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# **Counterfeit and Substandard Drugs in Myanmar and Viet Nam**

**Report of a study carried out in  
cooperation with the Governments  
of Myanmar and Viet Nam**

**Eshetu Wondemagegnehu  
Essential Drugs and Other Medicines**

**Geneva 1999**

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The Division of Drug Analysis of the Department of Medical Sciences, Ministry of Health (MoH) of Thailand, which is also the WHO Collaborating Centre for the Quality Control of Drugs, carried out the laboratory tests on the samples collected.

A total of 18 drug regulatory authorities cooperated in providing the necessary information for the investigation of the samples: those of Australia, Cyprus, France, Germany, Hong Kong Special Administrative Region of China, India, Indonesia, Ireland, Israel, Malaysia, Myanmar, Pakistan, Republic of Korea, Singapore, Switzerland, Thailand, United Kingdom and Viet Nam.

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<sup>1</sup> The Department of Essential Drugs and Other Medicines (EDM) includes the former Action Programme on Essential Drugs (DAP) and most components of the Division of Drug Management and Policies (DMP).

## Acronyms and abbreviations

ASTM	American Society of Testing and Materials
BP	British Pharmacopoeia
BPTTT	Bureau of Patent, Trademark and Terminology Transfer
CFDSC	Central Food and Drug Supervisory Committee
CMSD	Central Medical Stores Depot
DAC	Drug Advisory Committee
DAP	Action Programme on Essential Drugs
DMP	Division of Drug Management and Policies
DQCC	Drug Quality Control Centre
DRA	drug regulatory authority
EDM	Department of Essential Drugs and Other Medicines
FDA	Food and Drug Administration
FDSC	Food and Drug Supervisory Committee
GMP	good manufacturing practices
IFPMA	International Federation of Pharmaceutical Manufacturers Association
LPDR	Lao People's Democratic Republic
MFDBA	Myanmar Food and Drug Board Authority
MMET	Medicines and Medical Equipment Trading
MoH	Ministry of Health
NDP	National Drug Policy
Philcap	Philippines Counterfeit Action Programme
USP	United States Pharmacopoeia
WHA	World Health Assembly
WHO	World Health Organization





## Executive summary

Drugs play an important role in improving human health and promoting well-being. However, to produce the desired effect, they have to be safe, efficacious and of acceptable quality, and have to be used rationally. The use of ineffective and poor-quality drugs will not only endanger therapeutic treatment but also erode public confidence in a country's health programme. For that reason, the production, storage, distribution and use of drugs in each country need to be regulated by the government.

During the past few decades, many pharmaceutical industries and distribution channels have flourished throughout the world, leading to an increase in the number of products circulating in national and international markets. At the same time, however, the presence of counterfeit and substandard drugs in those markets has increased substantially as a result of ineffective regulation of the manufacture of and trade in pharmaceutical products by both exporting and importing countries.

Counterfeit drugs have been reported in both developed and developing countries, but there are no accurate data on the extent of the problem. Studies conducted in several countries to assess the quality of pharmaceutical products have been based mainly on laboratory tests. Little or nothing has been done to ascertain whether mislabelled products were mislabelled deliberately and/or fraudulently.

This report presents the result of studies conducted in two Asian countries — Myanmar and Viet Nam. They were undertaken in order to obtain independent information about the problem of counterfeit drugs which will help to develop measures to combat counterfeiting.

The study involved the collection of background information on the status of drug regulation by means of a questionnaire, and the collection of samples of selected products, which were subjected to both laboratory quality testing and investigation.

The pharmaceutical products surveyed were amoxicillin, ampicillin, chloramphenicol, chloroquine, co-trimoxazole, diazepam, metronidazole, paracetamol, ranitidine, rifampicin, salbutamol and tetracycline. The criteria used for the selection of the products were inclusion in the country's essential drugs list, high consumption rate, therapeutic importance and likelihood, on the basis of previous reports, of being counterfeited.

A total of 503 samples of the 12 products were collected from both countries. Out of these, 500 samples were subjected to laboratory testing to determine the identity and content of the active ingredients, a portion of each sample being sent

to the WHO collaborating laboratory. Fifty-six of these (11%) failed the quality test.

To ascertain whether or not the samples were counterfeit, 214 of the 500 tested were selected and investigated, a portion of each being sent to the drug regulatory authorities of the countries of manufacture.

Of the 214 samples investigated, replies were received for 169. Five of those 169 were shown to be mislabelled with respect to their source (country of manufacture and name of manufacturer), but all of them passed the laboratory test. One sample contained the wrong ingredient but was produced by a licensed manufacturer. The total number of counterfeit drugs was found to be 6 out of 169. The remaining 163 samples were reported as genuine (i.e. produced by licensed manufacturers), but 18 (11%) failed the laboratory test. Of the 45 samples for which replies were not received, 10 (22%) failed the laboratory test; it was not possible, however, to ascertain whether these 45 products were produced by licensed manufacturers or not.

The overall failure rate in the case of the 214 samples, assuming that all the 45 products for which replies were not received were genuine, was 16% (34 out of 214), which is higher when compared with the 11% failure rate for the 500 samples subjected only to laboratory testing.

## **Conclusions**

The findings of the study show that counterfeit drugs exist in Myanmar. Also, they confirm previous reports on the existence of substandard drugs in both Myanmar and Viet Nam. Although it may not be safe to draw any conclusions based on this limited study, it is to be noted that no counterfeit drugs were found in Viet Nam among the samples surveyed. The findings also show that the prevalence of substandard drugs is in general a much greater problem than counterfeit drugs in both countries.

The study showed that products which have passed laboratory tests may sometimes be found to be counterfeit (deliberately mislabelled products are counterfeit according to the WHO definition) upon investigation, as in the case of the five samples from Myanmar. This means that laboratory tests alone will not be adequate to determine whether a product is counterfeit. Any investigation has to be carried out in collaboration with the drug regulatory authorities of the countries of manufacture and the manufacturers of the products.

The findings also confirm that regulatory measures such as drug registration can greatly enhance the quality of drugs in the market if effectively implemented.

# 1. Introduction and background

Medicines must be safe, effective and of acceptable quality, and should be used rationally in order to produce the desired effect. They can be dangerous if there is no adequate control over their manufacture, storage and distribution or their use by the patient.

During the past few decades, tremendous advances have been made in pharmaceutical technology and science. As a result, a large number of preventive and curative medicines are now available to fight diseases. Similarly, sophisticated and highly sensitive methods have been developed to ensure the quality of drugs. Unfortunately, however, despite all the advances made, concern about the quality of drugs has not abated.

In the past few years, the number of pharmaceutical manufacturers and distribution channels has proliferated. The export of pharmaceutical products, which used to be direct from a manufacturing country to an importing country, is now taking place from stocks held in one or more intermediate countries or through trading houses via duty-free ports/zones. The activities in intermediate countries or trading houses may sometimes involve repackaging and/or relabelling which may be carried out without any controls and under conditions that do not comply with good manufacturing practices (GMP) requirements. This situation, coupled with ineffective drug regulation in many countries, has facilitated the appearance of diverse problems, one of which is the counterfeiting of pharmaceutical products.

The counterfeiting of commercial products has existed for a very long time. Counterfeit drugs, however, are a relatively new phenomenon. It was first mentioned as a problem at the World Health Organization (WHO) Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985.<sup>1</sup>

At the World Health Assembly (WHA) in May 1988, a number of countries expressed concern about counterfeit drugs that were circulating in their markets. The Assembly adopted resolution WHA41.16,<sup>2</sup> which requested governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations.

In 1988, the WHO Expert Committee on Specifications for Pharmaceutical Preparations discussed the issue of pharmaceutical products that are poorly formulated, degraded or criminally inspired. It concluded that only adequate administrative measures in both exporting and importing countries can ameliorate the situation.<sup>3</sup> It recommended that importing countries:

- (a) establish an effective national product-licensing system for pharmaceutical products;

- (b) incorporate the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce into national statutes or regulations;
- (c) establish a small national drug quality control laboratory as recommended by WHO; and
- (d) undertake sampling of products within the distribution chain as an element in quality surveillance.

In 1992, WHO and the International Federation of Pharmaceutical Manufacturers Association (IFPMA) organized a joint workshop on counterfeit drugs in Geneva. The workshop discussed the problems of pharmaceutical counterfeiting, identified the possible facilitating factors and made recommendations. It also defined a counterfeit medicine as one that is deliberately and fraudulently mislabelled with respect to identity and/or source.<sup>4</sup>

During the past 15 years WHO has been collecting and collating data related to counterfeit drugs, which have formed the basis of a database on counterfeit drugs. Although most of the reports are not independently verified, as at April 1999 some 771 reports of counterfeit drugs had been received by WHO and entered into its database.<sup>5</sup> Twenty-two per cent of them came from industrialized countries, and 78% from developing countries.

## 2. What are counterfeit drugs?

There is no universal definition of counterfeit drugs, and legal definitions vary from country to country. Six different definitions are set out below.

*Black's law dictionary*<sup>6</sup> defines counterfeiting as “to copy or imitate, without authority or right, and with a view to deceive or defraud, by passing the copy or thing forged for that which is original or genuine”.

The American Society of Testing and Materials (ASTM)<sup>7</sup> has produced a classification system that describes the various ways in which intellectual property rights contained in a product and/or its presentation, including packaging and labelling, may be hijacked. According to the classification, counterfeiting is the reproduction of a document, article or security feature with the intent to deceive close scrutiny by a qualified examiner.

The United States Federal Food, Drug and Cosmetic Act<sup>8</sup> defines a counterfeit drug as “a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor”.

According to the *Pakistan manual of drug laws*,<sup>9</sup> a counterfeit drug is “a drug the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacturer”.

The Republic Act No. 8203 of the Philippines<sup>10</sup> defines counterfeit drugs/medicines as:

medicinal products with correct ingredients but not in the amounts as provided thereunder, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packing, and can apply to both branded and generic products. It also refers to:

- a) the drug itself, or the container or labeling thereof or any part of such drug, container or labeling bearing without authorization the trademark, trade name, or identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Terminology Transfer (BPTTT) in the name of another natural or juridical person;
- b) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;

c) an unregistered imported drug product, except drugs brought into the country for personal use as confirmed and justified by accompanying medical records; and

d) a drug which contains no amount of, or a different active ingredient, or less than eighty percent (80%) of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration.

WHO<sup>11</sup> defines a counterfeit pharmaceutical product as a product that is deliberately and fraudulently mislabelled with respect to identity and/or source. The definition applies to both branded and generic products. According to the WHO definition, counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging.\* The following are a few examples of counterfeit pharmaceutical products according to the WHO definition:

- fake packaging + correct quantity of correct ingredient = counterfeit
- fake packaging + wrong ingredient = counterfeit
- fake packaging + no active ingredient = counterfeit
- fake packaging + incorrect quantity of correct ingredient = counterfeit
- genuine packaging + wrong ingredient (deliberate) = counterfeit
- genuine packaging + no ingredient (deliberate) = counterfeit
- genuine packaging + incorrect quantity of ingredient (deliberate) = counterfeit
- genuine packaging + incorrect quantity of ingredient (not deliberate) = substandard
- genuine packaging + correct quantity of ingredient = genuine

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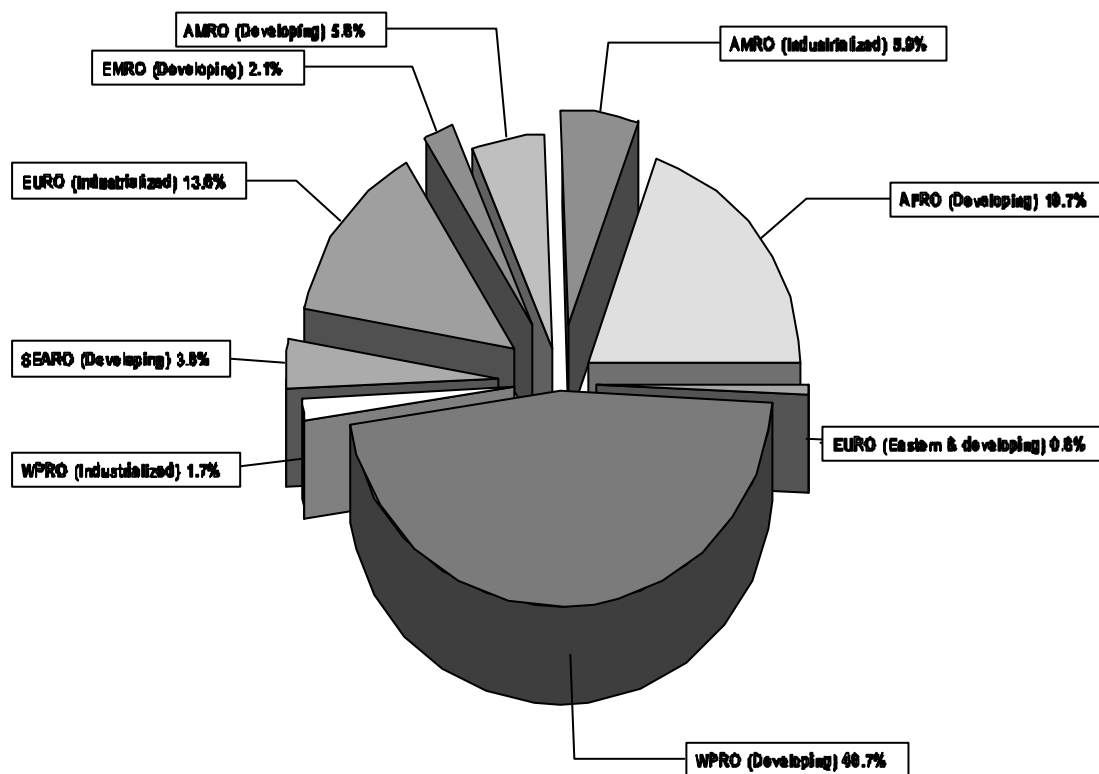
\* Packaging, according to WHO, means all operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Packaging material is any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment.

### 3. The problem of counterfeit drugs

#### 3.1 WHO counterfeit drug database

Since the Nairobi meeting, public awareness of the problem of counterfeit medicines has been growing. Both government authorities and manufacturers have been giving attention to its prevention, and WHO has been receiving reports related to counterfeit drugs. According to this database, the problem of counterfeit drugs is known to involve both developed and developing countries. For instance, between 1982 and April 1999, 771 confidential and public reports relating to such drugs were received by WHO.<sup>12</sup> The geographical origin of these reports is shown in Figure 1.

Figure 1: Geographical origin of cases (1982 - April 1999; total: 771)\*



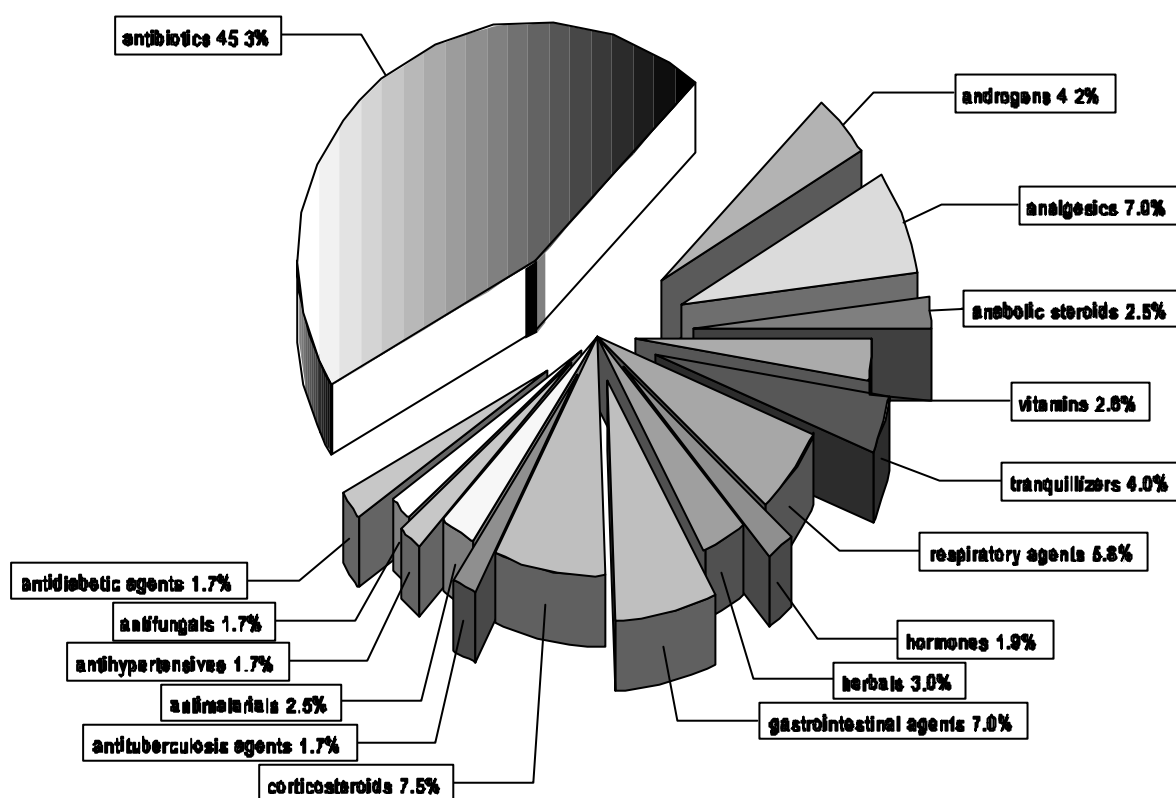
\* Countries classified according to WHO Regional Offices:

- AFRO – Regional Office for Africa
- AMRO – Regional Office for the Americas
- EMRO – Regional Office for the Eastern Mediterranean
- EURO – Regional Office for Europe
- SEARO – Regional Office for South-East Asia
- WPRO – Regional Office for the Western Pacific

The public reports received include some anecdotal accounts which were published in journals. The confidential reports were received from national authorities for regulatory information purposes. Although most of the reports are not confirmed, and bias is likely, they provide some insight into the problem.

The pharmaco-therapeutic classes of the cases reported are shown in Figure 2, which indicates that the majority of detected counterfeit products in the database are the “life-saving” drugs, i.e. antibiotics.

Figure 2: Pharmaco-therapeutic classes of cases reported (1982 - April 1999; total: 771)



In developing countries, the two top-ranking classes of medicines reported to be counterfeited are anti-infectives and anti-parasites, whereas in industrialized countries anabolic steroids and dermatological products accounted for the majority of counterfeit products.

Out of the 771 cases reported, indications about the quality of the active ingredients contained were supplied only for 325 cases. Of these, about 59% contained no active ingredients, 7% contained the correct amount of active ingredients, 17% contained the incorrect amount of active ingredients and 16% contained different active ingredients. No indication was given about the quality of the active ingredients of the remaining 58% of the case reports.<sup>13</sup>



To further supplement the database, in May 1996 the WHO Division of Drug Management and Policies (DMP) sent a questionnaire to the information officers\* of Member States, the six WHO regional offices and other organizations to obtain information on counterfeit drugs. Of the 46 countries that had responded to the questionnaire as of March 1997, 41% recognized the existence of problems of counterfeit drugs in their domain.<sup>14</sup>

### **3.2 Previous country studies related to counterfeit drugs**

In addition to the WHO database, there are reports on studies carried out in different countries to assess the quality of pharmaceutical products available on the market and to establish whether they are counterfeit. For instance, between 1990 and 1993 the Drug Quality Control Centre (DQCC) of the Lao People's Democratic Republic (LPDR) carried out three studies.<sup>15</sup>

In the first study 502 samples were examined. Of these, 247 were examined in relation to drug registration and 168 in relation to post-marketing monitoring. The results of laboratory tests showed 87 (17%) of the samples to be substandard.

In the second study, the DQCC tested 112 samples collected from different provinces, 37 (33%) of which failed to meet quality standards. Out of the 37 samples, 18 (49%) contained less than 50% of the amount of active ingredients claimed. In the third study, 25 samples were analysed and the results indicated that the amount of active ingredients contained ranged from 0% to 95%. All products without active ingredients were classified as counterfeit.

A similar study carried out in 1995 on samples of pharmaceutical products taken from the markets of different provinces of the LPDR showed several of the products to be substandard. Some products contained no active ingredient.<sup>16</sup>

A WHO mission that visited Viet Nam<sup>17</sup> reported that counterfeit drugs prevail nationwide, including in the rural areas. The products counterfeited were antibiotics, vitamins, antimalarials and oral corticosteroids. Laboratory tests revealed three categories of fake drugs — those with no active ingredients, substandard products and those containing wrong ingredients.

A survey conducted by the National Institute of Drug Quality Control of Viet Nam over a period of two years (1990-1991) reported that out of 25,000 samples collected from 20 provinces, 1771 (7%) failed on testing.<sup>18</sup> The types of counterfeiting were reported to include the following: wrong ingredients, without active ingredients, containing incorrect quantities of active ingredients, and with fake packaging.

Similarly, nationwide quality monitoring was carried out in 1995.<sup>19</sup> Out of 31,123 samples tested, 1703 (6%) samples failed to pass quality tests. Of these, 166 (0.5%) contained wrong ingredients or no active ingredients.

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\* These are information officers nominated in accordance with resolution WHA15.41 for the regular exchange of information on the safety and efficacy of pharmaceutical preparations as well as on drug regulatory decisions taken in Member States.

In Africa, a survey of the quality of drugs moving in the markets of three countries was carried out between 1991 and 1993.<sup>20</sup> Some 519 samples were collected from private, public and nongovernmental drug outlets as well as from illegal markets in three countries. The quality of 429 samples was assessed by sending them to independent laboratories for testing. A total of 352 were found to be in conformity with the specifications, while the remaining 77 (18%) were found to be substandard. Of the 77 samples that failed the tests, 16 contained no active ingredients.

In the Philippines, a study called Project Philcap (Philippines Counterfeit Action Programme) was conducted in 1995.<sup>21</sup> A total of 1359 samples were bought from 473 drug stores and tested. Of the samples, approximately 8% were reported to be counterfeit. About 11% of the drug stores visited were found to be dealing in counterfeit products.

According to the WHO definition of counterfeit drugs, the following actions need to be carried out to establish whether a given pharmaceutical product is counterfeit:

- the identity and content of the active ingredient(s) in the product should be determined by laboratory tests;
- the source of the product, the manufacturer and the country of manufacture have to be confirmed through investigation;
- in circumstances where the product is found to be from a genuine source (manufacturer and country of manufacture) but contains no active ingredient(s), or contains the wrong ingredient(s), or contains the incorrect quantity(ies) of active ingredient(s), an investigation should be carried out to establish whether this is deliberate or not.

This investigation should be carried out by contacting the drug regulatory authority (DRA) of the country of manufacture and the manufacturer of the product.

The findings reported in the above-mentioned studies are based solely on results of laboratory tests of samples of products. None of them indicated the types of investigations carried out to establish whether the products were counterfeit. It may be possible to classify a product as counterfeit if laboratory tests show that it does not contain any active ingredient(s) or contains wrong ingredient(s). But problems will arise if laboratory tests show that the product under study contains incorrect quantity(ies) of the active ingredient(s) or correct quantity(ies) of the active ingredient(s). In this case, depending on the genuineness of the source, manufacturer and country of manufacture, the product may be classified as a counterfeit, genuine-substandard or genuine-correct quality product.

## 4. The WHO country study

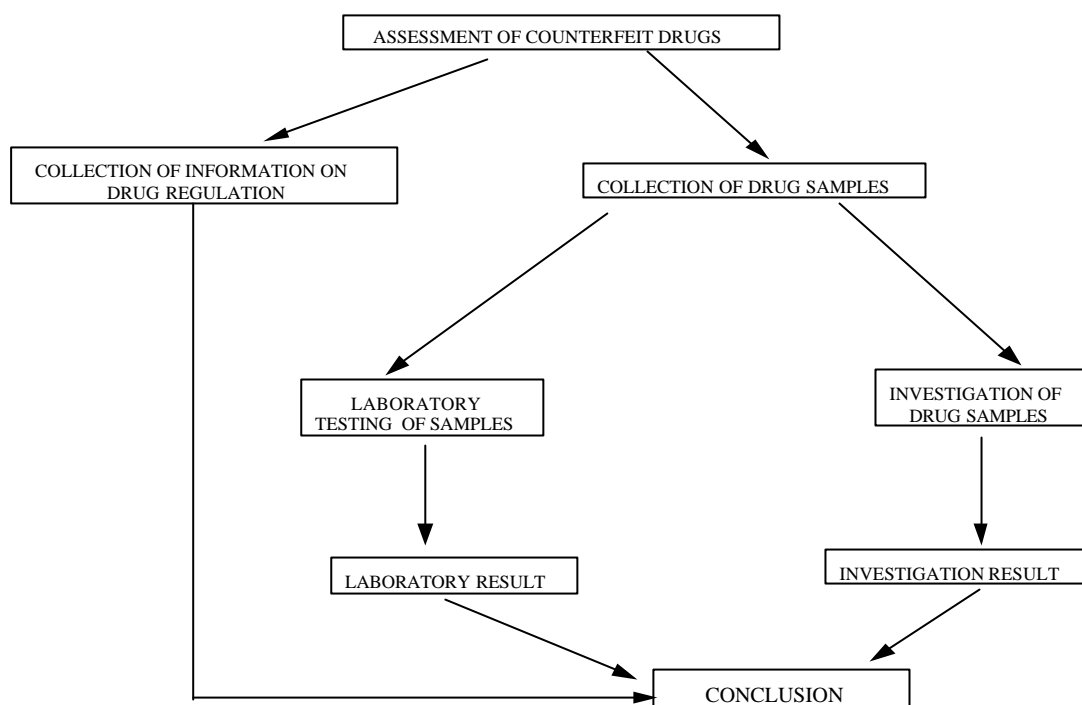
This WHO country study on counterfeit drugs was one of the components of the WHO project on counterfeit drugs. It was a joint activity between WHO's Action Programme on Essential Drugs (DAP) and the Division of Drug Management and Policies (DMP), and was launched to obtain independent information on the problem of counterfeit drugs in selected countries and to develop measures for combating pharmaceutical counterfeiting. The Government of Japan financed the project.

### 4.1 Study method

The study involved:

- (a) gathering information, by means of a questionnaire (Annex 2), about drug regulation and the problem of counterfeit drugs in the countries studied;
- (b) collecting samples of selected products from different drug outlets in the countries studied;
- (c) investigating suspect samples by contacting the drug regulatory authority of the country of manufacture (Annex 3);
- (d) determining the identity and content of the active ingredients in each sample through laboratory testing.

*Figure 3: Schematic presentation of the approach to the country study on counterfeit drugs in Myanmar and Viet Nam*



## 4.2 Preparatory work

The first phase of the study involved the development of methodology. This included:

- criteria for the selection of countries;
- criteria for the selection of the types of drug preparations to be included in the study;
- a questionnaire to collect information about the drug regulation situation;
- a questionnaire to obtain specific information about each drug sample.

The criteria used for the selection of countries were the following: willingness to participate in the study, existence of a scarce/erratic supply of drugs, existence of multiple import and distribution channels, weak drug regulation and enforcement, and illegal importation of drugs. On the basis of these criteria and in view of the limited amount of funds available, Myanmar and Viet Nam were selected for the study.

Ten products were selected for study in each country on the basis of the following criteria: inclusion in the country's list of essential drugs, high consumption, therapeutic importance, and likelihood (on the basis of previous reports) of being counterfeited. Since the two countries are geographically close a core list of five products common to both of them was selected. These were: amoxicillin, chloroquine, metronidazole, paracetamol and tetracycline.

In consultation with local counterparts, the researchers selected a further five drugs from an additional list of ten products comprising: ampicillin capsules/paediatric syrup; chloramphenicol capsules/powder for injection; cimetidine/ranitidine tablets; co-trimoxazole tablets/paediatric syrup; diazepam tablets;

erythromycin tablets/capsules; multivitamin/vitamin B complex tablets; prednisolone tablets; rifampicin tablets/capsules or a combination of products containing rifampicin; and salbutamol tablets. This selection process was country-specific. The outcome was that both countries chose in common another three products: ampicillin, chloramphenicol and rifampicin. Myanmar's total of ten was then completed by the selection of co-trimoxazole and ranitidine. Viet Nam's list was completed by diazepam and salbutamol.

To summarize, 12 products were included in the overall study. Eight products were common to both countries' lists and two products on each list were different.

Before the field visits began, official letters were sent to the Ministry of Health (MoH) of each country requesting its participation and asking it to nominate counterparts to collaborate in the study. Copies of the questionnaire (Annex 2) were then sent to the respective counterpart to obtain information on the drug regulation situation and the problem of counterfeit drugs. The information obtained was assembled, and was used as background during the field visits. A researcher from WHO/EDM went to each country to collect drug samples and additional information in collaboration with the local counterpart. Field visits were made in 1996 and 1997.

### 4.3 Field survey

In each country, survey sites were selected in consultation with the local counterpart. The following criteria were considered in the selection of survey sites: the size and population, commercial importance and the existence of a referral health care unit. In each survey site, drug outlets were selected randomly. Samples were collected on payment and the operations were carried out under cover by people recruited locally so that the vendors had no indication as to the purposes of the purchases.

In the collection of samples, care was taken to purchase adequate quantities from the same batch of the product. In the case of solid oral dosage form preparations (capsules/tablets), a minimum of 100 unit doses were purchased. In the case of oral liquid dosage forms, small volume parenterals, and dry powders for injection, 7 to 10 bottles, 30 ampoules and 20 vials respectively were bought.

In Myanmar two types of samples were collected. The first group (Table 1) consisted of 215 samples of the 10 pharmaceutical products. They were purchased from public and private drug outlets and market places in the cities of Mandalay, Monywa, Sittway and Yangon. All the samples were contained in their original primary containers and had shelf-lives ranging from one to three years.

*Table 1: Samples of products collected from four survey sites in Myanmar, shown by country of manufacture*

Preparation	Australia	Bangladesh	China	Cyprus	France	Germany	Greece	Hungary	India	Indonesia	Ireland	Israel	Italy	Malaysia	Myanmar	Pakistan	Singapore	Switzerland	Thailand	United States	United Kingdom	Unknown	TOTAL	
Amoxicillin			1	4		1			9	2				3			1		4					25
Ampicillin			2	2		2			4	1				3	1			1	5		1			22
Chloramphenicol	1		7	1		1			4	2				2	2				3					23
Chloroquine		1	3		1			1	2						1									9
Co-trimoxazole	1		2	2		2			5	1	1				3		1		2		1			21
Metronidazole		1	7						3	2					2									15
Paracetamol	1	2	3		2	1			5	2		1		2	4	2	2	1	14				2	44
Ranitidine		3	3				1		14	3									1					25
Rifampicin	1		2	2		1			3	1			2						1					13
Tetracycline	1		4	2		1			1					1	1		1		4	1	1			18
<b>TOTAL</b>	<b>5</b>	<b>7</b>	<b>34</b>	<b>13</b>	<b>3</b>	<b>9</b>	<b>1</b>	<b>1</b>	<b>50</b>	<b>14</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>11</b>	<b>14</b>	<b>2</b>	<b>5</b>	<b>2</b>	<b>34</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>215</b>	

The second group of samples (Table 2), numbering 23, were purchased from market places in Yangon. These samples were taken from products that had been removed from their original primary containers and repacked in polyethylene plastic bags by the vendors. The products were sold without labels. The vendors claimed the preparations to be amoxicillin capsules, ampicillin capsules, chloramphenicol capsules, tetracycline capsules, and vitamin B1 and vitamin B complex tablets. They were tested to see whether they contained the active ingredients claimed by the vendors.

Table 2: Unlabelled samples collected from Yangon markets

Preparations as claimed by vendors	Dosage form	Code
Amoxicillin	Capsules	AMO-19
Amoxicillin	Capsules	AMO-10
Amoxicillin	Capsules	AMO-11
Ampicillin	Capsules	AMP-04
Ampicillin	Capsules	AMP-12
Ampicillin	Capsules	AMP-13
Ampicillin	Capsules	AMP-14
Ampicillin	Capsules	AMP-15
Ampicillin	Capsules	AMP-16
Ampicillin	Capsules	AMP-21
Chloramphenicol	Capsules	CHR-03
Chloramphenicol	Capsules	CHR-17
Chloramphenicol	Capsules	CHR-18
Chloramphenicol	Capsules	CHR-19
Chloramphenicol	Capsules	CHR-23
Tetracycline	Capsules	TET-02
Tetracycline	Capsules	TET-20
Tetracycline	Capsules	TET-22
Paracetamol	Tablets	PAR-01
Vitamin B complex	Tablets	VIT-05
Vitamin B1	Tablets	VIT-06
Vitamin B complex	Tablets	VIT-07
Vitamin B1	Tablets	VIT-08

In Viet Nam samples were collected from Hanoi, Ho Chi Minh City, Ha Long and Hai Hung. A total of 288 drug samples (Table 3), imported as well as locally manufactured, were purchased from public and private pharmacies and market places.

Table 3: Samples of products collected from four survey sites in Viet Nam, shown by place of manufacture

Preparation	Austria	Australia	Canada	France	Germany	Hong Kong SAR	Hungary	India	Italy	Malaysia	Philippines	Rep. of Korea	Switzerland	Taiwan (China)	Thailand	Viet Nam	Unknown	TOTAL
Amoxicillin	2			1	3	2		10		1				1		18	2	40
Ampicillin	1			1	3	2		4		1						28		40
Chloramphenicol				2				5								20		27
Chloroquine				2			1									4		7
Diazepam							1									6		7
Metronidazole			1				2	13								13		29
Paracetamol		3		2				6			1		2		2	37	2	55
Rifampicin				1	2	3		14	2			2				5	2	31
Salbutamol			1					10		1						4	1	17
Tetracycline						2		5								26	2	35
<b>TOTAL</b>	<b>3</b>	<b>3</b>	<b>2</b>	<b>9</b>	<b>8</b>	<b>9</b>	<b>4</b>	<b>67</b>	<b>2</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>161</b>	<b>9</b>	<b>288</b>

In both countries, information about each sample, including the name of the product, the dosage form and the batch number, was recorded on a pre-prepared form (Annex 1). Each sample was then divided into three portions. The first portion served as control, the second portion was submitted for laboratory testing and the third portion was used for those drugs sent for further investigation to their country of origin.

Samples to be tested were removed from their primary containers and repacked in high-density polyethylene bottles, labelled, coded and sent to the WHO collaborating laboratory in Thailand for testing.

Additional information about each drug sample was obtained from the DRAs of Myanmar and Viet Nam through the questionnaire shown in Annex 3. Products confirmed as registered and genuine by the responsible staff of the DRAs were separated from those not registered. The samples of unregistered products were sent to the DRAs of the countries of manufacture. The DRAs were requested to indicate whether the products were manufactured in their countries, whether the manufacturers were licensed, whether the products were authorized/registered for sale in the countries, and whether they were genuine.





## 5. Results of the study

### 5.1 Myanmar

Myanmar occupies an area of about 677,000 square kilometres. Administratively, the country is divided into seven states and seven divisions. Each state/division is further divided into districts and townships. The country's population was estimated at 44 million in 1996. In 1991, the per capita income was US\$ 178.

#### **Pharmaceutical situation**

The study found that the total public sector drug expenditure in 1994/1995 was US\$ 6.5 million and the total value of drug imports during the same period was US\$ 0.9 million. At the time of the survey the country had one school of pharmacy, 146 pharmacists, one state-owned pharmaceutical industry, about 60 private small-scale pharmaceutical industries, 20 importers and 275 wholesalers. In the public sector there were 144 drug outlets. The number of private pharmacies was estimated at 8500. The total number of products registered in the country up to 1995 was 1600.

#### ***Drug supply***

Over the years there was a proliferation of drug shops, including booths located in market places in the country. Some of the drugs sold were of unknown quality, efficacy or safety and were imported/smuggled into the country through unauthorized channels.

Authorized manufacturing, importation and distribution of drugs are carried out by the private and public sectors. In the public sector, the MoH, the Ministry of Trade and Commerce and the Ministry of Industry are involved. The MoH has a Central Medical Stores Depot (CMSD) which imports drugs and distributes them to government hospitals and health care facilities. Nearly all its supplies of drugs are purchased from the Myanmar Pharmaceutical Factory, the only state-owned pharmaceutical plant in the country, which is under the Ministry of Industry. The Ministry of Trade and Commerce also runs Medicines and Medical Equipment Trading (MMET), which imports drugs and distributes them to the public and private clinics.

At the time of the study, about 60 small-scale private manufacturers were known to exist, but none of them had been issued with a licence from the MoH to manufacture drugs. During the study, products manufactured by these industries were seen on the market.

During the field survey it was noted that both the state-owned and private industries do not comply with GMP requirements. In Yangon, one of the cottage industries visited was found to be operating in a building partly used as a residence. Production activities were carried out using inappropriate machines and under extremely unhygienic conditions. The industry was managed and

operated by people who had no qualifications or training in pharmaceutical production or quality control. The plant did not have a quality control laboratory or any means of quality assurance.

## **Drug regulation**

Until 1992, the Public Health Law enacted in 1972 served as the legal instrument for drug control. However, there were no specific activities to exercise regulatory control over importation, manufacture and distribution of medicines. In 1991, Myanmar adopted a National Drug Policy (NDP). The policy clearly delineates objectives, which include ensuring the availability of effective and safe drugs of acceptable quality. The National Drug Law was enacted in 1992 and regulations for enforcement were issued by the MoH in 1993. The drug law and regulations cover importation, manufacture, distribution, drug registration, inspection and quality control of drugs. Under the National Drug Law, terms such as “fake drugs” and “drugs differing from standards” defined, and there are prohibitions with regard to those drugs.

Several authorities are responsible for enforcement of the drug law. The Myanmar Food and Drug Board Authority (MFDBA), under the chairmanship of the Minister of Health, provides guidance on the implementation of the NDP and for establishing the Food and Drug Supervisory Committees (FDSCs) at central level as well as in states/divisions, districts and townships.

The State/Division Food and Drug Supervisory Committees, under the Director General of the Department of Health (who is chairman of the Central Food and Drug Supervisory Committee (CFDSC)), license drug wholesalers and retailers. The CFDSC licenses the local drug manufacturers and gives drug importation approval certificates to the importers. At township level the FDSCs are managed by the Township Medical Officers. The committees consist of the Township Medical Officer, the Commander of the Police, and the representatives of the City Development Committee and the General Administration Committee.

Applications for licences are submitted to the respective Township Food and Drug Supervisory Committee, which will inspect the shops, and then refer them to the State/Division Food and Drug Supervisory Committee for decision. Licences are issued by the Township Medical Officer on the basis of the decision of the State/Division Food and Drug Supervisory Committee.

### **(a) drug registration**

The Food and Drug Administration (FDA), which was established in January 1995, is responsible for issuing marketing authorization for pharmaceutical products, inspection of manufacturing plants and importers, and testing the quality of drugs. There is a Drug Advisory Committee (DAC) delegated to evaluate and register drugs. Prior to submission to the DAC, applications are reviewed by the staff of the registration section of the FDA, which consists of the Assistant Director of the Drug Control Section and two pharmacists.

Registration applies to imported as well as domestically manufactured products, and covers both the public and private sectors. Guidelines for drug registration have been formulated and they require that anyone applying for registration

should be a resident of the Union of Myanmar. In the case of foreign companies, the applicant must be a legal representative domiciled in Myanmar but need not be the sole importer of the drug. Once a drug is registered, it can be imported into the country by anyone who has a licence to import pharmaceuticals.

For a product to be registered, clinical trials have to be carried out in Myanmar. The WHO-type Certificate of a Pharmaceutical Product is a prerequisite for registration.

There is a fee system consisting of an assessment fee of US\$ 100, a registration fee of US\$ 200, a renewal fee of US\$ 200 and a variation fee of US\$ 100. Fees collected go to the DAC's account. Registration is valid for five years.

Over 50% of the drugs seen in the market, including those domestically produced, had not been registered by the FDA at the time of the study.

***(b) inspection***

Inspection of manufacturing plants is carried out by two inspectors of the FDA. The FDA has a non-descriptive list (checklist) of GMP requirements for manufacturers. Industries owned by nationals of Myanmar are expected to meet only a part of these requirements, while foreign companies are obliged to comply with all the requirements. There were no standard procedures for inspectors. The inspectors need training and experience in GMP inspection. Their number was inadequate at the time of the study.

Inspection of drug distribution channels is the responsibility of the Food and Drug Supervisory Committees at the different levels. In reality, inspection services exist at the central level only. Even there, they are not fully operational and inspection is rarely carried out. Members of the committees do not have expertise in pharmaceutical matters. Moreover, there is no post-marketing surveillance. According to information gathered during the study, drugs are known to enter the country through unauthorized channels. Tampering with labels and transferring products from one container to another are reported to be common practices.

The drug law requires distribution channels to operate under the supervision of technically qualified persons. During the survey, it was noted that most distribution outlets were being run by unqualified people. The storage and distribution conditions were very bad and needed drastic improvement.

In all the four geographical areas surveyed, drugs were sold in booths as well as in shops. Preparations in solid oral dosage form, capsules and tablets, coming in hospital packs, were removed from their original containers and repacked in transparent plastic bags and displayed for sale. Dealers identified the preparations by their colours. In some of the market places visited, expired drugs, drugs without expiry dates and drugs without the names of manufacturers were being sold.

***(c) quality control***

The quality control laboratory under the FDA tests the quality of drugs in connection with registration. Very little analytical activity was noted during the

visit. In 1994-1995, the laboratory tested only 32 samples. Out of these, 8 (25%) failed to meet quality standards. Three of the failed samples were substandard and 5 (15.6%) contained no active ingredients.

### Results of assessment of registration status of samples

The registration status of the 215 samples in the first group of samples was assessed in collaboration with the FDA. The result (Table 4) shows that of those samples, 201 (93%) were imported products, while the remaining 14 (7%) were samples of locally manufactured products. Of the 14 samples of domestically manufactured products, 6 (43%) were not registered. In the case of samples of imported products, 117 (58%) out of 201 were not registered.

*Table 4: Registration status of samples of pharmaceutical preparations collected from Myanmar*

Preparation	Domestically produced		Imported		Total
	Registered	Not registered	Registered	Not registered	
Amoxicillin	-	-	17	8	25
Ampicillin	1	-	13	8	22
Chloramphenicol	-	2	7	14	23
Chloroquine	1	-	1	7	9
Co-trimoxazole	1	2	7	11	21
Metronidazole	2	-	3	10	15
Paracetamol	2	2	15	25	44
Ranitidine	-	-	10	15	25
Rifampicin	-	-	7	6	13
Tetracycline	1	-	4	13	18
<b>Total</b>	<b>8</b>	<b>6</b>	<b>84</b>	<b>117</b>	<b>215</b>

Of the 215 samples, only 92 (43%) were confirmed to be registered with the FDA.

It was not possible to assess the registration status of the second group, consisting of 23 samples (Table 2) collected in Yangon, since they were not contained in their original primary containers, having been repacked in unlabelled plastic bags by the dealers.

### Results of laboratory testing of samples

Out of the 215 samples, 212 were submitted to the WHO collaborating laboratory in Thailand to determine the identity and content of the active ingredients. Tests were carried out according to the specifications of the British and the United States pharmacopoeias. Table 5 shows the results of the tests.

Out of the samples tested, 34 (16%) failed to pass quality tests because they contained active ingredients below the limits specified in BP93 and USP23. Of these, one sample contained the wrong ingredient. The content of active ingredients in six samples ranged from 2 to 60% of the labelled amount. Out of the 10 products sampled, chloramphenicol preparations showed a high failure rate (35%), followed by ranitidine, co-trimoxazole and amoxicillin with failure rates of 20%, 19% and 16% respectively. All the samples tested had a shelf-life ranging from one to three years at the time of testing.

Table 5: Summary of results of laboratory tests on samples from Myanmar

Preparation	Total tested	Wrong	2-5% of labelled amount	25-60% of labelled amount	61-85% of labelled amount	86-89% of labelled amount	Total failed
Amoxicillin	25				4		4 (16%)
Ampicillin	22				3		3 (13.6%)
Chloramphenicol	23		1		7		8 (34.8%)
Chloroquine	9						0
Co-trimoxazole	21	1		2		1	4 (19.1%)
Metronidazole	14			1			1 (7.1%)
Paracetamol	44			3	1	3	7 (15.9%)
Ranitidine	25				2	3	5 (20%)
Rifampicin	11				1		1 (9.1%)
Tetracycline	18		1				1 (5.6%)
<b>Total</b>	<b>212</b>	<b>1</b>	<b>2</b>	<b>6</b>	<b>18</b>	<b>7</b>	<b>34 (16.0%)</b>

Table 6 sets out the results of laboratory tests of the unlabelled samples collected in Yangon. Thirteen of the preparations contained ingredients other than those claimed by the dealers, three preparations contained no active ingredients, and the remaining seven preparations contained in varying quantities the active ingredients claimed by the vendors.

Table 6: Results of laboratory tests of unlabelled samples collected from Myanmar markets

Product as claimed by vendors	Dosage	Code	Result of laboratory identity test
Amoxicillin	Capsule	AMO-19	Diphenhydramine
Amoxicillin	Capsule	AMO-10	Diphenhydramine
Amoxicillin	Capsule	AMO-11	Diphenhydramine
Ampicillin	Capsule	AMP-04	Tetracycline
Ampicillin	Capsule	AMP-12	Diphenhydramine
Ampicillin	Capsule	AMP-13	Diphenhydramine
Ampicillin	Capsule	AMP-14	Diphenhydramine
Ampicillin	Capsule	AMP-15	Diphenhydramine
Ampicillin	Capsule	AMP-16	Diphenhydramine
Ampicillin	Capsule	AMP-21	Tetracycline
Chloramphenicol	Capsule	CHAR-03	Tetracycline
Chloramphenicol	Capsule	CHR-17	Negative
Chloramphenicol	Capsule	CHR-18	Negative
Chloramphenicol	Capsule	CHR-19	Negative
Chloramphenicol	Capsule	CHR-23	Tetracycline
Tetracycline	Capsule	TET-02	Tetracycline 8.8mg/cap.
Tetracycline	Capsule	TET-20	Tetracycline 209.5 mg/cap.
Tetracycline	Capsule	TET-22	Tetracycline 253.8 mg/cap.
Paracetamol	Tablet	PAR-01	447mg/tab.
Vitamin B complex	Tablet	VIT-05	Positive
Vitamin B1	Tablet	VIT-06	Positive
Vitamin B complex	Tablet	VIT-07	Positive
Vitamin B1	Tablet	VIT-08	Chloroquine

### Summary of results of assessment of registration status and laboratory testing of samples

Table 7 combines information on the registration status of the 212 samples and the respective results of laboratory testing. Out of the 14 samples of domestically

manufactured products, eight registered products contained active ingredients within the limits specified in the British and United States pharmacopoeias. Two of the 6 samples of domestically manufactured but unregistered products failed the tests. Of the 81 samples of imported but registered products, 5 were found to be substandard. Of the 117 samples of imported but unregistered products, 27 failed laboratory tests. The failure rate in the case of domestically produced products was 14%, while for imported products it was 16%. On the other hand, the failure rate among non-registered products (both imported and domestically produced) was 24%, which is four times greater compared with the failure rate among registered products, which was 6%. Among both the domestically produced and imported samples, a high failure rate was observed in the case of unregistered products. The overall rate of failure was 16%.

*Table 7: Summary of registration status and results of laboratory testing of samples from Myanmar*

Preparation	Samples tested	Domestically produced				Imported			
		Reg.	Reg.; failed	Not reg.	Not reg.; failed	Reg.	Reg.; failed	Not reg.	Not reg.; failed
Amoxicillin	25	-	-	-	-	17	3	8	1
Ampicillin	22	1	-	-	-	13	1	8	2
Chloramphenicol	23	-	-	2	-	7	-	14	8
Chloroquine	9	1	-	-	-	1	-	7	-
Co-trimoxazole	21	1	-	2	1	7	1	11	2
Metronidazole	14	2	-	-	-	2	-	10	1
Paracetamol	44	2	-	2	1	15	-	25	6
Ranitidine	25	-	-	-	-	10	-	15	5
Rifampicin	11	-	-	-	-	5	-	6	1
Tetracycline	18	1	-	-	-	4	-	13	1
<b>Total</b>	<b>212</b>	<b>8</b>	<b>-</b>	<b>6</b>	<b>2</b>	<b>81</b>	<b>5</b>	<b>117</b>	<b>27</b>

### Results of investigation of samples

Out of the 215 samples collected in the first group, 147 manufactured in 17 countries (Table 8) were sent for investigation to the drug regulatory authorities of the countries of manufacture. The samples sent were those reported as non-registered by the regulatory authorities of Myanmar and those suspected, on the basis of physical examination, of being counterfeit.

Only 14 countries replied. Of these, 10 confirmed that the products were genuine and the manufacturers were licensed. The remaining four countries provided the information given below.

One country reported that the samples sent for investigation represented products which were traded in transit via a free port and that the products were not registered in the country. The report also indicated that the company mentioned on the label of the samples was licensed to manufacture pharmaceuticals in the country, but the products under investigation were produced by contract manufacturers outside the country. The products were confirmed to be genuine.

The second country responded that the company in question was licensed to manufacture veterinary pharmaceuticals. Medicines for human use were said to be produced by the company for export only, and the product under investigation was not registered with the drug regulatory authority.

The regulatory authorities of the other two countries replied that the products sent to them were mislabelled with respect to their source. They said that the companies whose names appeared on the labels of the products existed in their countries but they were not licensed to manufacture, import or distribute pharmaceutical products in their countries. They confirmed that although the products were labelled as though they were manufactured in their countries, they were actually produced, packaged and labelled by manufacturers operating in other countries and exported direct to the countries under study. They indicated that the products were neither registered nor distributed in their countries.

*Table 8: Samples of products collected from Myanmar and investigated, shown by country of manufacture*

Preparation	Australia	Bangladesh*	China*	Cyprus	France	Germany	India	Indonesia	Ireland	Israel	Italy*	Malaysia	Pakistan	Singapore	Switzerland	Thailand	United Kingdom	TOTAL
Amoxicillin			1	3		1	8	2				2		1				18
Ampicillin			2	2		2	3	1				2		1				13
Chloramphenicol	1		5	1		1		2				2						12
Chloroquine		1	1		1		1											4
Co-trimoxazole	1		3	2		2	4	1	1					1				15
Metronidazole		1	5				1	2										9
Paracetamol		2	1		1	1	5	2		1		2	2	2	1	8		28
Ranitidine		3	3				14	3								1		24
Rifampicin	1		2	1		1	3	1			1							10
Tetracycline	1		1	2		1	1	1				1		1		4	1	14
<b>TOTAL</b>	<b>4</b>	<b>7</b>	<b>24</b>	<b>11</b>	<b>2</b>	<b>9</b>	<b>40</b>	<b>15</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>9</b>	<b>2</b>	<b>6</b>	<b>1</b>	<b>13</b>	<b>1</b>	<b>147</b>

\* Did not reply.

## Summary of laboratory test results and investigation findings

Table 9 summarizes the laboratory test results and the investigation findings for 147 samples from Myanmar. Of those samples, 110 were confirmed to be genuine and 5 mislabelled with respect to their source, and 1 contained the wrong ingredient. No reply was received for the remaining 31 samples. The five mislabelled products contained the claimed active ingredients in quantities within the pharmacopoeial limits. Of the 110 genuine products, 5 contained active ingredients below the pharmacopoeial limits. The content of active ingredients ranged from 80 to 87% of the labelled amount. Ten (32%) of the 31 samples for which investigation replies were not received were found to be substandard and the content of active ingredients ranged from 26 to 89%. However, since no replies were obtained from the drug regulatory authorities of



the countries approached, it was not possible to be certain whether the 31 products were genuine or not.

*Table 9: Summary of laboratory results by outcome of investigation, Myanmar*

Preparation	Mislabelled/counterfeit: (6 products)		Genuine: (110 products)		No reply: (31 products)	
	Passed lab. test	Failed lab. test	Passed lab. test	Failed lab. test	Passed lab. test	Failed lab. test
Amoxicillin	0	0	16	1 (84.2%)	0	1 (76.3%)
Ampicillin	0	0	11	1 (81%)	0	1 (72%)
Chloramphenicol	1	0	6	0	3	2 (70-86%)
Chloroquine	0	0	2	0	2	0
Co-trimoxazole	2	1 (wrong ingredient)	9	0	3	0
Metronidazole	0	0	3	0	5	1 (53.3%)
Paracetamol	0	0	25	0	1	2 (26-63%)
Ranitidine	0	0	15	3 (80-87%)	4	2 (87-89%)
Rifampicin	1	0	6	0	2	1 (82%)
Tetracycline	1	0	11	0	1	0
<b>Total</b>	<b>5</b>	<b>1</b>	<b>105</b>	<b>5</b>	<b>21</b>	<b>10</b>

## 5.2 Viet Nam

Viet Nam has an area of about 330,000 square kilometres and is divided into 53 provinces. In 1995, it had an estimated population of 75 million and the annual per capita income was US\$ 280.

In 1986, the Communist Party congress adopted a new economic policy — “doi moi” (economic renovation) — which brought about changes from a command economy to a free market economy but with many sectors still managed by the Government. In the last ten years many private companies have sprung up. In the pharmaceutical sector these changes have caused a considerable increase in the number of private pharmaceutical companies. Also, pharmaceutical imports into Viet Nam have increased very substantially since the introduction of “doi moi”.

### Pharmaceutical situation

The value of drug expenditure in the public sector in 1995 was estimated at US\$ 240 million. Local production and total imports during the same year amounted to US\$ 87 million and US\$ 195 million respectively. There were 7500 pharmacists and 16,376 pharmacy technicians. An NDP was established in 1996. One of its specific objectives is to ensure drug quality in production, storage and distribution.

### Drug supply

Viet Nam has a fairly large domestic pharmaceutical industry, which may be divided into two groups. The first group consists of state-owned manufacturing industries. There were 154 such industries in 1995. These industries are organized into 35 different companies under one corporation, called the General Pharmaceutical Company. The MoH is the supervisory body. These companies manufacture, import, export and distribute (wholesale and retail) finished products and raw materials.

The second group consists of 135 manufacturing plants owned by different provinces/cities. They are managed by the People's Committee of the respective province/city. A small number of these companies are engaged in manufacturing and import-export activities, while most of them also distribute pharmaceuticals and manufacture traditional medicines. In addition, the Ministries of Internal Affairs, Defence and Transportation run companies which manufacture and distribute pharmaceuticals.

In 1995, there were 265 wholesalers, 22,450 public drug outlets and more than 7000 private pharmacies throughout the country. Pharmacists working in government institutions, with the exception of those holding high government posts, are allowed to open their own private pharmacies and run them outside office hours. According to information provided informally during the survey, drugs are also smuggled into the country.

### **Drug regulation**

Drug regulation is the responsibility of the MoH of Viet Nam. The Drug Law provides for regulation of the manufacture, importation and distribution of drugs.

Three bodies, each reporting directly to the Vice Minister for Pharmaceuticals, are charged with drug regulation. These are the Drug Administration, formerly known as the Pharmacy Department, the Pharmaceutical Inspection Department and the National Institute of Drug Quality Control.

#### **(a) drug registration**

The Drug Administration is responsible for coordinating and monitoring the implementation of the NDP, developing drug legislation/regulations, registering drugs, issuing import-export licences, and controlling manufacture, importation, and promotion and advertising. It also carries out post-marketing surveillance and dissemination of drug information. At the time of the survey, it had about 20 staff members working in its various sections.

The Drug Administration is assisted by the Drug Registration Commission in the registration of drugs. In addition, part-time experts assist in the evaluation of drug submissions. Registration applies to both imported and locally manufactured drugs. At the time of the study there were 8000 products registered. All locally manufactured products were reported to be registered. In the case of drugs imported by the public sector, only 75% were said to be registered.

Different fee rates are applied for the registration of domestically produced and imported products. The time required for drug approval varies from 12 months for imported drugs to three months for locally manufactured products. Registration is valid for five years.

During the study several unregistered imported drugs were seen on the market. Although the process of registration is said to include the colour, imprint, trademark etc. of the product, several different preparations with identical distinguishing marks, imprints and colours (lookalikes) were seen on the market.

**(b) inspection**

Drug inspection responsibility is divided between the central and provincial authorities. At central level inspectors of the Drug Administration carry out inspection. In 1995, there were only two inspectors at national level and one or two in each province. The total number of inspectors in the country was 61. There were no inspection services provided by the MoH at customs warehouses or ports of entry. In general, the emphasis was on strengthening laboratory services rather than inspection services, which is contrary to what one would expect in view of the large number of pharmaceutical industries in Viet Nam.

There were no GMP guidelines and no manual for inspectors and manufacturers at the time of the survey in 1996. But it was reported that ASEAN GMP guidelines would be adopted. Only a few of the manufacturing plants complied with GMP requirements. Most of the plants had old equipment and inadequate premises. Inspections of industries were very weak and were not carried out very often.

In the distribution channels, it was found that private outlets had been tampering with labels, selling/dispensing drugs imported through unauthorized channels and counterfeit drugs. The drugs commonly sold through unauthorized outlets were antibiotics, analgesics, vitamins and traditional medicines. Inspectors had also come across mislabelled ampicillin, tetracycline and phenoxymethylpenicillin preparations. In general, inspections of premises were found to be ineffective and the number of inspectors was inadequate.

In most of the wholesale and retail outlets visited, drugs were stored under poor conditions exposed to sunlight. Preparations in blister/strip packs were removed from their secondary containers (boxes) and displayed unprotected from sunlight, and inserts accompanying blister/strip packs were in most cases discarded.

**(c) quality control**

A system for quality control of drugs has existed in Viet Nam since 1958. Quality control is carried out by the National Institute of Drug Quality Control in Hanoi, the Sub-Institute of Quality Control in Ho Chi Minh City and the drug quality control laboratories of the provincial health departments. In 1995, the number of staff working in the two institutes and the provincial laboratories was estimated to be 701 (42 with postgraduate degrees, 313 pharmacists, 212 technicians and 134 administrative personnel). The Institute and Sub-Institute are well equipped. In contrast, provincial laboratories have basic equipment only.

The institutes and the laboratories are engaged in post-marketing surveillance activities. In 1995, 31,125 samples collected from different parts of the country were tested and 1703 samples failed to meet quality standards. Of these, 1537 were substandard, while the remaining 166 were counterfeit. Reports show that the rate of failure of drugs has decreased very much after the introduction of an intensive post-marketing quality surveillance system using the simple testing kits developed by the National Institute of Drug Quality Control.

## Results of assessment of registration status of samples

Investigation of the samples in collaboration with the Drug Administration produced the results shown in Table 10. Of the 288 samples collected, 127 were found to be samples of imported products, while the other 161 were domestically manufactured. Only 51 (40%) of the 127 samples of imported products were registered. The domestically produced products were all registered with the Drug Administration. Hence, 76 (26%) of the 288 samples were found to be non-registered.

Table 10: Registration status of samples collected from Viet Nam

Preparation	Imported		Domestically produced	
	Registered	Not registered	Registered	Not registered
Amoxicillin	9	13	18	0
Ampicillin	5	7	28	0
Chloramphenicol	3	4	20	0
Chloroquine	1	2	4	0
Diazepam	1	0	6	0
Metronidazole	7	9	13	0
Paracetamol	6	12	37	0
Rifampicin	10	16	5	0
Salbutamol	6	7	4	0
Tetracycline	3	6	26	0
<b>Total</b>	<b>51</b>	<b>76</b>	<b>161</b>	<b>0</b>

## Results of laboratory testing of samples

Laboratory tests on the 288 samples produced the results shown in Table 11. The findings indicate that 21 (7%) products contained active ingredients below the labelled amount (60-89%), one contained active ingredients above the pharmacopoeial limit and the remaining 266 (92%) samples contained active ingredients within the limits specified in the British Pharmacopoeia (BP) and the United States Pharmacopoeia (USP). The rate of failure was 8%.

Table 11: Summary results of laboratory tests on products collected from Viet Nam

Preparation	Samples tested	60-70% of labelled amount	71-80% of labelled amount	81-89% of labelled amount	Within BP/USP limit	Above 110%
Amoxicillin	40	2	1	2	35	0
Ampicillin	40		0	2	38	0
Chloramphenicol	27	0	0	0	27	0
Chloroquine	7	0	0	1	6	0
Diazepam	7	0	0	0	7	0
Metronidazole	29	0	0	0	29	0
Paracetamol	55	1	0		54	0
Rifampicin	31	0	1	8	22	0
Salbutamol	17	0	0	3	13	1
Tetracycline	35	0	0	0	35	0
<b>Total</b>	<b>288</b>	<b>3</b>	<b>2</b>	<b>16</b>	<b>266</b>	<b>1</b>

## Summary of results of assessment of registration status and laboratory testing of samples

Comparison of the results of the laboratory tests with registration status (Table 12) shows that among the 51 samples of imported but registered products, 3 (6%) failed the laboratory test, while out of the 76 samples of imported unregistered products, 15 (20%) contained active ingredients below the labelled amount. On the other hand, only 4 (3%) of the 161 samples of domestically produced/registered products failed the laboratory test. The failure rate among non-registered products (imported and domestically produced) was 20%, compared with about 3% in the case of registered products.

Table 12: Registration status and results of laboratory testing of samples from Viet Nam

Preparation	Samples collected	Domestically produced products				Imported products			
		Reg.	Reg.; failed	Not reg.	Not reg.; failed	Reg.	Reg.; failed	Not reg.	Not reg.; failed
Amoxicillin	40	18	0	0	0	9	1	13	4
Ampicillin	40	28	0	0	0	5	0	7	2
Chloramphenicol	27	20	0	0	0	3	0	4	0
Chloroquine	7	4	1	0	0	1	0	2	0
Diazepam	7	6	0	0	0	1	0	0	0
Metronidazole	29	13	0	0	0	7	0	9	0
Paracetamol	55	37	1	0	0	6	0	12	0
Rifampicin	31	5	2	0	0	10	1	16	6
Salbutamol	17	4	0	0	0	6	1	7	3
Tetracycline	35	26	0	0	0	3	0	6	0
<b>Total</b>	<b>288</b>	<b>161</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>51</b>	<b>3</b>	<b>76</b>	<b>15</b>

## Results of investigation of samples

A portion of each of 67 of the 288 samples collected was sent to the drug regulatory authorities of the ten countries and one region claimed to be the places of manufacture (Table 13). None of the samples investigated was registered with the drug regulatory authorities of Viet Nam.

Table 13: Samples collected from Viet Nam and investigated, shown by country of manufacture

Preparation	Australia	Canada	France	Germany	Hong Kong SAR	India	Italy	Malaysia	Rep. of Korea	Switzerland	United States	TOTAL
Amoxicillin			1	2	1	5			1			10
Ampicillin			1		1	4						6
Chloramphenicol			1			3						4
Chloroquine			1									1
Metronidazole		1				9						10
Paracetamol	2	1	2			4				2	1	12
Rifampicin			1		1	8	2	1				13
Salbutamol		1				5						6
Tetracycline						5						5
<b>TOTAL</b>	<b>2</b>	<b>3</b>	<b>7</b>	<b>2</b>	<b>3</b>	<b>43</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>67</b>

Replies received from six countries confirmed 53 of the samples of products to be genuine, i.e. produced by licensed manufacturers. No replies were received for samples of 14 products, and it was therefore not possible to confirm their genuineness.

### Summary of laboratory test results and investigation findings

Of the samples of 53 products reported to be genuine, 13 (19%) failed laboratory tests and the content of active ingredients ranged from 60 to 89% of the label claim. Of these, 11 were antimicrobial preparations—amoxicillin, ampicillin and rifampicin. The 14 samples of products for which replies were not received contained active ingredients within the limits specified in the British and United States pharmacopoeias.

Table 14: Summary of results of investigation and laboratory test of samples from Viet Nam

Preparation	Total investigated	Investigation: genuine 53 products		Investigation: no reply, 14 products	
		Passed lab. test	Failed lab. test	Passed lab. test	Failed
Amoxicillin	10	5	3 (60-88%)	2	0
Ampicillin	6	3	2 (80-87%)	1	0
Chloramphenicol	4	3	0	1	0
Chloroquine	1	0	0	1	0
Diazepam	0	0	0	0	0
Metronidazole	10	9	0	1	0
Paracetamol	12	8	0	4	0
Rifampicin	13	4	6 (78-88%)	3	0
Salbutamol	6	3	2 (82-89%)	1	0
Tetracycline	5	5	0	0	0
<b>Total</b>	<b>67</b>	<b>40</b>	<b>13</b>	<b>14</b>	<b>0</b>



## 6. Summary of findings

Drug regulation needs to be appropriately organized, and it is essential to have the necessary trained staff, resources and implementation tools. Moreover, enforcement powers are required in order to make regulation fully functional.

Responses to the questionnaires received from national counterparts and information gathered during the study revealed drug regulation to be ineffective in Myanmar but relatively better functioning in Viet Nam.

In both countries drug regulation activities were widely distributed among different agencies at central, provincial/state and peripheral levels without any clear definition of responsibilities, accountability or powers of enforcement. There was also a shortage of trained human resources and implementation tools.

Although each country's national drug policy document indicates the government's commitment to ensure the quality of drugs available on the market, in reality GMP were not a legal requirement nor were they implemented in either country. In Myanmar a checklist for GMP inspectors existed, but there were no GMP guidelines for manufacturers. Compliance with the checklist involved double standards in that industries owned by nationals were required to meet only a few of the conditions, whereas those owned by foreign investors were required to meet all of them. This suggests that there is no clear understanding of the principles and objectives of GMP and quality assurance among decision-makers. In Viet Nam too there were no GMP guidelines for manufacturers or inspectors. In both countries, manufacturers not complying with GMP requirements produce and distribute drugs.

A system of product assessment and registration exists in both countries. Nevertheless, out of products collected from Myanmar and Viet Nam for the survey, 57% and 26% respectively did not have marketing authorization.

In Viet Nam, it was found that importation of pharmaceutical products was not linked to the WHO certification scheme, whereas in Myanmar the scheme was a prerequisite. In both countries smuggling of drugs from neighbouring countries was reported to exist.

A basic but by far the most important activity in drug regulation is to ensure that drug manufacturing, importation and distribution are carried out in approved premises by qualified people and are regularly monitored by the competent national authorities. This requires the availability of written procedures for issuing and revoking licences and their strict implementation. In both countries, the study team observed drugs being sold in market places and booths. The storage conditions in some places were extremely bad.



In Myanmar, people without a licence or qualifications manufacture and distribute drugs. Vendors repack drugs in plastic bags and sell them without labels.

Distribution channels and manufacturing plants are seldom inspected, and there is a lack of adequately trained people in both countries. The countries gave less emphasis to preventive inspection, particularly at ports of entry. Consequently, illegally imported drugs were found on the markets of both countries.

In Viet Nam, more emphasis was given to quality control services than to inspection services. Because the powers and responsibilities of the inspection services at the different administrative levels are not clearly defined, enforcement was very weak.

Laboratory tests carried out on 500 samples of 12 pharmaceutical products collected from both countries in order to determine the identity and content of the active ingredients yielded the combined results shown in Table 15. Among these samples, one contained the wrong ingredient, while 54 contained between 2 and 89% of the correct ingredient and one contained above 110% of the labelled amount. These figures do not include the five samples reported to be mislabelled with respect to their source but which contained the labelled amount of active ingredients. The failure rates were 16% for Myanmar and 8% for Viet Nam.

*Table 15: Combined results of laboratory tests on samples collected from Myanmar and Viet Nam*

Preparations collected from Myanmar and Viet Nam					Laboratory test results				
Preparations	Total tested	Total failed	% failed	Wrong ingredient	2-25%	25-60%	61-85%	86-89%	Above 110%
Amoxicillin	65	9	13.8				7	2	
Ampicillin	62	5	8.1				5		
Chloramphenicol	50	8	16		1		7		
Chloroquine	16	1	6.3						1
Co-trimoxazole	21	4	19.1	1		2			1
Diazepam	7		0						
Metronidazole	43	1	2.3			1			
Paracetamol	99	8	8.1			3	2		
Ranitidine	25	5	20				2	3	
Rifampicin	42	10	23.8				5	3	
Salbutamol	17	4	23.5				1	5	1
Tetracycline	53	1	1.9		1				2
<b>Total</b>	<b>500</b>	<b>56</b>		<b>1</b>	<b>2</b>	<b>6</b>	<b>29</b>	<b>17</b>	<b>1</b>

In both countries high failure rates were observed in the case of unregistered drugs. For instance, in Myanmar (Table 7) 5 (6%) out of the 89 registered products failed compared with 29 (24%) out of 123 unregistered products.

In Viet Nam (Table 12) the failure rate for registered products was 7 (3%) out of 212, compared with 15 (20%) out of 76 for unregistered products. This confirms the argument that implementing an effective drug registration system can improve the quality of drugs in the market.

Of the 12 products, rifampicin showed the highest failure rate (26%), whereas salbutamol, co-trimoxazole and ranitidine had failure rates of 24%, 24% and 20% respectively (Table 16).

*Table 16: Combined results of investigation of 214 samples and laboratory tests on 500 samples from Myanmar and Viet Nam*

Product	Total sample	Mislabeled source *	Failed laboratory test	Total failed
Amoxicillin	65		9	9 (14%)
Ampicillin	62		5	5 (8%)
Chloramphenicol	50	1	8	9 (18%)
Chloroquine	16		1	1 (6%)
Co-trimoxazole	21	1	4**	5 (24%)
Diazepam	7		0	0 (0%)
Metronidazole	43		1	1 (2%)
Paracetamol	99		8	8 (8%)
Ranitidine	25		5	5 (20%)
Rifampicin	42	1	10	11 (26%)
Salbutamol	17		4	4 (24%)
Tetracycline	53	2	1	3 (6%)
<b>Total</b>	<b>500</b>	<b>5</b>	<b>56</b>	<b>61 (12%)</b>

\* The names of the countries of manufacture on the label were incorrect, but all samples contained correct quantities of the active ingredients.

\*\* One product contained the wrong ingredient but was reported to have been produced by a legitimate manufacturer.

Investigation of 214 samples collected from both countries yielded the combined results shown in Table 17. Of the 169 samples of products for which replies were received, 6 (4%) were reported to be counterfeit (one wrong ingredient and five wrong sources) and the remaining 163 samples of products were reported as genuine (i.e. manufactured by licensed manufacturers). It was not possible to confirm the genuineness of the remaining 45 samples.

Laboratory tests on the 163 samples of genuine products showed that 145 (89%) contained active ingredients as claimed on the label. The contents of the other 18 samples (11%) were below the labelled amount. In the case of the 45 samples for which replies were not received, 10 contained active ingredients at substandard levels.

*Table 17: Results of investigation and laboratory testing of 214 samples from Myanmar and Viet Nam*

Country	Number of samples	Reply received			No reply	
		Counterfeit	Genuine		Passed	Failed
			Passed	Failed		
Myanmar	147	6	105	5	21	10
Viet Nam	67	0	40	13	14	0
<b>Total</b>	<b>214</b>	<b>6</b>	<b>145</b>	<b>18</b>	<b>35</b>	<b>10</b>



## 7. Conclusions and recommendations

The results of laboratory tests and the investigation findings show the existence of counterfeit drugs in Myanmar. They also confirm previous reports on the availability of substandard drugs on the markets of Myanmar and Viet Nam. In addition, the study revealed that the prevalence of substandard drugs is in general a much greater problem than the existence of counterfeit drugs. In this study, however, no counterfeit drugs were identified among the samples collected from Viet Nam.

The study indicated that products which have passed laboratory tests may sometimes prove to be counterfeit (deliberately mislabelled products are counterfeit according to the WHO definition) upon investigation, as in the case of the five products from Myanmar. This means that laboratory tests alone will not be adequate to tell whether a product is counterfeit or not. Investigation has to be conducted in collaboration with the drug regulatory authorities of the countries of manufacture and the manufacturers of the products.

The findings confirmed that regulatory measures such as drug registration can greatly enhance the quality of drugs on the market if effectively implemented.

The contents of active ingredients of the products that failed laboratory tests varied greatly, with 6 out of the 56 products that failed containing less than 50% of the label claim and 8 out of 56 containing between 50 and 75%.

To combat the incidence of counterfeit and substandard drugs, the governments of both countries need to strengthen their drug regulatory authorities and give them power to enforce the drug laws and regulations. The manufacture, importation, exportation, distribution and sale of counterfeit and substandard drugs should be prohibited by law as a serious criminal offence. Those who break the law should be subject to severe penal sanctions.

An effective licensing system should be maintained to ensure that the manufacture, importation, storage, supply and sale of drugs are carried out by qualified people on premises that meet regulatory requirements.

Drug registration should be strengthened to ensure that all drugs, domestically produced and imported, are assessed for safety, efficacy and quality before they are placed on the market. To achieve this, drug regulatory authorities should have an adequate number of qualified human resources.

Drug inspectors play a crucial role in the identification and investigation of counterfeit and substandard drugs and in the prosecution of counterfeiters. There should be sufficient and adequately trained inspectors with authorization to enter premises and seize any drugs suspected of being counterfeit or substandard. The inspectorates in both countries should be strengthened to

ensure the compliance of domestic pharmaceutical industries and distribution outlets with good manufacturing practices and good distribution practices respectively.

The points of entry for drugs should be defined and rigorous inspection and surveillance conducted in collaboration with customs and police to prevent smuggling.

The sale of drugs in market places and booths, and on street corners, should be prohibited and the public should be advised to buy drugs from legitimate drug outlets only.

Combating counterfeit and substandard drugs at national level is a shared responsibility involving the relevant government agencies, pharmaceutical manufacturers, distributors, health professionals and the general public. The governments of both countries should take action to create an appropriate environment for the participation of all parties concerned.

At the international level, there is a need for cooperation between the governments/drug regulatory authorities of drug exporting and importing countries and between governments and international organizations such as WHO in the fight against counterfeit and substandard drugs. Suitable channels of communication should be established for the exchange of information.

Finally, it should be understood that conducting a study on the prevalence of counterfeit and substandard drugs is a complex task which requires adequate financial resources, expertise, systematic planning and undercover work. It is usually difficult to find where counterfeit and substandard drugs are sold or distributed. A lengthier period of surveillance may be needed than normally anticipated. Sometimes even the timing of the study may have an influence on the results. Investigation to establish whether products are counterfeit or substandard also requires the cooperation of the drug regulatory authorities of those countries where the products are claimed to have been manufactured. It is therefore necessary to take all these factors into consideration when planning to carry out a study.

## Annex 1: Form for collecting information on pharmaceutical preparations sampled during field surveys

Country: \_\_\_\_\_

City: \_\_\_\_\_

Name of drug outlet: \_\_\_\_\_

Type of outlet: private \_\_\_\_\_ public \_\_\_\_\_

Name of product: \_\_\_\_\_

Name of active ingredient and content per unit dose:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Batch /lot number: \_\_\_\_\_ Date of manufacture: \_\_\_\_\_ Expiry date: \_\_\_\_\_

Description of primary container: \_\_\_\_\_

Description of secondary container: \_\_\_\_\_

Pack size: \_\_\_\_\_

Quantity collected: \_\_\_\_\_

Description of preparation: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Special comments: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Date of collection: \_\_\_\_\_

Name and signature of collector: \_\_\_\_\_

\_\_\_\_\_



## Annex 2: Questionnaire for collecting information on drug regulation and the problem of counterfeit drugs

The purpose of the questionnaire is to collect information on the pharmaceutical sector with special emphasis on drug regulations that have relevance to the assessment of the problem of counterfeit drugs.

### A. COUNTRY INFORMATION (year of data)

Total population: \_\_\_\_\_

GNP per capita: \_\_\_\_\_

Area of country: \_\_\_\_\_

### B. GENERAL DRUG SECTOR INFORMATION

*Economic data (most recent data and date, value in local currency and US\$)*

B.1 Total public drug expenditure

\_\_\_\_\_

B.2 Total private drug expenditure

\_\_\_\_\_

B.3 Total value of international aid in drugs (cash + kind)

\_\_\_\_\_

B.4 Total value of local production

\_\_\_\_\_

B.5 Total value of drug imports (CIF)

\_\_\_\_\_



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***Human resources (year of data)***

B.6 Total number of pharmacists in the country

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B.7 Total number of pharmacy technicians or other assistants in the country

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***Drug sector organization***

B.8 Total number of drug manufacturing units in the country

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B.9 Total number of importers in the country

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B.10 Total number of wholesalers (those who do not import but distribute drugs in bulk to retail outlets)

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B.11 Total number of pharmacies and drug outlets in the country in the public sector (hospitals and other health facilities)

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B.12 Total number in the private sector

a) Pharmacies: \_\_\_\_\_

b) Other outlets: \_\_\_\_\_

B.13 Estimated number of unauthorized drug outlets in the country, if any

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***Number of drugs (year of data)***

B.14 Total number of drug products on the market (including dosage forms and strengths)

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**C. LEGISLATION AND REGULATION**

- C.1 Is there drug legislation?  Yes  No

If yes, please indicate year of enactment and enforcement and date last revised/updated:

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- C.2 Have regulations, codes, rules, guidelines, based on the drug legislation, been issued?  Yes  No

- C.3 Are there provisions in the legislation/regulations concerning the following?

- |                             |                              |                             |
|-----------------------------|------------------------------|-----------------------------|
| a) Control of importation   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b) Control of exportation   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c) Control of production    | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d) Control of distribution: |                              |                             |
| * wholesale                 | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| * retail                    | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e) Drug registration        | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f) Inspection               | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g) Quality control          | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- C.4 Are any of the following terms mentioned/defined in the drug/or any other legislation/regulations?

- |                                |                              |                             |
|--------------------------------|------------------------------|-----------------------------|
| a) Counterfeit drug            | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b) Fake (fictitious) packaging | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c) Fake (fictitious) drug      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d) Mislabelling                | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e) Spurious drug               | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f) Substandard drug            | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

(Attach copies of the legislation and the regulations)

C.5 Name of authority responsible for the enforcement of the drug legislation/regulations?

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If more than one organization is involved in the enforcement of the drug legislation and regulations, please indicate their names and respective roles.

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C.6 Does the regulatory authority have a legal mandate for:

- |                          |                              |                             |
|--------------------------|------------------------------|-----------------------------|
| * registration of drugs? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| * inspection?            | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

C.7 Is there a licensing system to regulate:

- |                                   |                              |                             |
|-----------------------------------|------------------------------|-----------------------------|
| * production of drugs?            | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| * import of drugs?                | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| * distribution and sale of drugs? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

C.8 Are there penal sanctions for violation of drug legislation?  Yes  No

C.9 Are there formal procedures for the registration of drugs?  Yes  No

C.10 Is there a drug registration committee?  Yes  No

C.11 What is the period of renewal for drug registration?

---

C.12 Is the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used as a prerequisite:

- a) At the time of registration of drugs?  Yes  No

- b) At the time of import:
- |                  |                              |                             |
|------------------|------------------------------|-----------------------------|
| * public sector  | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| * private sector | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

C.13 Does registration of a product include the following: name of the product (brand name), international nonproprietary name, colour of product, type of primary and secondary containers, label, insert, any distinguishing mark or imprint? (Please underline the relevant ones)

#### D. LOCAL PRODUCTION

D.1 The total number of manufacturing plants in the:

a) government sector

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b) private sector

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c) others (specify)

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D.2 Number of manufacturers of:

a) bulk material \_\_\_\_\_

b) formulations \_\_\_\_\_

c) packaging only \_\_\_\_\_

d) labelling only \_\_\_\_\_

D.3 Who issues licences to drug manufacturers?

a) The MoH  Yes  No

b) The Ministry of Industry  Yes  No

c) The drug regulatory authority  Yes  No

d) Others (specify)

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D.4 Are you aware of any unlicensed drug manufacturers in the country?  Yes  No

If yes, why are they not licensed?

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D.5 Is there a GMP guideline for local production?  Yes  No

D.6 How many manufacturers fully meet GMP requirements? \_\_\_\_\_

D.7 Give details of major deficiencies where GMP are not met:

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D.8 Do all local manufacturers have a quality control  Yes  No  
laboratory?

If no, do they get the quality of their products  Yes  No  
tested?

If yes, where? Give the name(s) and address(es) of the laboratory(ies):

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D.9 Are manufacturing plants inspected for GMP  Yes  No  
compliance?

If yes, how frequently are they inspected?

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D.10 Are the inspectors trained in GMP inspection?  Yes  No

D.11 Are samples of locally produced drugs taken by  Yes  No  
inspectors for testing?

If yes, how often are samples collected? what is the rate of failure? Mention  
the main reasons for failure.

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D.12 Are all locally manufactured drugs registered?  Yes  No

If not registered, give reasons. Please also indicate what percentage of locally produced drugs is registered.

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D.13 Are the starting materials required for manufacturing:

\* imported?  Yes  No  
 \* available locally?  Yes  No

D.14 Are the packaging materials required for manufacturing:

\* imported?  Yes  No  
 \* available locally?  Yes  No

D.15 Number of complaints received regarding locally produced drugs in the last 5 years?

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D.16 Number of locally produced drugs in the last 5 years found to be:

- a) Containing wrong ingredient? \_\_\_\_\_  
 b) Mislabelled with respect to identity/or source? \_\_\_\_\_  
 c) Substandard? \_\_\_\_\_  
 d) With fake packaging? \_\_\_\_\_  
 e) Without active ingredient? \_\_\_\_\_

What measures were taken in each category?

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## **E. IMPORT**

E.1 Who imports drugs legally into the country?

MoH  Yes  No  
 Government parastatal organization  Yes  No  
 Private drug importers  Yes  No  
 Private medical practitioners  Yes  No

Others (specify)

---

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E.2 From whom are imported drugs procured?

- |    |                   |                              |                             |
|----|-------------------|------------------------------|-----------------------------|
| a) | Manufacturers     | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b) | Wholesalers       | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c) | Retail pharmacies | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d) | Others (specify)  |                              |                             |
- 
- 

E.3 Are importers required to have a technically qualified person?  Yes  No

E.4 Is manufacturer/supplier required to have an agency agreement with the importer?  Yes  No

If no, does it mean that once a drug is registered it can be imported by any importer?  Yes  No

E.5 What percentage of the drugs imported by the following sectors is registered?

a) private sector:

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b) public sector:

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E.6 Are drug consignments received by importers accompanied?  Yes  No

E.7 Are drugs also entering into the country through unauthorized people?  Yes  No

If yes, what will be the estimated value in % when compared to the annual drug expenditure of the country? Can you give some examples of drugs that enter into the country unauthorized?

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E.8 Number of complaints/reports received by the drug regulatory authority in the last 5 years which show that imported/registered drugs are:

- a) mislabelled \_\_\_\_\_
- b) substandard \_\_\_\_\_
- c) with fake packaging \_\_\_\_\_
- d) without active ingredient \_\_\_\_\_
- e) with wrong ingredient \_\_\_\_\_

E.9 Number of complaints/reports received by the drug regulatory authority in the last 5 years regarding products imported through unauthorized channels:

- a) mislabelled \_\_\_\_\_
- b) substandard \_\_\_\_\_
- c) with fake packaging \_\_\_\_\_
- d) without active ingredient \_\_\_\_\_
- e) with wrong ingredient \_\_\_\_\_

## F. WHOLESALE

F.1 Are all wholesalers licensed?  Yes  No

If no, reasons why they are not licensed:

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F.2 Are wholesalers required to have a technically qualified person in charge of the operation?  Yes  No

F.3 Has any wholesaler been found distributing drug products imported through unauthorized channels?  Yes  No

If yes, what measures were taken?

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**G. DRUG OUTLETS**

G.1 What are the different categories of private drug outlets in the country?

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G.2 Mention the technical qualifications required for each category:

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G.3 Are all private outlets licensed?  Yes  No

If not, give reasons:

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G.4 How often are private drug outlets inspected?

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G.5 Has any of the private drug outlets been found:

- a) tampering with labels?  Yes  No
- b) transferring from one package to another  Yes  No
- c) selling or dispensing drug products imported through unauthorized channels  Yes  No
- d) selling or dispensing counterfeit drugs  Yes  No

If yes, what measures were taken in each category?

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**H. UNAUTHORIZED DRUG OUTLETS**

- H.1 Are you aware of any unauthorized drug outlets in  Yes  No your country?

If yes, give the estimated number of such outlets in the country.

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- H.2 Are they located throughout the country or confined to certain urban areas? Mention some of the places where they are found most.

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- H.3 Specify the names of drugs that are commonly sold through the unauthorized outlets, preferably in the order of prevalence.

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- H.4 Is there a government policy for stopping the operation of unauthorized drug outlets? If so, give details:

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- H.5 Have inspectors come across mislabelled/counterfeit drugs being sold by unauthorized outlets?  Yes  No

If yes, mention some of the drugs found by inspectors.

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**I. INSPECTION**

- I.1 Is the inspection service operational?  Yes  No

I.2 The total number of drug inspectors in the country: \_\_\_\_\_

- I.3 Is post-marketing quality monitoring carried out?  Yes  No

If yes, the number of samples tested in the last year: \_\_\_\_\_

- I.4 Are there inspection services at the following level?

- a) Central  Yes  No  
b) Regional  Yes  No  
c) Peripheral  Yes  No  
d) Customs warehouses/ports of entry  Yes  No

- I.5 Are inspectors technically qualified?  Yes  No

- I.6 Are inspectors skilled in detecting and verifying mislabelled/counterfeit drugs?  Yes  No

If no, what is required to upgrade their skills?

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I.7 Do inspectors have relevant information on drugs registered in the country?  Yes  No

I.8 What methods do inspectors use to confirm whether a drug is genuine or counterfeited?

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I.9 Are the ports of entry of drugs (customs) defined?  Yes  No

I.10 Who is responsible for the release of drugs from customs/ports of entry?

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I.11 Are drugs being inspected at the ports of entry before release?  Yes  No

If yes, who does the inspection?

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I.12 Are drugs tested at the time of import?  Yes  No

I.13 Is there a check list for carrying out inspections in different types of pharmaceutical establishments?  Yes  No

## **J. QUALITY CONTROL**

J.1 Is there a national institution within the country where drugs are tested?  Yes  No

If no, state the name(s) of laboratory(ies) where the drugs are tested:

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- J.2 Are drug samples tested in connection with:
- |                                    |                              |                             |
|------------------------------------|------------------------------|-----------------------------|
| registration?                      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| importation?                       | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| post-marketing quality monitoring? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

J.3 How many samples were tested in the last two years?

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J.4 How many of the samples failed quality control tests?

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J.5 Number of failures in the following categories:

- a) fake packaging \_\_\_\_\_
- b) mislabelling \_\_\_\_\_
- c) substandard \_\_\_\_\_
- d) wrong ingredient \_\_\_\_\_
- e) without active ingredient \_\_\_\_\_

## Annex 3: Questionnaire for use in sample collection and investigation of samples

Questionnaire to collect information about each sample of product collected. Section A refers to the drug regulatory authority of the country under study, B refers to the drug regulatory authority of the country mentioned on the label of the product and C refers to information to be collected from the manufacturer by the DRA stated under B.

Responses to A will be collected during sample collection. B and C will be sent together with a sample of the product to the drug regulatory authority and the manufacturer. The latter will be contacted by the drug regulatory authority.

### A. QUESTIONNAIRE TO THE DRUG REGULATORY AUTHORITY OF THE COUNTRY UNDER STUDY

A.1 Are you aware that this drug product is marketed in  Yes  No your country?

If yes, is it manufactured locally or imported?

*	Produced locally	<input type="checkbox"/> Yes	<input type="checkbox"/> No
*	Imported	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If no, who do you think is importing/distributing it?

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A.2 Is the importer/manufacturer licensed?  Yes  No

If yes, give details (importer/manufacturer licence no., name and address):

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If no, why is the manufacturer/importer not licensed?

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A.3 In case of import, give details of import (country from where it is imported, batch no., quantity, date of import):

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A.4 Is the drug product registered in your country?  Yes  No

If yes, the particulars of the drug product (date of registration and registration no.):

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If not registered, give reasons:

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**B. QUESTIONNAIRE TO THE DRUG REGULATORY AUTHORITY OF THE COUNTRY MENTIONED ON THE LABEL**

B.1 Does the manufacturer indicated on the label of this drug product exist in your country?  Yes  No

If yes, is the manufacturer licensed?  Yes  No

If yes, give details (name, address, licence no. and date):

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If not licensed, give reasons for not being licensed:

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B.2 Has the manufacturer been licensed to manufacture this drug product?  Yes  No

If yes, give details (licence no., date):

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If not licensed, give reasons for not being licensed to manufacture this drug product:

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- B.3 Do you know any case in which the drug product has been counterfeited?  Yes  No

If yes, when and who counterfeited the product?

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**C. INFORMATION TO BE COLLECTED BY THE DRA FROM MANUFACTURER STATED ON THE LABEL OF THE DRUG PRODUCT**

- C.1 Have you exported this drug product to the country under study?  Yes  No

If yes, give details (export date, batch no., quantity):

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- C.2 Has the drug product presented to you been manufactured by you?  Yes  No

If yes, give details (date of manufacture, batch no., quantity):

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If no, give details as to how this drug product differs from your product.

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- C.3 Do you have any indications on who could have counterfeited your drug product?  Yes  No

If yes, give details:



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