THE PRESENT DRUG CONTROL SITUATION IN THE COUNTRIES OF THE AMERICAS[1]

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The author discusses the findings of a survey conducted by the Pan American Health Organization in 1970 among the countries of the Americas to ascertain the current situation in regard to drug consumption, drug manufacturing establishments, and drug control activities.

In July 1970 the Pan American Health Organization sent to all the countries of the Region a questionnaire requesting information in regard to the drug control situation in each of them. On the basis of the replies, together with the information already available, PAHO prepared and issued a compilation which provides a brief description of the drug control procedures in use and includes a table presenting in summary form data on the magnitude of the control problem and governmental expenditure for drug control in each country (see Table 1). The compilation was distributed, in advance of the meeting, to the participants at the Seminar on Drug Control in the Americas (Maracay, Venezuela, 15-20 November 1970), sponsored by PAHO in collaboration with the Government of Venezuela.[3]

I should like to make only a few comments on the data contained in that compilation.

There are approximately 2,000 drug manufacturing establishments of significant size in the 22 Latin American and Caribbean countries included in the survey. Their annual production is valued at US$1,234,000,000 at the manufacturer's price level.

The volume of drugs imported into the Latin American and Caribbean countries exceeds the amount exported by $116,000,000 per year, thus raising the volume of drugs consumed in those countries to $1,350,000,000 annually at the manufacturer's or importer's price level. The cost at the retail price level is higher by a factor which is sometimes called the "mark-up."

Based on estimates of the mark-up factors in the different countries, we calculate that the final retail cost to consumers of the drugs used in those countries is approximately $1,950,000,000 per year.

From these figures, it is obvious that the drug manufacturing industry in Latin America and the Caribbean area has considerable economic importance in addition to its tremendous health importance as the purveyor of articles used for preventing and treating disease.

When we total the government expenditures for drug control in the 22 Latin American and Caribbean countries, we obtain the figure of $3,371,500, which represents an average of $1.7 per $1,000 of drugs consumed.

The 22 countries employ a total of 1,192 persons in drug control activities, including 250 inspectors and 314 scientists performing drug analysis. However, a large number of those workers spend only a fraction of their time in drug control activities and many of the analysts devote their time to testing registration samples submitted by the drug firms rather than testing market samples selected by government inspectors from drug stocks in distribution channels.

Twenty of the countries require registration of drugs but in only 12 of them are the

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[3] For the recommendations adopted at this Seminar, see p. 98 of this volume.

TABLE 1–Drug consumption, drug manufacturing establishments, and drug control situation in 24 countries of the Americas.

Country	Estimated retail cost of drugs consumed per year (in US$)	Number of drug manufacturing establishments	Government expenditure for drug control per year (in US$)	Total number of government drug control personnel	Number of government drug inspectors	Number of scientists testing drugs for Government	Government drug control expenditure per $1,000 of drugs consumed
Argentina	340,000,000	200	1,193,000	223	17	82	$3.5
Barbados	2,300,000	2		0	0	0	
Bolivia	11,000,000	7	20,000	13 [a]	3 [a]	3	1.8
Brazil	560,000,000	450	300,000 [b]	210 [a, b]	13 [b]	41 [b]	0.5 [b]
Canada	655,000,000	670	3,840,000	309	64	26	5.9
Chile	60,000,000	40	200,000	23	2	17	3.3
Colombia	200,000,000	82	120,000	30	4	13	0.6
Costa Rica	15,000,000	15	35,000 [c]	7 [c]	2 [c]	0	2.3 [c]
Dominican Republic	20,000,000	7	60,000	30 [a]	6 [a]	13	3.0
Ecuador	27,000,000	9	100,000	43 [a]	1	21	3.7
El Salvador	16,000,000	16	17,000 [d]	43 [a, d]	3 [a, d]	2 [d]	1.0 [d]
Guatemala	29,000,000	26	5,000	8 [a]	3 [a]	0	0.2
Guyana	5,500,000	1	7,500	5 [a]	1 [a]	1	1.4
Honduras	14,000,000	15	15,000 [e]	10 [a, e]	1 [a, e]	6 [a, e]	1.0 [e]
Jamaica	11,000,000	6	23,000	12 [a]	4 [a]	3	2.1
Mexico	315,000,000	750	618,000	294 [a]	140 [a]	28	2.0
Nicaragua	22,000,000	18	23,000	18 [a]	9 [a]	1	1.0
Panama	12,000,000	5	92,000 [f]	52 [a]	9 [a]	30 [a]	7.7 [f]
Paraguay	9,000,000	5	4,000	12 [a]	4 [a]	0	0.4
Peru	75,000,000	130	114,000	76 [a]	8 [a]	15	1.5
Trinidad and Tobago	8,000,000	5	20,000	17 [a]	9 [a]	4	2.5
United States of America	7,500,000,000	5,000	36,000,000 [g]	2,035 [a]	655 [a]	356	4.8 [g]
Uruguay	26,000,000	85	24,000	18 [a]	7 [a]	8	1.0
Venezuela	170,000,000	77	381,000	48	4	26	2.2

NOTES: [a] Some of these personnel work part time or have other duties in addition to drug control.
[b] These figures include state and national personnel and expenditures for drug control.
[c] These data refer to drug control activities conducted by the Pharmaceutical Society of Costa Rica.
[d] These data refer to drug control activities conducted by the Pharmaceutical, Medical, and Dental Surveillance Boards and the Superior Public Health Council. These units are autonomous but depend economically on the National Government of El Salvador. They are related to the Government through the Ministry of Public Health and Social Welfare.
[e] These data refer to drug control activities conducted by the Society of Chemists-Pharmacists of Honduras (analyses are conducted by the National University).
[f] Of the US$92,000 listed as Panama's annual expenditure for drug control, $75,000 relate to that portion of the budget of Panama's Specialized Analysis Laboratories (LEA) attributable to testing drug samples submitted by firms wishing to sell drugs in the country. LEA performs such registration analyses on a fee basis and is self-financing.
[g] These data refer only to drug control activities carried out by the U.S. Food and Drug Administration.

registration applications reviewed by a medical evaluation board.

The period of validity of an approved drug registration varies greatly among the 20 countries requiring drug registration: the period is one year for three of the countries, three years for two of them, five years for four of them, seven years for one country, and 10 years for three countries. In one country, the period of validity of a drug registration for a pharmaceutical specialty is 15 years and for a "generic drug," five years. In another, the period of validity for a drug manufactured within the country is 10 years and for an imported product, five years. In five of the countries, an approved registration is valid indefinitely.

Utilization of the available drug testing facilities varies considerably from country to country. More than half the countries devote the major effort to testing registration samples submitted by the companies. Only eight analyze a significant number of samples taken from stocks in distribution channels.

One country utilizes a large proportion of its drugs testing capacity for analyzing samples taken from each batch of those products designated as "biologicals" or "biochemicals."

In three of the Latin American countries, drug control activities are conducted by the country's professional societies of pharmacists and physicians, and not by units forming part of a governmental department such as the ministry of health.

In almost all the Latin American and Caribbean countries the unit responsible for inspecting drug manufacturers and collecting samples is separate from the laboratory testing unit.

In June 1968, PAHO made a similar survey of the drug control situation in the countries and reported the results to the Special Meeting of Ministers of Health of the Americas,[4] held in Buenos Aires in October of that year. In the 1968 report, we made the following comments under the heading of "Problem Areas":

1. The countries of Latin America are expending only $3,221,000 per year for inspecting their 2,200 drug firms and testing the $1,492,000,000 of drugs consumed per year by their citizens. This is an inadequate expenditure for drug control and results in such undesirable conditions as:

a) Lack of modern drug testing equipment.

b) Lack of specialists for each kind of drug testing.

c) Part-time employment which greatly limits the effectiveness of the personnel.

d) Curtailment of the laboratory's capacity for testing samples.

e) Low salaries which result in dissatisfaction among the personnel, particularly if their counterparts in private drug industry are much better paid.

2. In various countries, despite the efforts made by the authorities, there are weaknesses in the internal organization and the performance of the laboratories. A deep analysis of the situation should be made in each case, including a study of such factors as the level of training of the technical staff and the nature of the available testing equipment.

Although the basic training of the analysts is satisfactory, many of them have not had the specialized postgraduate analytical training that is needed for coping with the complex new drugs of today.

3. In all but two of the Latin American countries, the unit responsible for inspecting drug manufacturers and collecting samples is separated from the laboratory testing unit. This often results in an unregulated flow of samples to the laboratory, so that at times few samples arrive while at other times the laboratory has a great backlog of samples awaiting analysis.

The testing unit frequently does not receive adequate information from the inspection unit concerning the drug manufacturer and the reason for collecting the particular sample; consequently the testing unit is handicapped in deciding on the scope of analysis appropriate for the sample.

4. The government drug testing facilities are now devoted largely to analyzing samples submitted by drug firms for registration purposes. There should be increased testing of stocks in distribution channels, such as samples taken from wholesalers, hospitals, pharmacies, and other distribution levels close to the point of use. This would provide more meaningful information about the quality of the drugs administered to patients.

5. There is a diversity of drug laws and regulations among the countries. This may impede adoption of the common market prin-

[4] *Official Document PAHO 90* (1969), 311-314, 315-317.

ciple and hinder the area's international commerce in drugs.

Summary and Conclusions

A comparison of the findings of the survey conducted by the Pan American Health Organization in 1970, as presented in this paper, with the situation as it existed in 1968, indicates that although in those two years there has been an increase in the magnitude of the drug control problem in the Latin American and Caribbean countries as measured by the volume of drugs consumed, there has been no significant change in regard to expenditures for drug control and results in correcting existing deficiencies. □