The Pharmaceutical Situation in the Caribbean: Structure and Process – 2007



Pan American Health Organization

Regional Office of the World Health Organization

WHO PHARMACEUTICAL INDICATORS

The data presented is related to the pharmaceutical situation, using Level I monitoring indicators on structures and processes of the pharmaceutical system from the World Health Organization (WHO), in the 13 Caribbean countries: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominican Republic, Grenada, Guyana, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago. Given the low number of respondents, no great significance should be attached to the percentages[1] in the report. The Caribbean data are compared with that for the Americas region (with a total of 31 participating countries) and with data from 2003 (with participation of 9 Caribbean countries), where possible.

NATIONAL MEDICINES POLICY (NMP)

The primary objectives of a NMP are to ensure access, quality and rational use of medicines by health professionals and citizens.

Table 1. Status of national medicines policies (NMPs) in 2007

	CARIBBEAN		AMERICAS	
NMP Status	**Number of countries**	**%**	**Number of countries**	**%**
NMP document	7	54	22	71
NMP official	4	57	16	73
Official document updated < 5 years	2	50	9	60
Official document updates < 10 years	3	75	13	87
NMP implementation	5	56	13	57
updated within 5 years	4	80	10	83
NMP integrated in NHP	4	44	16	87

The number of countries with NMPs increased from three (27%) in 2003, of which two had officially adopted NMPs, to seven (54%) in 2007, four with officially adopted NMPs (57%). In 2003, two countries had an implementation plan and one had the NMP integrated into the National Health Policy. In 2007, slightly more than half (five, or 56%) of the countries had an implementation plan, and 44% of the NMPs were integrated into the NHP.

REGULATION OF MEDICINES

Table 2. Presence of Medicines Regulatory Authority (MRA)

	CARIBBEAN		AMERICAS	
Policy area covered	**Number of countries**	**%**	**Number of countries**	**%**
Legal provisions for establishment of MRA	11	85	28	90
Existing formal MRA	9	69	27	87
Legal provision requiring transparency	5	46	20	71
MRA involved in harmonization initiative	10	83	28	93
Publicly accessible MRA website	3	25	19	63
Sources of funding for MRA				
Government budget	11	92	29	97
Medicines registration fees	1	14	14	67
Other	1	20	7	54

In 2003, only four countries mentioned having legal provision for a **MRA** and four (67%) had a MRA established. In 2007, eleven (85%) had legal provision, with nine (69%) having an established MRA. Regarding legal provision for transparency, in 2003 three countries (60%) and in 2007 five out of 11 countries (46%) had this provision.

Marketing Authorization (MA)

Table 3. Legislation and regulation for MA of medicines

	CARIBBEAN		AMERICAS	
Policy area covered	**Number of countries**	**%**	**Number of countries**	**%**
Provisions for marketing authorization	6	46	24	77
Marketing authorization list publicly available	4	31	18	58
Computerized system for registered products	2	18	20	69
WHO Certificate Scheme part of MA	4	31	16	52
INN used in registration of medicines	6	46	24	77
Official registration committee	4	31	16	55
	Median [25th, 75th percentile]		**Median [25th, 75th percentile]**	
Total no. of products with MA	7,175 4,763 | 9,588 N=2		11,571 6,499 | 16,849 N=19	

[1]The percentages are presented in relation to the total number of respondents for each question.

In 2003, only three countries (50%) mentioned having legal provision for marketing authorization (MA) or registration, but only two of them (29%) had an operating MA system. As depicted in Table 3, in 2007, the number of countries with legal provision for MA increased to six (46%). In 2003, none of the Caribbean countries had information on MA publicly available, and in 2007 there were four (31%) countries making such information available. Regarding the use of the WHO Certification Scheme the number of countries varied from three (43%) in 2003 to four (31%) in 2007.

Licensing and Inspection

Table 4. Legal provisions for licensing

	CARIBBEAN		AMERICAS	
Legal provisions for licensing	**Number of countries**	**%**	**Number of countries**	**%**
Manufacturers	12	92	28	94
Distributors/ wholesalers	12	92	29	94
Importers or exporters of medicines	1	92	27	93
Prescribers	12	92	30	97
Pharmacy	13	100	31	100

In 2003, there were four countries in the Caribbean with legal provision for **licensing** manufacturers and wholesalers/ importers of medicines (67%) and three for importation (60%). In 2007, the number of Caribbean countries with legal provision in these areas increased considerably, to more than 90%.

The total number of respondents with legal provision for **inspection** of manufacturers (i.e. six) did not vary from 2003 to 2007 in the Caribbean. Regarding the legal provision for inspecting importers and wholesalers, the number of countries varied from five (71%) in 2003 to eight (62%) in 2007. In relation to legal provision for inspecting distributors and pharmacies, there was a small variation between 2003 and 2007, being six (86%) and eight countries (67%), respectively.

In 2007, all of the Caribbean countries reported having legal provision for the **control of narcotics** and psychotropic substances and were signatories to the relevant international conventions.

Quality Control

Quality control is less common in the Caribbean compared to the whole region of the Americas. Slightly more than 50% of the countries had a quality control system in place in 2007. In 2003, it was mentioned that a total of 172 samples were collected in four countries and all were tested (an average of 43 per country). However, the countries did not provide information about the number of samples that failed the tests. In 2006, a total of 1,236 samples were tested in five countries (a median of 206 samples). The total number of the samples that failed to meet the standards was 36 (3%), an average of 7 per country.

Table 5. Quality control

	CARIBBEAN		AMERICAS	
	Number of countries	**%**	**Number of countries**	**%**
Quality management system in place	6	46	24	77
Samples tested for				
Medicines registration	5	42	18	62
Post-marketing surveillance	6	55	20	74
Samples tested in				
Government quality control laboratory	5	56	19	79
Local academic institutions	1	17	8	42
Private laboratory	3	50	7	41
Mini laboratories (district, regional)	2	33	3	19
Quality control laboratory in another country	7	88	9	47
Quality control procedures for imported medicines	10	77	26	87
Legal procedures to recall/ dispose of defective products	8	62	23	77
Quality testing in 2006	**Median [25th, 75th percentile]**		**Median [25th, 75th percentile]**	
Number of samples tested	17 | 113.5 | 262 N=6		188 | 812 | 1,718 N=17	
Number of samples that failed	2 | 3 | 15 N=5		12 | 45 | 91 N=16	

Regarding **pharmacovigilance**, in 2003 only two countries (25%) reported monitoring Adverse Drug Reactions (ADR) and this number more than doubled in 2007, when five (39%) countries mentioned having ADR monitoring; two of them were participating in the WHO International Programme for Drug Monitoring. In March 2008, the Caribbean Network of Pharmacovigilance (Vigicarib) was established, supported by PAHO/WHO.

Regarding **counterfeit medicines**, only seven (54%) of the participating Caribbean countries reported having laws or regulations relating to counterfeit medicines.

Generic Medicines

There was no significant change in the number of countries with policies for prescribing **generics** in the public sector (five, or 63%, in 2003 and seven, or 54%, in 2007). However, in relation to mandatory prescribing of generics in the private sector, the number of countries doubled (one, or 13%, in 2003 to two, or 17%, in 2007) but still remained minimal. In all participating countries there was legal provision for generic substitution in the public sector pharmacies; that is, eight in 2003 and 13 in 2007. For generic substitution in private pharmacies, six countries (75%) in 2003 and nine countries (75%) in 2007 had legal provision.

Table 6. Legislation on the prescribing of generic medicines in the public and private sectors

	CARIBBEAN		AMERICAS	
Policies on generic medicines	**Number of countries**	**%**	**Number of countries**	**%**
Prescribing generics mandatory in				
Public sector	7	54	23	77
Private sector	2	17	10	37
Permitting generic substitution in				
Public pharmacies	18	100	27	90
Private pharmacies	9	75	21	78
Incentives to promote generics dispensing				
Public pharmacies	5	39	8	27
Private pharmacies	2	18	6	22

Regarding regulation of **advertising and promotion of medicines**, in 2003, there was one country (33%) where there was self-regulation of promotion/advertisement and in 2007 there were four (36%) such countries. There were three (60%) countries with governmental regulation in 2003 and six (55%) such countries in 2007. In 2003, none of the countries reported the participation of civil society or NGOs in monitoring advertising activities, while two countries (20%) reported having this type of monitoring in 2007.

MEDICINES SUPPLY SYSTEMS

All the participant Caribbean countries mentioned having public sector **procurement** pooled at the national level. In 2003, the Ministry of Health (MOH) performed the procurement function in all seven countries and in 2007 in 12 countries (92%). The distribution function was performed by the MOH in five countries (100%) in 2003 and in seven countries (88%) in 2007. The procurement activity was performed by a private institution in one country (50%) in 2003 and in 2007 the number of countries doubled (two countries, 29%). Procurement was performed by individual health institutions in three countries (75%) in 2003 and there was no such report in 2007. Three countries used more than one mechanism of procurement in both 2003 and 2007.

Table 7. Essential Medicines List (EML) procurement and tender process

	CARIBBEAN		AMERICAS	
	Number of countries	**%**	**Number of countries**	**%**
Public sector procurement limited to EML	4	100	11	92
If yes, are there provisions for purchasing medicines outside EML	5	42	13	46
Country participation in pooled procurement scheme	5	42	10	35
Tender board overseeing public sector procurement	11	92	23	32
If yes, are the key functions of the procurement office and tender	8	89	18	91
Use of WHO Prequalification system	6	87	19	50
Type of tender				
Public pharmacies	4	50	19	83
International competitive tender	9	82	19	73
Negotiation/ direct purchasing	6	75	19	83

There were four countries where procurement was limited to the EML - 2003 (67%), and 2007 (100%). The same number of countries (four) used a national competitive tender in 2003 (80%) and in 2007 (50%). Regarding the use of international competitive tendering, the variation was from six (86%) countries in 2003 to nine (82%) countries in 2007. The use of negotiation or direct purchasing increased from two countries (67%) in 2003 to six (75%) in 2007. Five (42%) of the countries that answered the questionnaire in 2007 participated in a pooled procurement scheme.

MEDICINES FINANCING

The number of countries having a **policy on medicines pricing** for the public sector varied from two (33%) in 2003 to six (50%) in 2007; for the private sector it varied from two (33%) in 2003 to four (33%) in 2007.

Table 8. Total and per capita public expenditure for medicines (TPE) in US$, 2007

	CARIBBEAN	AMERICAS
	Median [25th, 75th percentile]	**Median [25th, 75th percentile]**
Median Total public expenditure for medicine (TPE) in US$	$ 4,000,000 $815,000 | $13,000,000 N=9	$ 34,087,493 $3,750,000 | $53,081,172 N=24
Median Public medicines expenditure per capita in US$	**$20.90** N=9	**$11.50** N=24

The median total expenditure on medicines in the public sector in the Americas region (US$ 34,087,493) was considerably higher than in participant Caribbean countries (US$ 4,000,000), but the median public expenditure per capita was much higher in the participant Caribbean countries (US$ 20.90) when compared to the whole region of the Americas (US$ 11.50).

Table 9. Medicines provided free of charge

	CARIBBEAN		AMERICAS	
	Number of countries	**%**	**Number of countries**	**%**
National policy including some free medicines*	13	100	31	100
Types of free medicines at primary care level**				
All medicines	8	67	17	71
Malaria medicines	7	78	18	86
Tuberculosis medicines	7	78	24	92
Sexually transmitted diseases medicines	5	63	17	77
HIV/AIDS-related medicines	8	89	24	96
At least one vaccine	10	100	25	100
Patients, who receive free medicines				
Patients who cannot afford medicines	13	100	26	93
Children under 5 years of age	12	92	26	96
Older children	10	83	20	83
Pregnant women	9	75	24	89
Elderly persons	10	77	22	85

*Some countries have legal provisions regarding the universal access to medicines. ** Some countries provide more than one type of medicines

In 2003, the number of countries with all essential **medicines free of charge** at the public facilities was five (83%) and in 2007 it was six (60%), as outlined in Table 9. A greater variation, in percentage terms, was observed in the reporting for elderly persons, where the availability of free medicines varied from three (43%) countries in 2003 to 10 countries (77%) in 2007. Free medicines for HIV/AIDS varied from four (67%) to eight (89%) countries in 2003 and 2007, respectively.

PRODUCTION AND TRADE

In 2003, three (33%) countries reported having legal provision for patent protection of pharmaceutical products. In 2007, five (56%) countries reported having patents granted by a national office, and four countries (44%) mentioned having their legislation modified to implement the TRIPS Agreement. Four countries had provision for Article 65 of TRIPS, one of them (33%) had provision for Article 66 of TRIPS, and two of them (40%) had provision for Paragraph 7 (in accordance with the Doha Declaration). In 2003, the implementation of the **flexibilities of TRIPS** was under discussion. In 2007, only one country had already included this flexibility provision in its legislation. Regarding compulsory licensing, it had been discussed in four countries (57%) in 2003 and in 2007 only two countries (50%) had this legal provision. For the Bolar exception, three countries (50%) reported that it had been discussed in 2003 but none of the countries reported having such legal provision in 2007.

The lack of capacity for research and development (R&D) and for production of pharmaceutical starting materials did not change between 2003 and 2007 in the Caribbean. This capacity was also limited in the whole Americas region, as only six countries (21%) mentioned having R&D activities in 2007. The number of countries that reported capacity for formulation from starting materials doubled from 2003 (four, 50%) to 2007 (eight, 62%), and repackaging of finished dosage forms varied from four countries (50%) in 2003 to seven countries (58%) in 2007.

Table 10. Country capacity for the production of medicines

	CARIBBEAN		AMERICAS	
Legal provisions for licensing	**Number of countries**	**%**	**Number of countries**	**%**
Manufacturers	0	0	6	21
Distributors/ wholesalers	0	0	6	21
Importers or exporters of medicines	8	62	26	84
Prescribers	7	58	25	83

RATIONAL USE OF MEDICINES

There was a small variation in the number of Caribbean countries with an Essential Medicines List (EML) between 2003 (seven, 100%) and 2007 (10, 77%). The average of medicines in the National Lists varied from 614 in 2003 to 464 in 2007. All countries with an EML used it in public sector procurement (eight in 2003 and 10 in 2007). With regards to the public insurance reimbursement scheme, the usage of the EML varied from two countries (40%) in 2003 to five (50%) in 2007. The EML was also used for private insurance reimbursement by two countries in both 2003 (25%) and 2007 (22%).

The number of countries that reported having National Standard Treatment Guidelines (STGs) varied from four (50%) in 2003 to nine (75%) in 2007. For STGs at the hospital level, there were two countries (29%) in 2003 and seven (58%) in 2007, and at the primary health care level there were STGs in four countries (67%) in 2003 and eight countries (67%) in 2007.

Table 11. Availability of Standard Treatment Guidelines (STGs) and Medicines Formulary Manuals

		CARIBBEAN		AMERICAS	
		Number of countries	**%**	**Number of countries**	**%**
Standard Treatment Guidelines	National	9	75	25	86
	Hospital	7	58	19	68
	Primary care	8	67	23	82
Last update of STG < 5 years	National	5	83	12	92
	Hospital	3	100	7	100
	Primary Care	4	100	9	100
STGs for key paediatric illnesses		3	38	19	79
Medicines Formulary Manual		9	75	23	77
Last update < 5 years		5	63	16	76
Covering only EML, medicines		4	50	13	62

*Besides these nine countries, there are two countries that are members of the OECS who have a common medicines formulary but they did not mention it in the questionnaire.

In 2003, there were eight countries (89%) that reported having a **Medicines National Formulary (MNF)** and nine countries (75%) in 2007. In 2003, all countries stated that their national formularies covered only the EML and in 2007 there were only four such countries (50%). The number of countries that reported having done the last update of the MNF in less than five years varied from eight (100%) in 2003 to five (63%) in 2007.

Although great variation was observed between 2003 and 2007 regarding the presence of the concepts related to **Rational Medicines Use (RMU) in the education of health workers**, its presence is still small in the curricula. The number of countries with an Independent Medicines Information Centre remained the same from 2003 (three, 38%) to 2007 (three, 23%), with access for prescribers, dispensers and consumers. Most of the prescribing of medicines was done by doctors, but nurses and pharmacists also played a minimal role in this activity.

The number of countries with an antimicrobial resistance (AR) strategy remained the same (two) in 2003 and in 2007. The number of countries with an AR surveillance laboratory changed from five (56%) in 2003 to seven (54%) in 2007. Regarding the existence of an AR task force, in 2003 there were two countries (22%) that reported having one but by 2007 no country had an existing task force.

FINAL CONSIDERATIONS

The summarized information provided by the Level I indicators for the Caribbean countries is very valuable for analyzing progress in the six areas of the pharmaceutical system. It is important to take into consideration the limitations of the questionnaire, as it is evident that in some areas more specific information was needed. Some progress was observed in 2007, in relation to the baseline data in 2003, but there is still a significant amount of work required to improve the pharmaceutical sector in the Caribbean. The data is important for sub-regional stakeholders to identify gaps and establish priorities with an inter-sectoral approach.

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