of the International Conference of Drug Regulatory Authorities (ICDRA) could also be a useful tool.

Dr Kimura (Japan) supported the concept paper and stressed that such international cooperation could lead to strengthening of domestic effectiveness. She also reiterated that the basis for counterfeiting was mostly weakness in DRAs especially where there are no requirements for registration of medicines, no implementation of Good Manufacturing Practice in the production of pharmaceuticals and licensing of producers of pharmaceuticals. The convention was therefore to stress this. She also suggested the need to make information on counterfeits available to the public. The convention would then make it mandatory to members to submit reports.

Mr. Howels (Australia) suggested that there was a need to treat counterfeiting as a major transnational crime and not only as a public health matter. Use of a convention would remove jurisdictional problems amongst member states and would help in intelligence gathering.

Mr. Bennoson (ISPE, UK) indicated that the pharmaceutical industry would support the initiatives, including financially, as counterfeiting did affect them. Data generated from reports would also be used in public awareness campaigns and raise the profile of the menace of counterfeiting. Industry would also support requirements from DRAs for mandatory reporting of all incidences of counterfeiting.

Dr Sokhan Chroeng (Cambodia) supported the concept and mentioned that it would be an important tool for DRAs to sensitise and convince their governments to consider counterfeiting a major problem.

Mr. Thomas Kubik suggested that the following be noted and made a summary of the session discussions as follows:

- Delegates present agreed on a need to urgently endorse the concept
- DRAs should be in control of the development of the concept further
- Improvement of existing structures was to be encouraged
- There was need for a secretariat to coordinate the implementation of the convention

## **SESSION 6: CONCLUSIONS AND SUMMERY RECOMMENDATIONS**

Participants of the meeting appreciated the efforts made by governments, WHO and other international organizations, nongovernmental organizations and pharmaceutical industries to combat the circulation of counterfeit drugs in the national and international market and reminded us that more needs to be done at the national and global level to stop the problem. They recommended that:

### **Countries should:**

- adopt the WHO Guidelines on Developing Measures for Combating Counterfeit Drugs and make counterfeiting pharmaceuticals a specific crime punishable with appropriate severe sanctions

- establish effective pharmaceuticals regulation including export controls - licensing of establishments engaged in the manufacture, import, export, distribution, supply and sale of drugs; product registration, inspection, quality surveillance, etc
- increase local and international cooperation between DRAs, NGOs, law enforcement agencies and industry
- raise public and political awareness that counterfeiting of pharmaceuticals is a serious public health risk
- develop and implement best practice manuals regarding distribution and dispensing of medicines
- publish and provide information on drugs to consumers, health professionals and retailers
- report any suspected cases of counterfeit drugs to the national DRA, who should publish and disseminate the information
- mandate the reporting of the discovery of counterfeit drugs
- raise awareness of consumers and policy makers of the link between counterfeiting drugs and organised crime
- exchange data between DRAs, law enforcement, international organisations, industry and all stakeholders

**The World Health Organization:**

- in collaboration with other stakeholders, should consider and develop further the concept paper proposing a draft convention on counterfeit drugs.
- should convene prior to ICDRA 12 a meeting with other DRAs and stakeholders to specifically consider the concept paper.

The meeting also identified the following areas of immediate concern: clarifying national definitions and seeking harmonization for law enforcement purposes; aggregating databases, increasing transparency and functionality; building on and coordinating existing structures; considering the feasibility of having a functioning secretariat to administer and coordinate cooperation and collaboration; review and analyse of national and international laws relating to counterfeit drugs.