Quality Control

Legal provisions for the surveillance of quality in the pharmaceutical market exist in six of 12 responding countries/territories (50%). Five of 13 (38.5%) reported having an operational Quality Control testing laboratory; from those, the laboratory is a functional part of the MNRA in three of these five countries (60%) and the other two consider the CARPHA Drug Test Laboratory as their reference laboratory (CARPHA/DTL). In fact, the CARPHA DTL serves all CARICOM countries. Table 9 shows the reasons for which medicines are tested in the Caribbean and Americas.

Table 9. Summary of the reasons for testing medicines in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Quality monitoring in public sector (pharmacies and health facilities)	7/11	63.6	18/24	75.0
Quality monitoring in private sector (retail outlets)	3/11	27.3	12/24	50.0
Investigating complaints or problems	11/11	100.0	24/24	100.0
Product registration	3/6(*)	50.0	10/20(*)	50.0
Public procurement prequalification	6/12	50.0	12/25	48.0
Public program products prior to acceptance and/or distribution	3/11	27.3	12/24	50.0

(*) Total responding = Countries with legal provisions requiring a marketing authorization for pharmaceuticals

In the Caribbean, legal provisions to control the promotion and/or advertising of prescription medicines exist in 38.5% of countries/territories. Only one country (8.3%) has similar legislation for over-the-counter (OTC) medicines. Direct advertising of prescription medicines to the public is prohibited in 23.1% of the cases.

All the countries/territories within the Caribbean sub-region are signatories1 of the four main conventions relating to the control of narcotic and psychotropic substances and precursors: Single Convention on Narcotic Drugs (1961), Protocol amending the Single Convention on Narcotic Drugs (1972), Convention on Psychotropic Substances (1971) and the United Nations Convention against the Illicit Traffic on Narcotic Drugs and Psychotropic Substances (1988). Twelve countries/territories (100.0) have also instituted correlated legislation.

Pharmacovigilance

In three of the 13 countries/territories (23.1%), legal provisions exist for pharmacovigilance activities. Laws regarding the monitoring of Adverse Drug Reactions (ADR) have only been instituted in two of 12 cases. A National Pharmacovigilance Centre (NPC) exists in 15.4% of countries. In four of 13 countries/territories (30.8%), a national ADR database exists. Two of them have been reporting their data to the WHO Collaborating Centre in Uppsala, Sweden over the last two years.

Table 10. Summary of the legal provisions and structures relating to pharmacovigilance in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Pharmacovigilance activities legally established	3/13	23.1	16/27	59.3
Marketing authorization holders required to continuously monitor safety of products	3/6(*)	50.0	14/20(*)	70.0
Legal provisions for monitoring of ADRs	2/12	16.7	14/26	53.8
National Pharmacovigilance Center (NPC)	2/13	15.4	14/27	51.9
An official standardized form to report ADRs is used	11/12	91.7	24/25	96.0

(*) Total responding = Countries with legal provisions requiring a marketing authorization for pharmaceuticals

MEDICINES FINANCING

Table 11. Patients receiving medicines free of charge in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Patients who cannot afford them	13/13	100.0	27/28	96.4
Children under the age of 5	12/13	92.3	27/28	96.4
Pregnant women	6/13	46.2	21/28	75.0
Elderly persons	11/13	84.6	25/28	89.3

All the countries/territories in the sub-region have legal provisions for universal access to essential medicines or at least for certain groups to receive medicines free of charge (see Table 11). Furthermore, in the majority of cases medicines are provided free of charge for particular conditions by the public health system or social health insurance schemes (see Table 12).

Table 12. Conditions for which medicines are provided in the public sector free of charge in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
All medicines in the National Essential Medicines List (EML) or equivalent	9/12	75.0	22/26	84.6
Non-communicable diseases	9/12	75.0	22/27	81.5
Malaria	10/13	76.9	23/27	85.2
Tuberculosis	13/13	100.0	28/28	100.0
Sexually-transmitted diseases (STD)	12/13	92.3	27/28	96.4
HIV/AIDS	13/13	100.0	28/28	100.0
Expanded Program on Immunization (EPI) vaccines	13/13	100.0	28/28	100.0

The medicines financing structure in six of the 13 countries/territories in the sub-region (46.2%) requires co-payments or fees for consultations. Furthermore, 46.2% of the respondents impose co-payments for medicines.

PHARMACEUTICAL PROCUREMENT AND DISTRIBUTION

In the Caribbean there are different institutional arrangements for public sector procurement. Some countries conduct this activity individually, while the members of the Organisation of Eastern Caribbean States depend on the services of the Pharmaceutical Procurement Service (PPS/OECS). Within the sub-region, public sector procurement is centralized in 69.2% of countries/territories, and both centralized and decentralized in 30.8% of the cases.

SELECTION AND RATIONAL USE OF MEDICINES

Twelve of 13 countries/territories (92.3%) have a national Essential Medicines List (EML) or equivalent. All of them have been updated within the last five years. The number of medicines on the EMLs varies among countries from 291 (in St. Vincent and the Grenadines) to 700 (in Barbados and Jamaica), with a sub-regional average of 542. Three of the 13 countries/territories (23.1%) in the sub-region have a public or independently-funded National Medicines Information Centre providing information on medicines to prescribers, dispensers and consumers. Prescribing by International Nonproprietary Name (INN) is mandatory in the public sector of six of 13 countries/territories (46.2%), but in none of the cases does this provision affect the private sector. Generic substitution is allowed in the public sector in 100% of the cases and in 76.9% of the cases in the private sector.

Table 13. Essential Medicines Lists (EML), Standard Treatment Guidelines (STG) and harmonization mechanisms in the Caribbean and Americas, 2010-2012

		CARIBBEAN		AMERICAS	
		Yes/total responding	%	Yes/total responding	%
Essential Medicines List (EML) or equivalent exists		12/13	92.3	26/28	92.9
EML updated in the last two years		6/12 (*)	50.0	N/A	N/A
EML aligned with STG		4/9 (*)	44.4	16/26	61.5
National STGs produced by MoH for most common illnesses		7/12	58.3	20/27	74.1
National STGs updated in the last two years		5/7 (**)	71.4	N/A	N/A
Specific STGs for:	Primary care	3/7 (**)	42.9	14/20	70.0
	Secondary care	2/7 (**)	28.6	12/20	60.0
	Paediatric care	1/5 (**)	20.0	11/20	55.0

(*) Total responding = countries/territories with an EML – (**)total responding = countries/territories with national STGs

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THE PHARMACEUTICAL SITUATION IN THE CARIBBEAN

Monitoring Indicators 2010-2012

Pan American Health Organization/
World Health Organization (PAHO/WHO)

Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

WHO PHARMACEUTICAL INDICATORS

The data presented are related to the pharmaceutical situation of 11 Caribbean countries and two United Kingdom Overseas Territories (UKOTs)— Antigua and Barbuda, Barbados, Dominica, Grenada, Guyana, Jamaica, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, British Virgin Islands and Turks and Caicos Islands— using information collected from 2010 to 2012 within the framework of the Pharmaceutical Sector Country Profiles (PSCP) project. The percentages in the report have been calculated in relation to the total number of respondents for each question. The Caribbean data are compared with that for the Americas region (with a total of 28 participating countries/UKOTs), where possible. Only the information provided by the countries along with an official signed endorsement were included in the individual pharmaceutical country profile and in this publication. For the complete publication and the individual country reports, please go to http://prais.paho.org/rscpaho/ or http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html

HEALTH EXPENDITURES

Total Health Expenditure (THE) per capita ranges from US$ 152 to US$ 2,252 (Guyana and the British Virgin Islands, respectively) with an average of US$ 826. Average General Government Health Expenditure (GGHE) and Private Health Expenditure (PHE) in the sub-region make up approximately 60.59% and 38.91% of the average THE, respectively. As a percentage of their total budget, governments in the region spend a median of 10.0% on health. The percentage of GDP spent on THE ranges from 4.20% to 8.92% (Jamaica and Turks and Caicos, respectively), with an average of 6.85%. Public expenditure on pharmaceuticals per capita varies widely across countries and ranges from US$ 4.4 in Suriname to US$ 125.1 in Barbados. This study showed a serious lack of information about the private pharmaceutical expenditure in the sub-region.

POLICY ISSUES

The main objectives of a National Pharmaceutical Policy (NPP) are to ensure access, quality and rational use of medicines (RUM) by health professionals and citizens. NPPs must be incorporated into the National Health Plans and strategies.

Table 1. Health policies developed and implemented in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
National Health Policy (NHP)	7/12	58.3	21/27	77.8
NHP implementation plan	5/7 (*)	71.4	16/21 (*)	76.2
National Pharmaceutical Policy (NPP)	2/13	15.4	13/28	46.4
NPP implementation plan	1/2 (**)	50.0	9/13 (**)	69.2
NPP updated within last 5 years	0/2 (**)	0.0	N/A	N/A
National Good Governance Policy	1/13	7.7	11/28	39.3
National Clinical Laboratories Policy (NCLP)	1/11	9.1	N/A	N/A
Access to medicines is recognized in the constitution or national law	6/12	50.0	18/27	66.7

(*) Total responding = countries/territories with a NHP - (**) total responding = countries with a NPP

A National Health Policy (NHP) has been created in 58.3% of the countries/territories. Of the seven countries/territories with a NHP, five have also developed an associated implementation plan. An official NPP document only exists in 15.4% of the countries in the sub-region. Of the two countries with a NPP, only one (Suriname) has also developed an associated implementation plan. None of the two mentioned countries with an official NPP regularly monitors/assesses its implementation. Access to medicines as part of the fulfillment of the right to health is recognized in the constitution or national legislation of 50% of the countries/territories.

MEDICINES TRADE AND PRODUCTION

Table 2. Pharmaceutical manufacturing capabilities of countries/territories in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Research and Development (R&D) to discover new active pharmaceutical ingredients (API)	0/13	0/0	5/27	18.5
Production of API	0/13	0.0	4/27	14.8
Production of formulations from pharmaceutical starting material	5/13	38.5	19/27	70.4
Repackaging of finished dosage forms	4/13	30.8	18/27	66.7

Manufacturing capabilities in the sub-region are very limited, as highlighted in Table 2. The scarce industrial activities are mainly focused in production of formulations and repackaging of dosage forms.

Table 3. Enforcement of Intellectual Property Rights (IPR) in the Caribbean and Americas, 2010-2012

		CARIBBEAN		AMERICAS	
		Yes/total responding	%	Yes/total responding	%
TRIPS Agreement implemented through national legislation		7/11	63.6	19/27	70.4
TRIPS flexibilities and safeguards	Compulsory licensing	6/11	54.5	20/27	74.1
	Bolar exception	0/11	0.0	11/27	40.7
Parallel importing		3/11	27.3	16/27	59.3
Transitional period eligibility (until 2016)		1/9	11.1	7/22	31.8
Data exclusivity		3/11	27.3	16/27	59.3
Patent extension		0/10	0.0	9/26	34.6
Linkage between patent status and marketing authorization		0/9	0.0	8/25	32.0

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been implemented through national legislation in 63.6% of the countries in the subregion. Details regarding the enforcement of Intellectual Property Rights (IPR) are supplied in Table 3. Some countries (54.5%) have implemented the TRIPS-specific flexibility of compulsory licensing, but none of them has incorporated the Bolar exception to their national legislation. Countries that have also considered parallel importing provisions stands at 27.3%. Data exclusivity provisions exist in 27.3% of the cases, while patent extension legislation does not exist in any of the countries. Compared to data from the previous surveys, the number of countries with adjustment of national legislation according TRIPS Agreements increased from three (33%) in 2003 to four (44%) in 2007 to seven (63.6%) in 2011-12. Nevertheless, by this time all the respondent countries should be compliant with the TRIPS Agreement.

MEDICINES REGULATION

Regulatory Framework

Legal provisions establishing the powers and responsibilities of a Medicines National Regulatory Authority (MNRA) have been instituted in seven of the 13 countries/territories in the sub-region. Table 4 details the characteristics of the MNRAs in the Caribbean.

Table 4. Characteristics of the Medicines National Regulatory Authorities (MNRAs) in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Legal provisions establishing a MNRA	7/13	53.8	21/27	77.8
MNRA exists	6/13	46.2	18/25	72.0
MNRA is part of the Ministry of Health	7/7(*)	100.0	19/21	90.5
MNRA is semi-autonomous	1/7(*)	14.3	5/21	23.8

(*) Total responding = countries/territories with legal provisions establishing a MNRA

Although, in some cases, there is no established regulatory body, different organisms carry out various regulatory functions. Table 5 shows the execution of the mentioned functions.

Table 5. Summary of the regulatory functions performed in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Marketing authorization / registration	4/9	44.4	17/22	77.3
Inspection	10/10	100.0	23/23	100.0
Import control	9/10	90.0	20/23	87.0
Licensing	8/9	88.9	21/22	95.5
Market control	5/10	50.0	14/23	60.9
Quality control	6/9	66.7	18/22	81.8
Medicines advertising and promotion	3/9	33.3	15/22	68.2
Clinical trials control	1/9	11.1	10/22	45.5
Pharmacovigilance	7/9	77.8	19/22	86.4

Marketing Authorization

Legal provisions requiring a marketing authorization (registration) for all pharmaceutical products on the market exist in 46.2% of the countries/territories. Of these countries, three (60.0%) reported to have mechanisms for exception/waivers of the registration. Only one of the mentioned countries (20.0%) has mutual recognition mechanisms in place for medicines registered in other places.

Table 6. Summary of the characteristics of the marketing authorization for medicines in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Marketing authorization required for all pharmaceutical products	6/13	46.2	20/27	74.1
Mechanisms for exception/waivers of registration	3/5 (*)	60.0	13/18	72.2
Mutual recognition	1/5 (*)	20.0	7/18	38.9
Public transparency of criteria for assessment of applications	3/6 (*)	50.0	17/20	85.0
WHO Prequalification Programme information used for product registration	2/5 (*)	40.0	7/18	38.9

(*) Total responding = Countries requiring a marketing authorization for pharmaceuticals

The number of countries with legal provisions for marketing authorization required for all pharmaceutical products increased from four (30.8%) in 2003 to six (46.2%) in 2007 and remained the same in the current survey.

Regulatory Inspection

Legal provisions that allow for the appointment of government pharmaceutical inspectors exist in 10 of the 13 (76.9%) countries/territories that responded to this question in the Caribbean. Furthermore, legislation permits inspectors to review premises where pharmaceutical activities are performed in 76.9% of the respondent countries/territories.

Table 7. Summary of the legal provisions and requirements for regulatory inspection in the Caribbean and Americas, 2010-2012

		CARIBBEAN		AMERICAS	
		Yes/total responding	%	Yes/total responding	%
Legal provisions for the appointment of public pharmaceutical inspectors		10/13	76.9	21/26	80.8
Legal provisions for the inspection of premises where pharmaceutical activities take place		10/13	76.9	23/27	85.2
Inspection is a pre-requisite for licensing of:	Public facilities	4/11	36.4	17/25	68.0
	Private facilities	8/11	72.7	22/25	88.0
Inspection requirements are the same for public and private facilities		8/11	72.7	20/24	83.3

Legal provisions requiring authorization to import medicines exist in 10 of the 13 countries/territories (76.9%). Legal requirements allowing the sampling of imported products for testing are in place in 58.3% of the cases.

Licensing

Legal provisions exist in the Caribbean requiring the licensing of manufacturers (69.2%), importers (76.9%), wholesalers (69.2%), distributors (69.2%), public retailers (61.5%) and private retailers (100%). Table 8 shows the legal provisions made for compliance with Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Pharmacy Practice (GPP) in the sub-region and the Americas.

Table 8. Summary of the legal provisions regarding the compliance with Good Practices in the Caribbean and Americas, 2010-2012

	CARIBBEAN		AMERICAS	
	Yes/total responding	%	Yes/total responding	%
Good Manufacturing Practices (GMP)	4/12	33.3	18/26	69.2
Good Distribution Practices (GDP)	3/11	27.3	11/25	44.0
Good Clinical Practices (GCP)	0/12	0.0	10/24	41.7
Good Pharmacy Practices (GPP)	0/12	0.0	4/25	16.0

Legal provisions requiring authorization from the MNRA to conduct Clinical Trials are not in place in any of the countries/territories. There are no guidelines of GCP in the subregion.