



Caribbean Pharmaceutical Policy



**Pan American
Health
Organization**



**World Health
Organization**
REGIONAL OFFICE FOR THE **Americas**



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ABBREVIATIONS AND ACRONYMS

ACP	African, Caribbean and Pacific Group of States
ASEAN	Association of Southeast Asian Nations
CARICOM	Caribbean Community
CARIFORUM	Caribbean Forum of African, Caribbean and Pacific States
CARIPROSUM	Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities
CARPHA	Caribbean Public Health Agency
CCH III	Caribbean Cooperation in Health Initiative, Phase III
CMOs	Chief Medical Officers
COHSOD	Council for Human and Social Development
CPP	Caribbean Pharmaceutical Policy
CRDTL	Caribbean Regional Drug Testing Laboratory
CSME	CARICOM Single Market and Economy
DR-CAFTA	Dominican Republic–Central America Free Trade Agreement
DTL	Drug Testing Laboratory
EMA	European Medicines Agency
EML	Essential medicines list
EPA	Economic Partnership Agreement
EU	European Union
GMP	Good manufacturing practices
HERA	Health Research for Action
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
IPRs	Intellectual property rights
MOH	Ministry of Health
MRA	Medicines regulatory authority
NCDs	Non-communicable diseases
NMP	National medicines policy
NRA	National Regulatory Authority
OCPC	Office of Caribbean Program Coordination
OECS	Organisation of Eastern Caribbean States
PAHO	Pan American Health Organization
PANCAP	Pan Caribbean Partnership against HIV and AIDS
PANDRH	Pan American Network for Drug Regulatory Harmonization
PPS	Pharmaceutical Procurement Service
SADC	Southern African Development Community
STGs	Standard treatment guidelines
TAG	Technical Advisory Group
TECHPHARM	CARICOM Expanded Technical Advisory Committee on Pharmaceutical Policy

TRIPS
WHO
WTO

Trade-Related Aspects of Intellectual Property Rights
World Health Organization
World Trade Organization

EXECUTIVE SUMMARY

Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living in dignity. Access to health care, which includes access to essential medicines, is a prerequisite for realising that right. National medicines expenditures, as a proportion of total health expenditures, currently range from 7% to 66% worldwide.

In the Caribbean, the implementation of the Revised Treaty of Chaguaramas and the establishment of the CARICOM Single Market and Economy (CSME) provide a favourable environment for regional integration. However, there are challenges in the area of health, given the health situation, geography, limited human resources and continued migration. At the same time, the tourism sector is being challenged by poor sanitation, untreated sewage that may damage beaches, food-borne disease outbreaks in public places, the threat of natural disasters and the need to mount an effective, rapid response to manage and control epidemics. There is a need to focus on achieving a strong, comprehensive and integrated public health response through health environment strategies that address these priority areas.

Recognising the challenge of ensuring sustained access to adequate quality medicines at affordable prices, the CARICOM Ministers of Health, at the Tenth Meeting of the Council for Human and Social Development (COHSOD) (April 2003), mandated the establishment of a Technical Advisory Group (TAG) on Trade-Related Intellectual Property Rights (TRIPS). TAG, by means of a regional assessment of drug regulatory and registration systems and a regional assessment of patent and related issues and access to medicines in CARICOM countries and the Dominican Republic, sought to assess the current situation and to propose solutions for improving the situation with respect to medicines. Complementary to these studies, PAHO/WHO published a report on the pharmaceutical situation in the Caribbean in 2007, with the participation of 13 Caribbean countries.

At the Eighteenth Meeting of the Caucus of CARICOM Health Ministers, held in 2009 in Washington, D.C., the ministers supported an accelerated approach to a series of projects related to improving quality of life, establishing partnerships in pharmaceutical policies, addressing intellectual property rights, and strengthening the functions of the health sector, among others. The Caucus also urged that there be coordinated collaboration among the Chief Medical Officers (CMOs), the CARICOM Health Desk and PAHO on the issue.

Based on the findings of the above-mentioned studies and within the framework of the Caribbean Cooperation in Health Initiative, Phase III (CCH III), the development of a Caribbean Pharmaceutical Policy (CPP) was proposed. Earlier, in 1999, a draft Model National Medicines Policy had been developed after a series of steps in that direction. Although the document was updated in 2001, it was never officially adopted. This draft served as the main starting point for developing the current CPP proposal. At a workshop convened in Barbados on 5–6 July 2010, a proposal prepared by TAG was discussed with participation from the main regional and national stakeholders, including representatives of the Organisation of Eastern Caribbean States (OECS), the former Caribbean Regional Drug Testing Laboratory (CRDTL; now the Caribbean Public Health Agency Drug Testing Laboratory [CARPHA/DTL]) and Caribbean Ministries of Health and universities.

The proposal for the Caribbean Pharmaceutical Policy was presented at the Eighteenth Meeting of Chief Medical Officers (CMOs) on 19 May 2010 and at the Nineteenth Meeting of the Caucus of CARICOM Health Ministers in September 2010. The ministers agreed that a decision should be taken on this matter at the next COHSOD meeting, to be held in April 2011, when the policy was finally approved.

The goal of the Caribbean Pharmaceutical Policy is to guide Caribbean countries in ensuring:

- **Access:** equitable access to, availability of and affordability of essential medicines;
- **Quality:** quality, safety and efficacy of all medicines; and
- **Rational use:** therapeutically sound and cost-effective use of medicines by health professionals and consumers.

The regional pharmaceutical policy is guided by the main principle of access to medicines as a human right. Additionally, it is guided by the values and principles of public health, with an emphasis on the renewed Primary Health Care strategy.

The policy has four main areas, namely:

- Pharmacy policy scope;
- Regulatory framework;
- Access; and
- Rational use of medicines.

The CPP encompasses pharmaceutical products and services and related issues, with objectives as follows.

Pharmaceutical policy scope

- Support collaboration mechanisms and develop regional guidelines in key areas of implementation of the Caribbean Pharmaceutical Policy.
- Promote the development and management of human resources in the areas of the pharmaceutical policy.

- Promote the use of evidence in decision-making for the development, implementation and assessment of pharmaceutical policies, both at the sub-regional and national levels.

Regulatory framework

- Develop a sub-regional regulatory framework for medicines and strengthen the collaboration among Caribbean countries to ensure the performance of the essential components of medicines regulation.

Access

- Strengthen the collaboration among the national pharmaceutical systems and promote and support the development and implementation mechanisms for joint negotiation of medicines procurement.
- Develop a sub-regional mechanism to strengthen patent examination systems with a “pro–public health” approach and support the countries’ efforts to promote and protect public health and access to medicines, in order to take advantage of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities in conformity with the Doha Declaration on Public Health.

Rational use of medicines

- Develop a sub-regional strategy and work plan for strengthening the rational use of medicines in the Caribbean as part of the pharmaceutical policy.

Mechanisms for implementation, monitoring and evaluation

An implementation plan with indicators for monitoring and evaluation will be developed. The proposed mechanism, with responsibility for overseeing policy implementation, includes the establishment of the Expanded Technical Advisory Group on Pharmaceutical Policy (TECHPHARM). The policy establishes TECHPHARM and its responsibilities for overseeing the implementation, monitoring and evaluation of the CPP. These responsibilities are shared with the national health authorities and stakeholders from the Caribbean, with technical and financial support from the CARICOM Secretariat and PAHO/WHO.

TECHPHARM will assess the progress of the implementation of the policy in an annual report to the Ministers of Health, embedded in the reporting mechanisms of the CMOs regarding CCH III implementation. It is necessary to establish a sustainable financing mechanism for the proposed policy, which provides guidelines for regional donors’ support in a synergistic way.

The CPP will be an integral part of policies developed by Caribbean states and, to the extent possible, will be incorporated into other policies related to public health.

1. INTRODUCTION

Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The realisation of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, the implementation of health programmes, or the adoption of specific legal instruments. Moreover, the right to health includes certain components which are legally enforceable (1).

Access to health care, which includes access to essential medicines, is a prerequisite for realising that right. It is part of the governance and steering role of the state to ensure the fulfilment of the right to health. National medicines expenditures, as a proportion of total health expenditures, currently range from 7% to 66% worldwide, and proportions are higher in developing countries (24%–66%) than in developed countries (7%–30%) (2).

In accord with the mandates of the Tenth Meeting of COHSOD and the Eighteenth Meeting of the Caucus of CARICOM Health Ministers, a Caribbean Pharmaceutical Policy (CPP) has been proposed and approved in order to promote a sub-regional policy framework and to support and facilitate the development of individual pharmaceutical policies in the Caribbean countries. It aims to support the sustainability of the progress achieved, to date, and to address remaining gaps as well as new challenges.

1.1 Background and context

The Caribbean includes countries and territories with different political structures and status, as follows:

- Republics: Cuba, the Dominican Republic, Haiti, Suriname;
- Republics within the Commonwealth of Nations: Dominica, Guyana, Trinidad and Tobago;
- Independent countries that are part of the Commonwealth: Antigua and Barbuda, the Commonwealth of The Bahamas, Barbados, Belize, Grenada, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines;
- UK Overseas Territories: Anguilla, Bermuda, the British Virgin Islands, the Cayman Islands, Montserrat, Turks and Caicos Islands;
- Entities of the Kingdom of the Netherlands: Aruba, Bonaire, Curaçao, Sint Maarten, Special Municipalities of the Netherlands;
- French Overseas Territories of the Americas: Guadeloupe, Guyana, Martinique, Saint Martin; and

- United States (US) Overseas Territories: Commonwealth of Puerto Rico, US Virgin Islands.

Not only is there diversity in political status and language, Caribbean countries also have different legal systems: most English-speaking territories operate under a common law legal system, while the other territories tend to operate under a civil law system. Most territories are considered small developing states, due to their geographic size and population size as well as the scale of their respective economies.

Caribbean countries have been aligned to a number of regional integration mechanisms and associations. In this context, sub-regional collaboration is crucial to respond to a set of persistent challenges, including the need for state reforms as well as increased pressure due to globalisation and the economic recession. These challenges are reflected in the establishment of the Caribbean Community (CARICOM)¹ and the steps taken towards the implementation of the Revised Treaty of Chaguaramas, establishing the CARICOM Single Market and Economy (CSME) (2001). Article 6 of CSME outlines a set of objectives that include improved standards of living and work, more efficient operation of common services and activities, full employment of labour and other factors of production, and accelerated, coordinated and sustained economic development and convergence. Article 17 addresses the promotion of human and social development and the development of coordinated policies and programmes to improve the living and working conditions of workers. In the Revised Treaty of Chaguaramas, allowances also have been made for new issues such as e-commerce, government procurement, trade in goods from free zones, free circulation of goods and the right of free movement of persons (3).

The 15 CARICOM countries and the Dominican Republic make up the Caribbean Forum of African, Caribbean and Pacific States (CARIFORUM). These countries, together with countries of Africa and the Pacific, constitute the ACP (African, Caribbean and Pacific Group of States) countries that negotiated an Economic Partnership Agreement (EPA) with the European Union (EU) in April 2004.² The framework for ACP-EU relations is centred on economic development, reductions in and eventual eradication of poverty and the smooth and gradual integration of ACP states into the global economy (4).

In addition to CARIFORUM, Caribbean countries participate in several other sub-regional integration or strategic development groups, including the Association of Caribbean States, the Organisation of Eastern Caribbean States (OECS), the Rio Group, the Union of South American Nations, the Central American Integration System and the Association of Small Island States. These collaborations lead to opportunities for cooperation among the countries in areas related to health and development.

¹ a) CARICOM Member States: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago; and
b) CARICOM associate members: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands.

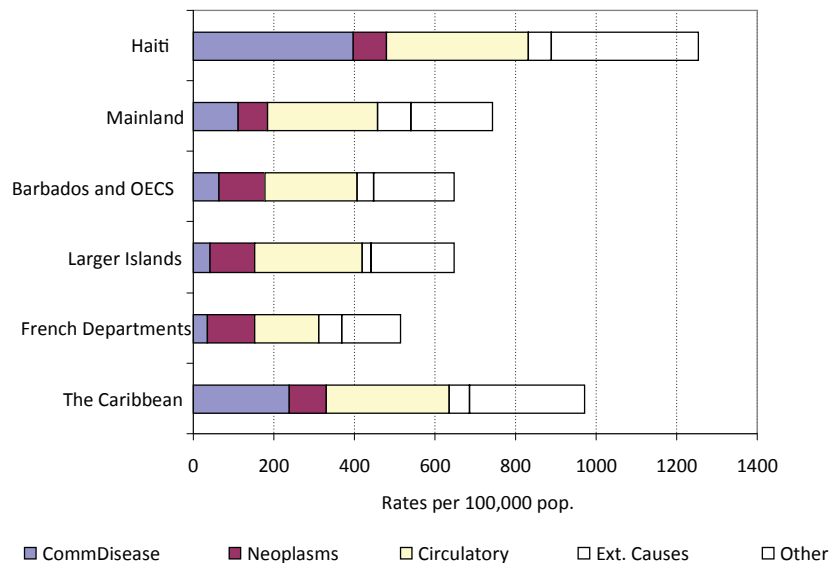
² The countries are as follows: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago. The EPA was signed on 15 October 2008 by each of these countries with the exception of Guyana (which signed on 20 October 2008) and Haiti (which signed on 11 December 2009).

1.2 Health and the pharmaceutical situation in the Caribbean

According to PAHO/WHO (5):

“given the health situation, the geography, the lack of human resources and continued migration, health challenges in the Caribbean require reviews of the incomplete agendas with regard to malaria, TB, leprosy, as well as the epidemic of non-communicable diseases. At the same time, the tourism sector is being challenged by poor sanitation, untreated sewage that may damage beaches, food borne disease outbreaks in public places, the threat of natural disasters, and inadequate capacity to mount an effective, rapid response to manage and control epidemics. As such, there is the need for the Caribbean to focus on achieving a strong, comprehensive and integrated public health response through Health Promotion Strategies that address these priority needs”.

Figure 1. Leading causes of mortality in the Caribbean (2006)



Source: PAHO/WHO (6)

Over the past few decades, death rates in the Caribbean sub-region have been gradually decreasing. Figure 1 shows that the French Departments of the Americas have the lowest mortality rates, whereas Haiti has the highest. The other countries are similar in their mortality profiles.

Between 1980 and 2000, the leading cause of mortality across all ages in the English-speaking Caribbean was ischemic heart disease, followed by cerebrovascular disease, diabetes mellitus, other heart diseases and hypertension. These conditions accounted for 47% of deaths in 1980 and 51% in 2000. Approximately 15%–20% of adults have diabetes, and about 20%–30% have hypertension. Problems related to these major non-communicable diseases (NCDs) represent the largest expenditures in national medicines budgets. The situation is similar in the non-English-speaking countries.

Overall, NCDs are the leading cause of death. They share common underlying risk factors, namely unhealthy eating habits, physical inactivity, obesity, tobacco and alcohol use and inadequate utilisation of preventive health services. This situation suggests that providing medicines alone is not enough; a different and more comprehensive approach is required.

During the period 2004–2010, the WHO/EU/ACP Partnership on Pharmaceutical Policies was an important source of financing for the technical cooperation of CARICOM countries and the Dominican Republic³ through PAHO/WHO.

1.3 Proposal Model National Medicines Policy and Technical Advisory Group

In 1999, a draft Model National Medicines Policy was developed following a series of steps in that direction. First, a consultative workshop took place in May 1999 in Jamaica under the auspices of the CARICOM Secretariat. As stated in the Introduction, the model policy resulted from the pooling of opinions of key role players, primarily chief pharmacists of the CARICOM countries as well as representatives of the Eastern Caribbean Drug Service (ECDS) (since renamed the OECS Pharmaceutical Procurement Service [OECS/PPS]), the CARICOM Secretariat and PAHO/WHO.⁴ Although the document was updated in 2001, it was never officially adopted. The draft model served as the main starting point for developing the proposal for the Caribbean Pharmaceutical Policy. Recognising the challenge of ensuring sustained access to adequate quality medicines at affordable prices, the CARICOM Ministers of Health, at the Tenth Meeting of COHSOD in April 2003, mandated the establishment of a Technical Advisory Group (TAG) on Trade-Related Intellectual Property Rights (see Annex I). TAG, by means of a CARICOM regional assessment of drug regulatory and registration systems (7) and an assessment of patent and related issues and access to medicines in CARICOM and the Dominican Republic (8), sought to assess the current situation with respect to medicines and to propose improvements for the situation.

The two above-mentioned assessments were part of the TAG mandate. Annexes II and III, respectively, present executive summaries of these two studies, which were commissioned by the CARICOM Secretariat, conducted by Health Research for Action (HERA), technically supported by PAHO/WHO and financed by the Pan Caribbean Partnership against HIV and AIDS (PANCAP) and the World Bank.

Complementary to these studies, PAHO/WHO published a report in 2010 on the pharmaceutical situation in the Caribbean, with the participation of 13 Caribbean countries (9).

³ The agreement for this project was signed on 7 March 2004. In the Caribbean, technical cooperation is provided by PAHO/WHO through its Office of Caribbean Program Coordination (OCPC). The original duration of the project was five years (until September 2009), but a “non-cost extension” was received and the project continued until September 2010. In addition to the mandates from PAHO/WHO, project activities were guided by sub-regional mandates and country priorities.

⁴ The CARICOM Draft Model National Medicines Policy (2001 version) is an unpublished document.

At the Eighteenth Meeting of the Caucus of CARICOM Health Ministers, held in September 2009 in Washington, D.C., the ministers, with respect to PAHO's Regional Strategic Framework, supported an accelerated approach to a series of projects related to improving quality of life, establishing partnerships in pharmaceutical policies, developing a pro-public health approach to intellectual property rights, and strengthening the functions of the health sector, among others. The Caucus also urged that there be coordinated collaboration among the CMOs, the CARICOM Health Desk and PAHO on the issue. The proposal for the Caribbean Pharmaceutical Policy was presented on 19 May 2010, at the Eighteenth Meeting of Chief Medical Officers, and in September 2010 at the Nineteenth Meeting of the Caucus of CARICOM Health Ministers in Washington, D.C. The ministers agreed that a decision would be taken at the Twenty-First Meeting of COHSOD in April 2011; at that meeting, the policy was approved.

There have also been efforts to contribute to and achieve the goals established by the Declaration of Port of Spain (2007), one of which is that, *by 2012, 80% of people with NCDs would receive quality care and have access to preventive education based on regional guidelines (10)*. Therefore, it is necessary to guarantee access to high-quality and safe medicines and to promote their rational use.

In 2009, the Caribbean Cooperation in Health Initiative, Phase III (CCH III), Investing in Health for Sustainable Development, was adopted by the Ministers of Health. According to the CCH III, one of the expected results related to the strategic objective of ensuring that health services respond effectively to the needs of the Caribbean people is improvements in access to safe, affordable and efficacious medicines (11).

One of the areas for joint collaborative action is to support the design *and implementation of a Caribbean Pharmaceutical Policy and mechanisms to enhance access, quality and rational use of medicines in the Region*. In the same way, one expected result at the national level would be improving *access to safe, affordable and effective medicines and their rational use*. This document represents the mandate for developing the pharmaceutical policy and its components at both the sub-regional and national levels (11).

The Caribbean Public Health Agency (CARPHA) was established by a CARICOM intergovernmental agreement in June 2011, with the following objectives:

- a) to promote the physical and mental health and wellness of people within the Caribbean;
- b) to provide strategic direction in analysing, defining and responding to public health priorities of the Caribbean Community;
- c) to promote and develop measures for the prevention of disease in the Caribbean;
- d) to support the Caribbean Community in preparing for, and responding to public health emergencies;
- e) to support solidarity in health, as one of the principal pillars of functional cooperation in the Caribbean Community; and

- f) to support the relevant objectives of the CCH as approved by the Council. The Caribbean Regional Drug Testing Laboratory (CRDTL)⁵ will become part of CARPHA.

1.4 Overview of the pharmaceutical situation

A variety of sources have been used to present the information in this section, including a PAHO/WHO assessment of the pharmaceutical situation in Caribbean countries (9), based on the responses of 13 countries to a WHO questionnaire; a regional assessment of drug registration and regulatory systems in CARICOM Member States and the Dominican Republic (7); and a regional assessment of patent and related issues and access to medicines in CARICOM Member States and the Dominican Republic (8).⁶ The results show that progress has been made in six areas:

- National Medicines Policy;
- Regulatory System;
- Medicines Supply System,
- Medicines Financing;
- Production and Trade; and
- Essential Medicines and Rational Use.

The main results in each of these areas related to CARICOM members and the Dominican Republic are highlighted in this document.

According to PAHO/WHO, the number of countries with a national medicines policy (NMP) increased from three in 2003—with only two of them officially adopted—to seven in 2007, with four officially adopted. In the 2009 assessments commissioned by CARICOM, seven of the 16 countries included had an NMP, but only three of them had been officially adopted. In addition, only two countries declared that intellectual property and access to medicines were covered in their respective NMPs. Of the two countries reporting that they had a written policy on intellectual property rights (IPRs), neither reported having a policy on pharmaceutical innovation. The data suggest that special attention has to be given to:

- 1) the implementation, monitoring and evaluation of the existing policies; and
- 2) the development of a sub-regional pharmaceutical policy.

At the same time, these policies need to address aspects related to access to medicines, IPRs and innovation and adopt a clear position on access to pharmaceuticals.

⁵ The Caribbean Regional Drug Testing Laboratory was established through an intergovernmental agreement among members of the Caribbean Community; since the establishment of CARPHA, the laboratory has been renamed the Drug Testing Laboratory (DTL).

⁶ The two regional surveys commissioned by the CARICOM Secretariat and conducted by Health Research for Action (HERA) were part of the mandate of the Technical Advisory Group for Trade-Related Intellectual Property Rights (TAG/TRIPS), which included the 15 CARICOM Member States and the Dominican Republic. The executive summaries of the two CARICOM/HERA studies are presented in Annexes II and III of this document.

According to PAHO/WHO (9), in 2003, only four countries reported that they had legal provisions for the establishment of a medicines regulatory authority (MRA). By 2007, this number had increased to 11. According to the CARICOM report (7), none of the existing legislation is fully comprehensive. Even though progress can be observed with regard to several individual components of the regulatory structure, it is a priority to strengthen the institutional capacity of MRAs and, in particular, their technical capacity. This is important to ensure the performance of several essential functions of medicines regulation, such as registration or marketing authorisation, inspection and licensing of facilities and personnel, and marketing surveillance and pharmacovigilance. In this regard, there is a need for a sub-regional regulatory framework and a network among the MRAs to improve harmonisation and integration efforts as well as collaboration.

According to the CARICOM report (7), seven of the countries studied have privately owned pharmaceutical manufacturing plants that produce multi-source (generic) products only; four of these countries have export capacity. Private sector pharmaceutical importers and/or wholesalers are operating in 14 of the 16 countries, while all of the countries have private retail pharmacies (ranging from one pharmacy in Montserrat to 2,812 in the Dominican Republic). In view of this multitude of stakeholders and actors, it is necessary to establish a comprehensive regulatory framework.

In the PAHO/WHO assessment (9), all participating Caribbean countries reported having public sector procurement pooled at the national level. In 2003, in all seven responding countries, one of the functions of the Ministry of Health was procurement of medicines. In 2007, this was the case in 12 of the 13 responding countries (92%). The distribution function was performed by the Ministry of Health in five countries in 2003 and in seven countries in 2007. Three countries used more than one procurement mechanism in both 2003 and 2007; one of them was through OECS/PPS. The median total expenditure on medicines in the public sector in the Americas region (US\$ 34,087,493) was considerably higher than the expenditure in participating Caribbean countries (US\$ 4,000,000), but the median per capita/per year public expenditure was nearly twice as high in the participating Caribbean countries (US\$ 20.90) as in the Region of the Americas as a whole (US\$ 11.50). Factors to consider in conducting a comparative analysis include a country's size and, consequently, its scope of pharmaceutical marketing, the complexity of its health systems and the effectiveness of its procurement mechanisms and negotiating capacity, including the use of brand or generic medicines and levels of government subsidies for medicines.

The CARICOM report (7) stated that establishing an effective regional negotiation platform for medicines requires that needs and benefits are clearly defined, political will is present and a regional body can be established. With respect to these areas, it is necessary to strengthen medicines procurement and supply systems, thereby ensuring sustainability and cost containment. It is also important to strengthen collaborative mechanisms, such as the Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities (CARIPROSUM), and to work towards a sub-regional mechanism for pooled negotiations. Additional studies should be conducted with regard to price and expenditure of medicines for supporting these proposed activities.

Although the issue of implementation of TRIPS flexibilities had been under discussion for several years, only one country had included TRIPS flexibility provisions in its legislation as of 2007. "Compulsory licensing" was under debate in four countries (57%) in 2003 and in 2007, but

only two countries (50%) had adopted this legal provision. In 2003, three countries reported that they had discussed incorporating Bolar exceptions; none of the countries, however, reported having such legal provisions in 2007. In 2007, the number of countries that had changed their national legislation to implement the TRIPS Agreement and its flexibilities was still minimal (9).

In 2009, according to the CARICOM assessment (8), all 16 countries under study had patent acts. In seven of these countries, however, the acts were considered outdated, and in nine of them the legislation was being reformed so that it would be TRIPS compliant. Hence, the study considered that TRIPS flexibilities were not well implemented in the region. Only three countries permitted international exhaustion of IP rights and thus allowed parallel import” from the world market. The other 13 countries permitted regional or national exhaustion, reducing their options to purchase more affordable brands elsewhere in the world. No country, at that time, had enacted the “30 August decision” or the “Article 31bis amendment”. Both could become relevant with respect to the import and regional distribution of multi-source products in the future.

According to the study, the Dominican Republic was the only country that prohibited new use or second use patents, whereas three countries explicitly allowed this so-called evergreening of patents. Nine countries allowed experimental use, but only the Dominican Republic had an early working or Bolar clause (allowing manufacturers of multi-source products to apply for medicine registration before patent expiry). Seven countries permitted de minimis exceptions, which allow travellers to import small amounts of patented medicines. The situation was better regarding compulsory licensing, which is allowed in 12 countries and authorised in draft laws in two other countries. However, seemingly these clauses have never been used for medicines. Additionally, although all 16 Caribbean countries under study reported that they had a patent office, only 10 reported that they processed patent applications and only two indicated that they carried out substantive examinations of patent applications. Special attention should be given to this area, in particular, to implement the Global Strategy on Intellectual Property Rights in the Caribbean and to support Member States in implementing TRIPS flexibilities (8).

The availability and utilisation of essential medicines lists (EMLs) and standard treatment guidelines (STGs) increased in the Caribbean between 2003 and 2007. It would be useful to obtain additional information regarding the utilisation of these tools and their impact on rational use of medicines and, in this regard, to conduct more specific studies such as household surveys. However, not enough progress has been achieved regarding the introduction of concepts related to rational use of medicines in the curricula of health professions programmes in the Caribbean. It is proposed that support be provided for the development of a sub-regional strategy for the rational use of medicines (9).

The progress observed in 2007 was compared with the 2003 baseline data in the different components of the Caribbean pharmaceutical sector (9). There is still a significant amount of work to be done to improve performance in these areas. The CARICOM report posits that a *Regional Medicines Policy needs to be developed, taking into account the ‘Model’ National Medicines Policy developed by CARICOM in 1999* (8). The formulation of a regional quality assurance policy (regulatory framework) is considered a critical part of the regional pharmaceutical policy to be adopted by Member States. A secretariat should be established, as well as a strategic work plan with funds secured for its implementation.

The second CARICOM study sheds light on the need to implement TRIPS intellectual property flexibilities related to public health and to study the possibility of establishing a model wherein patent rights are granted and enforced for each designated country. This would allow each country to retain flexibilities and exceptions in order to protect public health and consumer interests. Special attention is given to aspects of human resources, mainly due to current shortages and high levels of rotation, the need to strengthen regulation of medicines and, possibly, the need to establish a pool negotiation mechanism for procurement. All of these areas should be within the framework of a regional pharmaceutical policy (8).

Based on the findings of the above-mentioned studies and within the framework of CCH III, the Caribbean Pharmaceutical Policy (CPP) has been developed with participation from the main regional and national stakeholders, including representatives of OECS, CRDTL (now the CARPHA Drug Testing Laboratory [CARPHA/DTL]) (12), and Caribbean Ministries of Health and universities.

Considering the context of the work that has been conducted by TAG, in cooperation with the PAHO/WHO Office of Caribbean Program Coordination (OCPC) and funded by the WHO/EU/ACP Partnership on Pharmaceutical Policies project, this document cannot cover the varied integration mechanisms of all Caribbean countries. Hence, the document covers CARICOM Member States and the Dominican Republic.

Annex IV of this document presents a glossary of terms related to the CPP, and Annex V describes the development of the policy.

2. GOAL, PRINCIPLES AND VALUES OF THE POLICY

2.1. Goal of the policy

The goal of the Caribbean Pharmaceutical Policy (CPP) is to guide Caribbean countries in ensuring:

To guide Caribbean countries to ensure:

- **Access:** equitable access, availability and affordability of essential medicines
- **Quality:** quality, safety and efficacy of all medicines
- **Rational use:** therapeutically sound and cost-effective use of medicines by health professionals and consumers

2.2. Principles and values of the policy

The sub-regional pharmaceutical policy is guided by the main principle that access to medicines is a human right (1). Additionally, it is guided by the values and principles of public health, with an emphasis on the renewed Primary Health Care strategy (13).

The pharmaceutical policy has to be integrated into national (health) policies or plans. Pharmaceutical policies are part of the governance and steering role of the state and are among the essential public health functions, including the six building blocks of well-functioning health care systems identified by WHO: a service delivery health workforce; information; medical products, vaccines and technology; financing; and leadership and governance (12). The Caribbean Pharmaceutical Policy will also be guided by sub-regional mandates, with particular attention to the CCH III (11), the Declaration of Port of Spain (10) and the PAHO/WHO Sub-regional Cooperation Strategy for the Caribbean (5).

3. OBJECTIVES AND STRATEGIES

The priority areas, objectives and strategies related to the Caribbean Pharmaceutical Policy have been identified based on the findings of the existing surveys, the recommendations of the Eighteenth Meeting of the Caucus of CARICOM Health Ministers (held in Washington, D.C., in September 2009) and the Eighteenth Meeting of Chief Medical Officers (held in Trinidad and Tobago in March 2010), and discussions held during the sub-regional technical workshops.

3.1. Objectives

The CPP comprises four main areas, namely:

- Pharmaceutical policy scope;
- Regulatory framework;
- Access; and
- Rational use of medicines.

The policy encompasses pharmaceutical products and services and related issues, with objectives as follows.

3.1.1. Pharmaceutical policy scope

- Support the strengthening of collaboration mechanisms and develop regional guidelines in key areas of implementation of the Caribbean Pharmaceutical Policy.
- Promote the development and management of human resources in the areas related to the pharmaceutical policy.
- Promote the use of evidence in decision-making for the development, implementation and assessment of pharmaceutical policies both at the sub-regional and national levels.

3.1.2. Regulatory framework

- Develop a sub-regional regulatory framework for medicines and strengthen the collaboration among Caribbean countries to ensure the performance of the essential components of medicines regulation.

3.1.3. Access

- Strengthen the collaboration among the national pharmaceutical systems and promote and support the development and implementation mechanisms for joint negotiation of medicines procurement.
- Develop sub-regional mechanisms for strengthening patent examination systems with a “pro-public health” approach and support the countries’ efforts to promote public health and access to medicines in order to take advantage of TRIPS flexibilities in conformity with the Doha Declaration on Public Health.

3.1.4. Rational use of medicines:

- Develop a sub-regional strategy and work plan for strengthening the rational use of medicines in the Caribbean as part of the pharmaceutical policy.

3.2. Strategies

The strategies are presented according to the same approach as the CCH III, as national-level strategies and as areas for joint collaboration.

3.2.1. Pharmaceutical policy scope

Objective: Support the strengthening of collaboration mechanisms and develop regional guidelines in key areas of implementation of the Caribbean Pharmaceutical Policy.

Areas for joint collaborative action

- Develop an implementation plan for the Caribbean Pharmaceutical Policy, including collaboration and communication mechanisms among the national health authorities and establishment of regional structures for policy oversight;
- Strengthen pharmaceutical services within the network of health services, emphasising the renewed Primary Health Care concept;
- Develop a sub-regional legal framework and model legislation related to medicines and pharmaceutical services (with provisions for language and cultural idiosyncrasies);
- Develop sub-regional policies related to medicines pricing and generic medicines;
- Develop strategies for promoting the appropriate use of traditional and complementary medicines in the Caribbean; and
- Support countries in the planning and negotiation of international and inter-governmental agreements related to pharmaceutical policies.

At the national level

- Strengthen policy and regulation of pharmaceutical products and services as part of the steering role of the state to ensure essential public health functions;
- Update, monitor and evaluate the existing policies and the development of new national pharmaceutical policies; and
- Support the updating of the national legal framework related to medicines and pharmaceutical services.

Objective: Promote the development and management of human resources in the areas related to the pharmaceutical policy.

Areas for joint collaborative action

- Provide support for the Caribbean Network on Pharmacy Education and the rationalisation and harmonisation of pharmacy education programmes;

- Support capacity-building in all related areas, in collaboration with Caribbean tertiary-level educational institutions;
- Develop a strategic plan for human resource development, identifying needs and opportunities for training institutions;
- Support the development of a mechanism for accreditation of pharmacy programmes and the licensing of all categories of pharmacy professionals within the CSME;
- Collaborate with the Caribbean Accreditation Authority for Education in Medicine and other Health Professions to facilitate the accreditation of pharmacy programmes in the Region.

Objective: Promote the use of evidence in decision-making for the development, implementation and assessment of pharmaceutical policies both at the sub-regional and national levels.

Areas for joint collaborative action

- Develop the Pharmaceutical Observatory as a resource for evidence-based decision-making;
- Support the strengthening of the information systems; and
- Support the development of operational research in strategic areas of pharmaceutical policy.

3.2.2. Regulatory framework

Objective: Develop a sub-regional regulatory framework for medicines and strengthen the collaboration among Caribbean countries to ensure the performance of the essential components of medicines regulation.

Areas for joint collaborative action

- Develop a sub-regional platform for regulation of medicines, integrated with the regulation of other health technologies;
- Develop draft legislation for the Caribbean and the participating countries for the development of essential regulatory functions;
- Strengthen collaboration among the national authorities and establish a Caribbean Network of Medicines Regulation, including the existing Pharmacovigilance Network of the Caribbean, working in close collaboration with the Pan American Network for Drug Regulatory Harmonization (PANDRH);
- Strengthen the Caribbean Regional Drug Testing Laboratory (CRDTL)⁷ and support its incorporation into CARPHA; and
- Develop guidelines for a code of ethics for pharmacists, model codes of conduct for health professionals involved with issues related to the pharmaceutical policy and ethics guidelines for committees and advisory bodies to avoid conflicts of interest.

⁷Currently, Caribbean Public Health Agency/Drug Testing Laboratory (CARPHA/DTL).

At the national level

- Strengthen the existing national regulatory authorities to perform essential regulatory functions with the updating of national institutional arrangements and national legislation;
- Strengthen regulatory enforcement mechanisms and enhance the quality assurance of pharmaceutical products and services, in both public and the private sectors;
- Strengthen existing national laboratories for quality control of medicines and support the development of laboratories, when pertinent, integrated into the Pan-American Network of NLQCM.

3.2.3. Access

Objective: Strengthen the collaboration among the national pharmaceutical systems and promote and support the development and implementation mechanisms for joint negotiation of medicines procurement.

Areas for joint collaborative action

- Strengthen the Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities (CARIPROSUM) and the harmonisation of medicines supply systems in the Caribbean;
- Promote the development of a sub-regional platform for pooled negotiations; and
- Develop a sub-regional policy framework for cost-containment strategies, including use of generic medicines, sustainability of financing mechanisms and price regulation and monitoring.

At the national level

- Strengthen national medicines supply systems, including public procurement and supply management agencies, by ensuring sustainability and cost containment; and
- Develop and implement cost-containment strategies, including use of generic medicines, sustainable financing mechanisms and price regulation and monitoring.

Objective: Develop sub-regional mechanisms for strengthening patent examination systems with a “pro–public health” approach and support the countries’ efforts to promote and protect public health and access to medicines in order to take advantage of TRIPS flexibilities in conformity with the Doha Declaration on Public Health.

Areas for joint collaborative action

- Develop a work plan for implementing the Global Strategy on Intellectual Property Rights in the Caribbean as part of the pharmaceutical policy, including the development of strategic alliances;
- Develop and harmonise procedures for patent analysis with a pro–public health approach and support national patent offices in improving their procedures for analysis within this approach; and
- Support CARICOM Member States in adopting TRIPS flexibilities.

At the national level

- Promote legislative changes to adopt TRIPS flexibilities; and
- Strengthen collaboration between health and trade agencies and improve procedures for analysis of pharmaceutical patents with a pro–public health approach.

3.2.4. Rational use of medicines

Objective: Develop a sub-regional strategy and work plan for strengthening the rational use of medicines in the Caribbean as part of the pharmaceutical policy.

Areas for joint collaborative action

- Develop a model sub-regional EML and formulary;
- Develop and promote harmonised regional STGs; and
- Develop a regional medicines information centre in close collaboration with poisoning information centres, working as a network with national medicines information centres and in partnership with the Latin American and Caribbean Medicines Information Network.

At the national level

- Support countries in strengthening selection and use of medicines;
- Promote advocacy for strengthening access and rational use of medicines in the community; and
- Support the integration of the existing national medicines information centres into a regional scheme.

4. MECHANISMS FOR IMPLEMENTATION, MONITORING AND EVALUATION

4.1. Responsibility and oversight structure

The implementation of the Caribbean Pharmaceutical Policy is a shared responsibility of the national health authorities and stakeholders from the Caribbean institutions, with technical and financial support provided by the CARICOM Secretariat and PAHO/WHO. Establishment of the Expanded Technical Advisory Committee on Pharmaceutical Policy (TECHPHARM) will be part of the oversight mechanism. This committee will be responsible for facilitating the implementation, follow-up and assessment of the policy (see Annex VI). The secretariat for policy implementation will work under CARPHA. In the transition period for the establishment of CARPHA, PAHO/WHO, through OCPC, will provide support to the secretariat in close collaboration with the CARICOM Member States and associate members, as well as the CARICOM Secretariat and the CARPHA implementation team.

It is proposed that TECHPHARM be an advisory body. With respect to its operational procedures, a simple majority has been proposed for its quorum and for voting purposes. TECHPHARM should meet twice a year and, if necessary, schedule additional meetings and solicit the support of small working groups. In the meantime, members should make use of virtual collaborative mechanisms.

TECHPHARM will assess the progress of the implementation of the policy in an annual report to the CARICOM Ministers of Health, convening as COHSOD, that will be embedded in the reporting mechanisms of the CMOs regarding CCH III implementation. A set of core members and rotating country representatives will be present, as well as sub-groups and observers. The rotating portion of TECHPHARM should not exceed one third of its membership, to ensure the continuity of its work. Furthermore, in order to take informed decisions based on expertise, it is important to have senior representation in TECHPHARM.

A declaration of conflict of interest and impartiality should be signed by its members, and a code of conduct should be established and adhered to. The tenure for TECHPHARM members is set at three years.

TECHPHARM will support and oversee the proposed collaborative activities and mechanisms and integrate different related initiatives of, for example, the Caribbean network of pharmacy schools. TECHPHARM will also be responsible for identifying sources of financial support and submitting proposals for financing sub-regional structures.

Annex VII of this document outlines the proposed terms of reference for TECHPHARM at its inception.

4.2. Strategies for implementation

An implementation plan with performance indicators will be developed as part of the implementation, monitoring and evaluation of the Caribbean Pharmaceutical Policy. An outline of the implementation plan is presented in Annex VI of this document, and a roadmap for the plan is provided in Annex VIII. The plan will be developed once the policy has been approved.

The strategic implementation plan will be created as part of a participative process. A proposal has been made to organise the implementation plan within a matrix based on the six building blocks of well-functioning health care systems:

- governance and stewardship;
- management;
- service delivery, financing and accountability;
- human resources;
- knowledge management and information systems; and
- monitoring and evaluation.

All of these elements fit within the four above-mentioned areas of policy scope, regulatory framework, access and rational use of medicines.

4.3. Reporting mechanism

TECHPHARM will assess the progress of the implementation of the policy and will submit an annual report to the CARICOM Ministers of Health, embedded in the reporting mechanisms of the CMOs relating to CCH III implementation.

4.4. Financing

It is necessary to establish a sustainable financing mechanism for the policy, including TECHPHARM with respect to policy oversight. The policy document provides guidelines for regional donors' support to the community in a synergistic way, setting the priorities for the Region. Furthermore, it is necessary to cooperate with an increased set of donors in order to speed up the process and to establish mechanisms through which governments can participate in financing the strengthening of the public pharmaceutical sector.

5. FINAL CONSIDERATIONS

The establishment of the Caribbean Pharmaceutical Policy and the creation of national pharmaceutical policies are urgent priorities. For this purpose, the countries are urged to gradually incorporate the provisions of the policy into their respective national legal systems and to take the necessary steps to establish and participate in the proposed collaborative network approach.

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ANNEX I. Former Technical Advisory Group on Trade-Related Intellectual Property Rights (TAG)¹

Princess Thomas-Osbourne	Head of the Standards and Regulation Division, Ministry of Health, Jamaica
Maryam Hinds	Director, Barbados Drug Service Ministry of Health, Barbados
Miriam Naarendorp	Pharmacy Policy Coordinator Ministry of Health, Suriname
Richard Aching	Intellectual Property Office, Ministry of Legal Affairs, Trinidad and Tobago
Lucette C.M Cargill	Director, Caribbean Regional Drug Testing Laboratory
Francis Burnett	Managing Director, Pharmaceutical Procurement Services, Organisation of Eastern Caribbean States
Adriana Mitsue Ivama Brummell	Sub-Regional Advisor on Medicines and Health Technologies, Pan American Health Organization/World Health Organization Office of Caribbean Program Coordination
Malcolm Spence	Technical Advisor, Office of Trade Negotiations, CARICOM Secretariat
Rudolph Cummings	Programme Manager, Health Sector Development, CARICOM Secretariat
Rhonda Wilson	Deputy Programme Manager, External Economic and Trade Relations, CARICOM Secretariat

¹TAG was responsible for the development of the CPP as well as for the consultation process leading to its approval.

Annex II. Executive Summary - CARICOM Regional Assessment of Drug Registration and Regulatory Systems¹

CARICOM countries are faced with an increasing burden of chronic non-communicable diseases for which treatment and care need to be ensured. This, in addition to scaling up treatment of HIV/AIDS, requires sustained access to adequate quality medicines at affordable prices.

In this context the Technical Advisory Group, established at the 10th CARICOM Council of Human and Social Development, recommended that a study be conducted on regulatory systems for existing medicines in CARICOM countries with a view to establishing their adequacy for ensuring the timely supply of safe, effective and quality medicines. Realising that market, human and financial constraints might pose a potential barrier to effective and efficient medicines regulation in individual Member Countries, the study was also tasked with establishing strategies and an action plan for the development of a harmonised medicines regulation system for the Region.

Study Implementation

The 15 CARICOM Member States (Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago) were included in the study. The Dominican Republic had been identified as an additional beneficiary of the study in the Pan Caribbean Partnership against HIV/AIDS (PANCAP)/World Bank agreement.

The study was conducted in two main phases, i.e., a data collection phase and a consolidation phase. Data collection for the regulatory systems assessment in countries was based on the *Guide for Data Collection to Assess Drug Regulatory Performance*, developed by WHO and amended to suit the specific purposes of this study. Both the data collection instruments and implementation work plan were approved by the CARICOM Secretariat and the Technical Advisory Group.

Based on the WHO assessment instrument, stakeholder interviews were conducted in Barbados, the Dominican Republic, Guyana, Jamaica, Saint Lucia, Suriname and Trinidad and Tobago during the period 18 January to 15 February 2009. During the same period, questionnaires for self-completion were sent out to the remaining study countries. These countries were supported in person by HERA team members of the CARICOM Study on Intellectual Property Rights, TRIPS and Access to Medicines that was conducted in parallel and through telephonic follow-up by the study team leader.

During the consolidation phase, responses collected in countries were analysed and documented in specific reports for each study country (Volume 2), and summarised for the main report. In addition, study countries' medicines legislation was assessed.

Study findings and resulting recommendations for medicines regulatory harmonisation strategies presented in the draft report were discussed with the Technical Advisory Group. This Final Report includes the results of these discussions.

¹For further information, please see the complete report: *Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic* (July 2009).

Medicines Regulation

Medicines are a crucial input to improving and maintaining the health of the population, and considerable funds are dedicated by governments and individuals to the purchase of medicines. In order to be beneficial, medicines need to be safe, effective and of adequate quality—otherwise funds will be wasted, and the populations' health will be put at risk. However, neither the consumer nor the prescriber has the information and expertise needed to establish whether a particular product complies with these requirements. It is thus in the interest of public health that government intervenes in the medicines market through regulation.

According to international consensus, medicines regulation encompasses the following critical functions that need to be provided for in the national medicines legislation:

- Licensing (registration) of pharmaceutical products;
- Licensing of pharmaceutical premises (manufacturers, importers, distributors);
- Inspection of distribution channels and goods manufacturing facilities;
- Quality control laboratory testing;
- Adverse drug reaction monitoring;
- Control of advertising and promotion; and
- Control of clinical trials.

The National Regulatory Authority (NRA) is the authority empowered by law to carry out regulatory functions pertaining to medicines and to ensure compliance with the legal requirements.

Study Findings

Pharmaceutical sector characteristics define to a great extent the context within which medicines regulatory systems operate. National Medicines Policies provide guidance on governments' goals related to the public and private pharmaceutical sectors, including the commitment to ensure quality, safety and efficacy of the medicines marketed. Of the 16 study countries, seven have a National Medicines Policy, and of these three have been officially adopted by the government.

Seven of the study countries have privately owned pharmaceutical manufacturing plants producing multi-source (generic) products only, with production also for export in four countries. Private sector pharmaceutical importers and/or wholesalers are operating in 14 of the 16 countries, while all of the study countries have private retail pharmacies (ranging from 1 in Montserrat to 2,812 in the Dominican Republic).

Legislative provisions

All study countries have some type of medicines legislation, including specific acts providing for the control of narcotics and psychotropic substances. However, none of the existing legislation is fully comprehensive. Provisions frequently missing include:

- control of clinical trials;
- adverse drug reaction monitoring;

- control of product promotion and advertisement; and
- specific prohibition of counterfeit medicines.

Registration of pharmaceutical products is a requirement by law in seven of the 16 study countries.

Challenges identified include:

- legislation that is not being updated;
- provisions in “old” laws that have not been harmonised with newer legislation; and
- multiple amendments not consolidated into one revised law.

In some countries enforcement of laws is constrained by the lack of regulations. The passing of medicines-related bills and draft regulations has been found to be a very lengthy process.

Regulatory framework and institutional capacity

In those study countries with more comprehensive medicines legislation, the NRA is set up by law as a public sector entity operating under and/or reporting to the Ministry of Health. Of the six countries that have operational medicines registration systems, two have an NRA responsible for all regulatory activities. In the remaining four countries, responsibilities are spread over different Ministry of Health departments, with no dedicated overall responsible body. It was reported that this leads to coordination and communication challenges and is affecting the efficiency and effectiveness of regulatory performance.

All study countries reported a shortage of **human resources** assigned to medicines regulatory activities, which was attributed most frequently to low salaries, lack of funds and bureaucratic delays in approving restructuring proposals. Except for the Pharmacy Council in Jamaica, none of the regulatory authorities have the power to recruit or retrench their staff. Human resource capacity is further constrained by the general lack of adequate training activities to build the specific technical expertise required for medicines regulatory functions.

All but one study country reported that **financial resources** to carry out medicines regulatory functions were inadequate. Regulatory authorities are generally not aware of their operational budgets. While in eight countries fees are being collected for, e.g., product registration or licensing of premises and persons, only in one country can these fees be used to support NRA activities.

Some deficiencies regarding adequate **infrastructure** for NRAs were reported. These were mainly related to access to transportation to carry out inspections and, in a few cases, to availability of reliable communication tools (Internet and e-mail facilities).

Licensing and inspection

The following pharmaceutical licensing activities were reported to be conducted:

- licensing of manufacturers: seven countries (all countries with pharmaceutical manufacturing);

- licensing of importers and/or wholesalers/distributors: nine of 14 countries where these businesses are present;
- licensing of retail pharmacies: 11 of 16 countries; and
- licensing of other retail premises allowed to sell a restricted number of non-prescription medicines: seven of 16 countries.

Six countries that issue licenses for all types of pharmaceutical premises were questioned about the existence of unlicensed establishments: four countries were aware of or thought it very likely that unlicensed activities took place in their countries. The extent was not known.

None of the study countries license or otherwise control the operation of Internet pharmacies.

Import permits are required by all countries for controlled medicines falling under the respective UN conventions. Import permits for other pharmaceutical products need to be obtained from the NRA in five countries, while three require import permits for antibiotics only.

Distribution channel inspections are conducted in 11 of the 16 study countries. However, these are mainly pre-licensing inspections as compared to preventive planned inspections (surveillance). Nevertheless, violations of medicines legislation during the past three years were detected by inspectors in nine countries. These included the sale of medicines in street markets, operation of businesses without a licence, sale of unregistered and expired products, and improper storage conditions.

The seven countries with pharmaceutical manufacturing conduct good manufacturing practices (GMP) inspections, mainly in connection with licensing. However, GMP certificates for export are only issued by three countries.

Product assessment and registration

Pharmaceutical product registration is a legal requirement in seven of the 16 study countries, but is only being implemented in five countries. One additional country requires registration of medicines without having an explicit legal provision for this.

All six countries with an operational registration system require registration of new medicines and known multi-source (generic) medicines for human use. Some countries also register veterinary medicines, biologicals, herbal products, or medical devices. The number of products registered varied between 2,635 and 12,124. Information on how many of the registered products were actually available on countries' markets was not available from the NRAs.

One country makes the list of registered products publicly available on the department's web site, and four countries produce updated lists from time to time, which can be obtained on request by interested parties. In one country, the newly registered products are published in the official gazette, but a complete list is not available.

All countries collect registration fees for processing an application for registration. These fees varied between US\$ 10 and US\$ 128 for new medicines.

Four of the six countries have access to external expert committees for the assessment of application dossiers. Reported time needed to process registration applications was acceptable (between three and six months for new medicines).

While provisions are made for requiring proof of registration with other established NRAs, this was reported not to impact the regulatory assessment process. Likewise, different information requirements for the application for registration of new and known products are not always clearly specified in the legislation. In practice, clinical safety and efficacy studies are usually not required for registration of known (multi-source/generic) products. Only one country has different processes for assessment of applications for registration of new and known products.

Linkages between intellectual property laws and medicines registration were reported by three countries, where provisions for data exclusivity exist. Only one country reported implementing this provision.

Regulatory quality control laboratories

Thirteen of the 16 study countries are signatory to the agreement establishing the Caribbean Regional Drug Testing Laboratory (CRDTL), and 12 countries are using this facility (OECS Member States usually submit samples through the OECS Pharmaceutical Procurement Services [OECS/PPS]). CRDTL also conducts planned quality surveillance of priority pharmaceutical products where samples are to be submitted by individual countries as per established schedules. Out of 640 samples analysed by CRDTL during 2006-2008, 89 or 13.9% were found to be of unsatisfactory quality. Because there is inadequate random sample collection and testing, the general level of substandard pharmaceutical products in the CARICOM region is not known.

Four of the 16 study countries have in-country regulatory quality control laboratories that are all operating under the respective Ministries of Health. Sterility and microbial limit tests cannot be performed and are done by the CRDTL. Pyrogen and toxicity testing cannot be done by any of the regulatory quality control laboratories in the Region.

Challenges identified by the existing laboratories include inadequate human and financial resources to operate satisfactorily.

Specific quality assurance measures in countries without pharmaceutical product registration

Ten of the study countries do not have an operational registration system for pharmaceutical products that would require pre-marketing assessment of product quality, safety and efficacy. All of these countries do implement quality assurance measures during the processes of pharmaceutical procurement for the public sector, e.g., requiring proof of registration with other specified regulatory authorities, pre-registration of suppliers, or random quality control testing. For OECS Member States, quality assurance measures instituted by OECS/PPS apply. These include use of pre-qualified suppliers, specific tender conditions and quality control testing of samples in-house (qualitative) and at CRDTL.

Two of the 10 countries require import permits for the importation of antibiotics by the private sector. All import documents are screened in one country, and no specific quality assurance measures are taken in seven countries. Quality assurance of pharmaceutical products in the private sector is clearly inadequate in the 10 countries.

Discussion of Study Findings

The assessment indicated that effectiveness and efficiency of medicines regulation in the study countries is affected by delay in updating and passing legislation, human resources constraints, institutional constraints and inadequate access to fully functional regulatory quality control laboratories. While financial constraints were noted by 15 of the 16 countries, there was no detailed information available to establish the extent of the problem.

The risk of unsafe, ineffective or substandard medicines being sold or dispensed to patients clearly increases when the regulatory functions are being performed only partially or not at all. Only two countries provided concrete examples for counterfeit medicines. However, without effective registration and surveillance systems the chances for detecting counterfeit products are low. All study countries reported cases of substandard pharmaceutical products in the public sector, where quality assurance measures are more widely applied. Again, the low level of post-marketing surveillance (including random sample collection and testing) makes it difficult to detect substandard medicines in the private sector.

The recommendations should consider the different country contexts; For the smaller CARICOM Member States it will not be feasible to establish comprehensive medicines regulatory systems, taking into account market factors, specific technical expertise requirements, and associated costs. For the larger countries with established medicines registration systems, the required extension of regulatory activities to ensure adequate performance of inspection and surveillance systems will be a challenge. It is suggested that CARICOM countries establish a network for cooperation among NRAs to discuss viable approaches to address the identified common challenges.

Except for two countries, policy guidance on the envisaged development of the pharmaceutical sectors, including medicines regulatory systems, is either not available, not updated, or not being implemented. We would therefore recommend that National Medicines Policies be developed/ updated and implemented. In addition, the development of an overall CARICOM Regional Medicines Policy would be useful to comprehensively define regional goals, strategies and commitments.

Harmonisation of medicines regulation

Existing harmonisation initiatives usually focus on harmonisation of medicines registration, with the overall aim of reducing registration processing times due to different country requirements. Harmonisation should translate into significant cost savings to the pharmaceutical industry and quicker access to new and improved therapies at more affordable prices. Medicines regulatory harmonisation activities have often been triggered by wider regional integration activities aiming at the creation of single or common markets, and there has been an increasing trend towards harmonisation globally.

However, the focus on speedy approval of new products may impact appropriate pre-marketing evaluation. It is thus important to keep the primary objective of medicines regulation in mind—i.e., the protection of public health—when considering the harmonisation option. Harmonisation initiatives are ongoing in several regions worldwide. For example:

European Union

Harmonisation activities started in 1965, and in 1995, the European Medicines Agency was established. To date, three different routes exist through which applications for registration can be submitted:

- the traditional route (application to individual Member States' NRA);
- the decentralised procedure (mutual recognition); and
- the centralised procedure (simultaneous registration in all EU Member States through the EMA).

Association of Southeast Asian Nations (ASEAN)

The concept of pharmaceutical harmonisation was endorsed in 1999 and facilitated by the Pharmaceutical Product Working Group established under the ASEAN Consultative Committee for Standards and Quality. The focus is on the development of common technical dossiers and technical requirements for medicines registration. In April 2009, a mutual recognition arrangement for good manufacturing practices inspections was signed.

Southern African Development Community (SADC)

Harmonisation activities in the region started in 1995 with the development of technical guidelines. Currently the SADC Directorate of Social and Human Development/Health and Pharmaceuticals in Botswana coordinate activities. To date, 14 guideline documents have been approved by Member States. Challenges experienced included varying capacity of pharmaceutical sectors and level of economic development in Member Countries, language differences and a rather weak secretariat.

Pan American Region through the Pan American Network for Drug Regulatory Harmonization (PANDRH)

PANDRH was formally endorsed at the 42nd Meeting of the PAHO Directing Council in 2002. It comprises NRAs of all 35 PAHO Member States and representatives of the pharmaceutical industry. The secretariat is provided by PAHO and 12 working groups have been established to address specific regulatory sub-areas. To date, five conferences have been held, where decisions on adoption of harmonised guidelines were taken. Approved guidelines include those on bioequivalence testing and on the prevention and combat of counterfeit medicines.

CARICOM Member States' NRAs are members of PANDRH. Challenges regarding active participation, and communicating and implementing PANDRH decisions at the national level have been identified.

In addition, there are global harmonisation initiatives (e.g., the International Conference on Harmonisation), and initiatives supporting national NRAs' capacity (e.g., the United States Food and Drug Administration's tentative approval mechanism, the EMA's scientific opinion mechanism, the WHO pre-qualification project, and the International Conference of Drug Regulatory Authorities).

Harmonisation in the CARICOM context

In 2001, CARICOM Member States signed the Revised Treaty of Chaguaramas Establishing the Caribbean Community including the CARICOM Single Market and Economy (CSME). Part 2 of the treaty addresses consumer protection and provides-among others-for Member States to enact harmonised legislation.

Respondents in study countries were asked about their general perception regarding harmonisation of medicines regulation and any priority areas for harmonisation. Those countries that do not yet have registration systems were in favour of a central body for assessing applications for registration. The main reason provided was lack of expertise and human and financial capacity at the country level. Respondents that do register medicines were more in favour of enhanced cooperation between NRAs. In addition to assessment of applications for registration, priority areas for harmonisation included:

- technical support and information sharing;
- regional quality control; and
- harmonized norms for inspections.

It was also remarked that countries' sovereignty would need to be respected, and that any regional regulatory body should be built on existing structures.

Strategic options for medicines regulatory harmonisation in CARICOM

CARICOM countries can be divided into three groups, based on their medicines regulatory features:

- Group 1 comprises the five countries with more comprehensive medicines regulatory systems, including medicines registration. These countries account for approximately 91% of the total population of CARICOM Member States.
- Group 2 comprises the two countries where there are plans to implement the registration of medicines in the near future.
- Group 3 comprises the eight countries with limited regulatory systems and where there exist no plans to register medicines in the near future. Seven of these countries belong to the OECS. Due to limited market size and human and financial constraints, implementation of stand-alone medicines registration systems in each of these countries does not appear to be feasible.

However, public health in all countries needs to be protected by ensuring that only safe, effective and quality medicines are circulating and made available to patients. We therefore suggest, as the overall mission of a CARICOM medicines quality assurance policy and harmonised structure, ensuring that there is a provision in all CARICOM Member States that adequate pharmaceutical

products to address prevalent health conditions are marketed in a timely manner, and that these products are of proven safety, efficacy and quality.

Harmonisation Strategies

It is suggested that the policy principles guiding harmonisation efforts and strategy selection include the following:

- Member States' governments commit to support all areas of medicines regulation, considering this a critical step in protecting public health;
- Only medicines that have been assessed for safety, efficacy and quality will be allowed to be marketed;
- The assessment process will, as far as possible, be based on harmonised requirements and guidelines appropriate for the Region;
- Existing guidelines developed by PANDRH will be considered;
- There will be distinct requirements for the assessment of products containing new chemical entities and well-known multi-source (generic) products;
- There will be procedures to ensure priority assessment of dossiers for applications for registration of priority medicines;
- Joint support will be provided for Member States without a registration system to implement licensing requirements using a phased approach; and
- Existing resources will be shared among Member States.

The following strategies are recommended for consideration:

- Development of harmonised guidelines for application and assessment;
- Capacity-building of National Regulatory Authorities;
- Capacity-building of the local pharmaceutical industry;
- Promoting formal cooperation/exchange of information;
- Resource sharing;
- Supporting the licensing of medicines in countries without a registration system; and
- Strengthening quality control capacity.

The body of this Report provides detailed descriptions for each of the strategies, and summarises requirements, challenges and opportunities related to their implementation.

Institutional framework

For a sustainable harmonisation effort, it is imperative to have a formal structure that enables effective coordination of issues agreed by Member States, where the guiding principle should be to create efficient and effective systems without expensive structures.

Identifying as priority strategies those related to development/adoption of harmonised guidelines and general capacity-building, it is recommended that a small but permanent secretariat be established, charged with, e.g., establishment of relevant databases of guidelines, legislation, experts, etc.; communication with countries, relevant regional and international organisations, the pharmaceutical industry and the public; and coordination, and organisation of meetings (physical or virtual) per the established business and work plan.

Because of its regional public health responsibility, it is recommended that consideration be given to establishing the Secretariat under the planned Caribbean Public Health Agency (CARPHA). In the event that the establishment of CARPHA is delayed, possible options for provisional housing of the Secretariat include PAHO/OCPC in Barbados or CRDTL in Jamaica. This would ensure that none of the Member States feels disadvantaged (which is a possibility, should the Secretariat be established under one of the existing NRAs).

Due to the amount of work that will arise from listing products, and the time needed for establishing the legal requirement for registration for Group 2 and Group 3 countries, a recommendation has been made to handle this as a special project. Within the framework of this project the options for establishing a sub-regional regulatory authority for OECS could be explored. One option could include linking this authority to the Secretariat in charge of regional harmonisation activities. In that case, this sub-regional authority can serve as a 'pilot' for a CARICOM Medicines Regulatory Agency that may be envisaged.

Critical steps towards harmonisation

The report identifies five critical steps for commencing regional medicines regulatory harmonisation efforts:

- 1) Formulation of a regional quality assurance policy (to be integrated in a CARICOM Regional Medicines Policy);
- 2) Adoption of the regional policy by Member States;
- 3) Establishment of a harmonisation Secretariat;
- 4) Development of a strategic and annual work plan for policy implementation; and
- 5) Securing funding for work plan implementation;

Concluding Remarks

The report concludes by reiterating the key issues and lessons learnt for harmonisation of medicines regulation, i.e.:

- Medicines regulation serves the protection and promotion of public health;
- Harmonisation takes time;
- Commitment is essential;
- Legal backing, while important, is not absolutely necessary for all activities; and
- Building trust among Member States is key.

ANNEX III. Executive Summary: Assessment of Patent and Related Issues and Access to Medicines in CARICOM and the Dominican Republic (HERA Final Report, 31 December 2009)

CARICOM countries are faced with an increasing burden of communicable and non-communicable, chronic diseases for which they need to ensure appropriate treatment and care. Both require sustained access to good quality, essential medicines at affordable prices. Unfortunately, many of these medicines are patented and expensive. Since 2000, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) has required that CARICOM countries implement stronger patent protection for pharmaceuticals in their national legislation on intellectual property rights (IPRs).¹

In 2004, the 10th CARICOM Council for Human and Social Development (COHSOD), concerned about the increasing cost of antiretrovirals (ARVs) due to the TRIPS Agreement, mandated the establishment of a Technical Advisory Group (TAG) that would commission studies to address inter alia trade related health issues impacting access to medicines and make recommendations to policymakers in this regard.

Study Objectives

The objectives of this study were: (a) to explore the possibilities of developing a harmonised, pro-public health regional (Caribbean) IP (intellectual property) regulation and medicine policy (to include generic medicines) framework; (b) to make recommendations on the promulgation/updating of IP legislation and regulation that will maximise TRIPS flexibilities while being TRIPS compliant; (c) to identify the requirements and process for establishing a regional negotiating platform for medicines; (d) to identify mechanisms for building/strengthening coalitions and negotiating positions at WTO and in bilateral and regional forums for ensuring access to medicines; and (e) to make recommendations on the adequacy of the systems in Member States for regulation of the pharmaceutical market to ensure the timely supply of safe, effective and quality medicines.

Study Implementation

The 15 CARICOM Member States (Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago) were included in the study. The Dominican Republic had been identified as an additional beneficiary of the study in the Pan Caribbean Partnership against HIV/AIDS (PANCAP)/World Bank agreement.²

¹Except for Haiti (which, as a less developed country, has an exemption until 2016) and the Bahamas (not yet a WTO member).

²The Dominican Republic (DR) is not a CARICOM member, although high-level discussions have taken place regarding the possibility of it joining CARICOM. The Dominican Republic is a member of CARIFORUM and is party to the Dominican Republic–Central America Free Trade Agreement (DR-CAFTA) with the United States. The DR-CAFTA includes a substantial number of obligations with respect to IPR standards and enforcement that have resulted in significant changes in IPRs and related regulatory legislation in the Dominican Republic. These changes will affect the country's pharmaceutical market, and they potentially will affect public access to medicines. Implementation of the DR-CAFTA is at a relatively early stage, and it is difficult to draw conclusions about its actual impact. Nonetheless, in addition to providing a basis for suggestions regarding the Dominican Republic's legislation and policy on IPRs, its inclusion in this study may be useful to CARICOM members as they consider potential future free trade agreement commitments. The Dominican Republic has a robust local generic pharmaceutical manufacturing industry that distinguishes it from CARICOM members, so some caution must be exercised in making comparisons.

The study was conducted in two main phases, a data collection phase and a consolidation phase. All 16 study countries were visited between 24 January and 21 February 2009.

In the **data collection phase**, a specific data collection instrument was developed. The CARICOM Secretariat and TAG approved this instrument and the study work plan. The data collection instrument was pilot tested in Guyana and Trinidad and Tobago. Study consultants also developed a database of all relevant intellectual property and pharmaceutical and public health professionals in the 16 study countries, searched for the IP and patent laws in these countries, and collected relevant literature regarding the impact of the TRIPS Agreement on access to medicines in the Caribbean region. More than 30 specific articles and papers were summarised in a literature review.

During the **consolidation phase**, IP and patent legislation and the data collected from all 16 visited study countries were analysed (chapter 3) and documented in specific country reports (Volume II of the report). Interviews in Jamaica and Suriname were redone as original data were lost. Study findings and resulting recommendations presented in the draft report were shared with TAG. The present Final Draft Report takes note of the comments received.

Study Findings

Country-based findings

The Pan American Health Organization (PAHO) recommends that all countries develop a National Medicines Policy. The CARICOM Secretariat developed a Model National Medicines Policy in 1999 and updated it in 2001. At the time of the study, only seven of the 16 study countries had a written National Medicines Policy, and only three of these policies had been formally adopted by the respective government. Only two countries mentioned the issue of IPRs and access to medicines in their National Medicines Policy.

PAHO also recommends that each country have a medicines regulatory authority or at least a unit that regulates market access (registration) for medicines. This helps ensure that all products circulating in the country are effective, safe and of good quality. Only six of the 16 countries had a functional system of medicines regulation. In the 10 “non-regulation” countries, the burden was on the national (or regional) procurement agency to ensure quality in the public sector. In seven countries, there was no control at all on products imported by the private sector. This poses a significant health risk to the population.

Two of the 16 countries reported having a written policy on intellectual property rights. No country had a declared policy on pharmaceutical innovation or technical development. Only three countries reported carrying out pharmaceutical research and development. No country reported receiving any transfer of technology in the pharmaceutical sector, but several expressed an interest in receiving it.

All countries reported having an IP office, but only 10 countries are processing patent applications. Six countries were not administering patents due to absent or incomplete legislation or inadequate capacity, including lack of staff. Staffing levels were poor: three IP offices reported having patent examiners, but only two offices reported carrying out a substantive examination of patent applications.

To assess potential IP barriers, a basket of medicines was identified that could potentially be subject to patent protection (based on USA data). In most countries it was difficult or impossible to establish, during the two- to three-day mission, whether a specific product was covered by a valid patent. Only one IP office (Trinidad and Tobago) reported valid patents for two ARVs in the basket. Multi-source³ (generic) products seemed to enter the study countries without infringement problems; only Jamaica reported that a patent holder had stopped a multi-source product entering the country.

Study countries adhere to several international agreements relevant in terms of access to medicines, including the TRIPS Agreement, the Patent Cooperation Treaty, and the CARIFORUM-EC Economic Partnership Agreement (EPA). The last two have some aspects that go beyond the minimum required by the TRIPS Agreement and were thus considered “TRIPS plus”, even though the EPA specifically states that *[n]othing in this Agreement shall be construed as to impair the capacity of the Parties and the Signatory CARIFORUM States to promote access to medicines*.⁴ The Dominican Republic has signed the Dominican Republic–Central America Free Trade Agreement (DR-CAFTA), which is significantly “TRIPS plus”. This agreement may have an adverse impact on access to medicines.

All 16 countries were found to have patent acts, but the study results revealed that seven of them were “obsolete” and were therefore candidates for replacement or complete revision. Over the preceding 10 years, nine countries had developed patent legislation that could be considered TRIPS “compliant”. Haiti, the only Least Developed Country in CARICOM, is permitted to delay becoming TRIPS compliant with respect to pharmaceuticals until 2016. The 15 other study countries were all required to have become TRIPS compliant as of 2000.

In order to maximise access to medicines, it is crucial to have all “TRIPS flexibilities” enabled in national legislation. Unfortunately, this is not well implemented in the region. Only three countries permitted “international exhaustion” of IP rights and thus allowed “parallel import” from the world market. The other 13 countries permitted “regional” or “national” exhaustion. This reduces their options to source more affordable brands elsewhere in the world.

No country had yet enabled the “30 August decision” or the “Article 31bis amendment”, which could become relevant for import and regional distribution of multi-source products in the future. According to the study, only the Dominican Republic prohibited “new use” or “second use” patents, whereas three countries explicitly allowed them (allowing “evergreening” of patents). Nine countries allowed “experimental use”, but only the Dominican Republic had an “early working” or “Bolar” clause (allowing multi-source products to apply for medicine registration before patent expiry). Seven countries permitted *de minimis* exceptions, which allow travellers to import small amounts of patented medicines. The situation was better regarding “compulsory licensing”: this was enabled in 12 countries and authorised in draft laws in two other countries. However, these clauses appeared to have never been used for medicines. In summary, the study showed that many countries deprive themselves of the possibilities to make use of the full set of “flexibilities” permitted under TRIPS and confirmed by the 2001 Doha Declaration.

³WHO prefers the term “multisource” rather than “generic” which can be multi-interpretible. From this point forward this report refers to generic medicines as multisource medicines.

⁴EPA article 139.2

TRIPS-plus provisions go beyond the minimum protections required by TRIPS and therefore might unnecessarily hinder access to medicines. Several of the TRIPS-plus features are the result of the “Free Trade Agreements” such as DR-CAFTA, which bind countries to allow higher protection of IPRs than the minimum required under TRIPS. Next to IP or patent legislation as a potential barrier to access, several non-IP barriers to access exist. These include: bias against multi-source products, unmotivated preference for more expensive branded versions, slow registration processes, logistics, management and human resource issues. High margins, duties, taxes and VAT (value added tax) increased costs and made medicines less affordable for the uninsured. Also, treatment guidelines could be more evidence-based or better adhered to by prescribers.

Regarding regional collaboration, 14 study countries are part of the CARICOM Single Market and Economy (CSME); this should in the future allow inter alia the free flow of medicines among these countries. However, because medicines are subject to national regulation, the study suggested that the CARICOM countries harmonise their medicine regulation systems in order to make the single market a reality. The new Caribbean Public Health Agency (CARPHA) might be able to assist in this process.

Interestingly, the OECS (Organization of Eastern Caribbean States) countries have developed a successful regional “group contracting” system (the OECS Pharmaceutical Procurement Service, or PPS, is active in seven of the study countries), but it might not be easy to scale this model up to include other CARICOM countries. Seven other countries had joined the PAHO Regional Revolving Fund for Strategic Public Health Supplies. PAHO is also promoting regional cooperation in procurement through CARIPROSUM (Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities). While political will is present, many obstacles are still in the way of optimal regional collaboration.

Regional IP issues

As CARICOM countries are not obliged to go beyond the minimum required by TRIPS, it is recommended that TRIPS-plus legislation should be actively avoided as a balance between innovation and public health.

A CARICOM Regional Patent Policy and patent office may be desirable from a public health perspective. Therefore, the lessons learned from the long and slow development of the European patent system and the experiences from other regional patent offices have been noted. The analysis included a comparison of the “unitary” patent model with the “non-unitary” patent model and a “mixed” approach, as well as the public health perspectives of a possible regional patent system, including the need to enable regional “flexibilities”.

Furthermore, the Patent Cooperation Treaty (which has become an obligation for all EPA signatories) may have potential negative consequences by increasing the number of patent applications.

In order to strengthen initiatives and lobbying techniques regarding the regional position at WTO, one important strategy is to form coalitions of developing countries with similar interests (bearing in mind the risk that the richer countries would seek to target individual countries by offering them special incentives). Another suggested strategy is to collaborate with highly

specialised NGOs and to use the media. The risk that health and industry ministries are played against each other can be minimised by arranging regular meetings in the home countries.

Strengthening the bargaining position in bilateral negotiations with the USA or EC is more difficult. The role of sympathetic NGOs and individual congressmen or parliamentarians could be important, as large coalitions do not work so well. CARICOM would probably benefit from strengthening a “pro-public health” NGO in the region.

Regional pharmaceutical issues

Establishing an efficient regional negotiation platform for medicines requires that needs and benefits are clearly defined and political will present. A regional body needs to be set up (or the task allocated to an existing body). Technical solutions need to be considered, options analysed and a model chosen. There must be a Regional Medicine Policy, accurate information on what quantities of product are needed and where, a joint financing system, standardised and evidence-based treatment guidelines and essential medicines collection, harmonised medicine regulation, a joint policy on patents, reduced border procedures and free movement of goods in the region, agreement obtained on a price differentiation system, and legislation adopted for regional negotiation.

With a view to deal with existing problems in the CARICOM pharmaceutical market, a Regional Medicines Policy needs to be developed, taking into account the “Model” National Medicines Policy developed by CARICOM in 1999. The TAG has been mandated to strengthen regional collaboration on pharmaceutical issues and seems well placed to take the lead in developing this new policy.

Conclusions and Recommendations

The CARICOM countries and the Dominican Republic (CARICOM/DR) face many challenges common to developing and smaller economy countries around the world. These challenges include promoting economic growth and employment opportunities in a highly competitive global economic environment and promoting and protecting the public health of citizens and residents with budgets that are strained more than normal due to the extraordinary global financial and economic crisis. The Caribbean region also faces a high incidence of HIV infection, necessitating the development and maintenance of expensive prevention and treatment programmes, and an increasing burden of non-communicable diseases also requiring access to patented medicines.

In this environment, it is essential that the financial resources available to CARICOM/DR for the acquisition of public health–related supplies, most notably pharmaceutical products, are used in efficient and effective ways. As a general proposition, this implies that public health procurement authorities and private sector pharmaceutical procurement enterprises should emphasise the acquisition of safe and effective products at the lowest possible price. In some cases, procurement of new therapies requires negotiation with single-source originator or patent holder suppliers. In many cases, multi-source versions of pharmaceutical products, which are on patent in some countries, are available from sources where no patents are in force.

Multi-source products may be available because patents were never applied for, have expired, are invalid or because government-use or compulsory licenses have been issued.

The subject matter of IPRs is complex. It is made more so when a relatively large basket of international, regional and bilateral agreements and rules are brought into the picture. At the present time, patents and other forms of IPRs do not constitute a significant obstacle to the procurement of essential medicines by CARICOM/DR public health and private sector enterprises. The main reason is that the administrative systems for granting patents within the region are largely non-operational, and a relatively low volume of pharmaceutical related patents appears to have been granted up to this point. Perhaps largely as a consequence of this, there have been few efforts by pharmaceutical patent holders to block importation of multi-source versions of products into the region. If patents have not been granted in the country, there is no legal right to block importation and distribution. Although some countries in the region are beginning to implement data protection rules that may ultimately inhibit the registration of multi-source products, so far such rules do not appear to have been implemented and/or enforced in any significant way.

This does not mean that procurement enterprises within the region have been securing pharmaceutical products at, or near, the lowest possible prices. To the contrary, for reasons other than protection of IPRs, it appears that often procurement authorities have not sought to obtain multi-source versions of originator products that are available on the international market. These reasons include underdeveloped procurement systems, small markets (and thus limited interest of suppliers), an apparent preference for originator brand name products, slow efforts to register multisource products for import and sale and an element of non-transparency in international procurement. Moreover, procurement authorities in the region have, in general, not yet sought to coordinate or pool their pharmaceutical purchases, which might yield significantly lower prices (as has been the experience of the OECS PPS).

However, it is a “backward-looking” assessment that patents and other IPRs have not played a significant role to date in the procurement of medicines in the CARICOM/DR region. The CARICOM/DR countries have recently entered into new international agreements that promise to focus new attention on their intellectual property systems. These include for the CARIFORUM countries the EPA with the European Community (EC), and for the Dominican Republic a free trade agreement with Central America and the United States (DR-CAFTA). Each of these agreements includes new IP-related commitments, and in the case of the EPA, “aspirational” commitments on the part of CARIFORUM countries to move toward a regional system for administering IPRs.⁵ To this end, a study has already been undertaken under the auspices of WIPO (World Intellectual Property Organization) to consider the potential establishment of a regional patent system.

The consequence of these developments on IPRs is that patents and other forms of right holder protection will almost certainly play a larger role in the CARICOM/DR public health procurement process over the coming years. This fact must be taken into account in the larger context of an international patent system that has recently extended its scope such that developing countries (in particular, India, which for many years served as supplier of low-cost multi-source versions of new pharmaceutical products) will no longer be able to act freely in this way.

⁵see Article 141, CARIFORUM-European Community EPA

The forward-looking assessment and analysis in this report therefore urges CARICOM/DR countries to closely examine their existing patent and data protection legislation with a view towards implementing IP-related flexibilities that are permitted under international rules, but which have not yet been adopted or implemented. These flexibilities may well be critical to maintaining adequate supplies of new pharmaceutical products in the future.

The study examined the possibility of establishing a regional patent office and system, and this report makes recommendations about how that system might be structured in a way more likely to promote public health and consumer interests. It suggests that CARICOM countries avoid adoption of a “unitary” patent model and adopt instead a model in which patent rights are granted and enforced for each designated country, allowing each country to retain flexibilities and exceptions. It observes the potential advantages in establishing a regional patent office with consolidated technical capacity to examine pharmaceutical-related patent applications (consistent with whatever policies and rules CARICOM countries adopt). The report recommends the establishment of a working group or groups to consider the potential structure of a regional patent system, recognising that there are a number of difficult legal and technical issues to assess.⁶

The report notes that one problem confronting the region is the continuing movement of government staff between ministries and agencies. The laws and regulations affecting the pharmaceutical sector, including public health, trade and IPRs, are complex and require several years to master. The constant movement of staff means that officials who have mastered these laws and regulations will ultimately be moved into new positions; institutional memory is therefore limited. This report recommends that annual or biennial workshops be conducted on IP, patents and public health. These workshops should be attended by a cross-section of agency officials, representing public health, trade and intellectual property, to facilitate discussion and coordination among these various areas of regulation.

The report also recommends the initiation of work towards the development of a regional procurement negotiating platform. Such a platform would become increasingly important as multi-source supplies of new medicine therapies diminish over time and the region becomes increasingly dependent on more expensive, patented, single-source products. The region will have to be well-organised to negotiate better prices during procurement from the medicine companies. As the establishment of the platform is a medium- to long-term enterprise, the report advises CARICOM/DR countries to initiate work soon.

Among the foundations for the regional platform would be the development of a Regional Medicines Policy, including promotion of more harmonised regulatory standards, to facilitate common procurement efforts. This report provides a concept note with suggestions for this development, and for a possible way forward. Once CARICOM and the TAG have decided how they want to move forward, they need to commission development of a road map for action at different levels.

The IP legislation of the country studies was analysed, and specific recommendations regarding how access to medicines can be maximised while remaining TRIPS compliant are made in the 16 country reports in Volume II of the report.

⁶Consultants requested but did not obtain access to the WIPO regional patent office study. They were thus unable to provide specific comments on the WIPO study proposals.

ANNEX IV. Glossary of Terms

CODE OF CONDUCT (CODE OF BEHAVIOUR)

A code of conduct is a set of conventional principles and expectations that are considered binding on any person who is a member of a particular group.

[Source: <http://wordnet.princeton.edu/>]

CONFLICT OF INTEREST

A 'conflict of interest' is a situation in which a public official's decisions are influenced by the official's personal interests.

[Source: <http://wordnet.princeton.edu/>]

The common meaning of conflict of interest is a conflict between an individual's private or personal interest and his or her duty. However, conflict of interest may also refer to a situation in which an individual has several duties that conflict without the involvement of any private or personal interest. Mitigating conflict of interest means eliminating a conclusive or a reasonable presumption of bias in decision-making processes.

[Source: PAHO Governance Manual]

DRUG

See Pharmaceutical

DRUGS AND THERAPEUTICS COMMITTEE

A drugs and therapeutics committee is a group of people established and officially approved by the Ministry of Health and/or health facility management that promotes the safe and effective use of medicines in the area or facility under its jurisdiction.

[Source: <http://apps.who.int/medicinedocs/en/d/Js4882e/3.html>]

ESSENTIAL MEDICINES

Essential medicines are defined by WHO as medicines that "satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility."

[Source: http://www.who.int/topics/essential_medicines/en/]

LEGISLATION

The first stage of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter such as the control of pharmaceuticals. Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms (see also Regulations, below).

[Source: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

MEDICINE

See Pharmaceutical

MEDICINES REGULATORY AUTHORITY

A national body that has the legal mandate to set objectives and administer the full spectrum of medicines regulatory activities, including the following functions, in conformity with national drug legislation:

- Marketing authorisation of new products and variation of existing products;
- Quality control laboratory testing;
- Adverse drug reaction monitoring;
- Provision of medicine information and promotion of rational use of medicines;
- Good manufacturing practices (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels;
- Enforcement operations; and
- Monitoring of medicines utilisation.

[Source: <http://infocollections.org/medregpack/interface/files/glossary.pdf>]

NATIONAL DRUG POLICY

See National Pharmaceutical Policy

NATIONAL MEDICINES POLICY

See National Pharmaceutical Policy

NATIONAL MEDICINES POLICY IMPLEMENTATION PLAN

A national medicines policy implementation plan is a written expression of the government's plans to put into action the national medicines policy, setting out activities, responsibilities, budgets and timelines.

[Source: http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/]

NATIONAL PHARMACEUTICAL POLICY (NMP)

A national pharmaceutical policy (also referred to as a national medicines policy or national drug policy) is a commitment to a goal and a guide for action. It expresses and prioritises the medium- to long-term goals set by the government for the pharmaceutical sector and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors and involves all of the main actors in the pharmaceutical field. A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood. The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment must be built.

[Source: <http://apps.who.int/medicinedocs/en/d/Js2283e/#Js2283e>]

NATIONAL REGULATORY AUTHORITY (NRA)

See Medicines Regulatory Authority

PHARMACEUTICAL (MEDICINE, DRUG)

A pharmaceutical is any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

[Source: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

QUALITY ASSURANCE

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of pharmaceuticals. It is the totality of the arrangements made with the object of ensuring that pharmaceuticals are of the quality required for their intended use.

[Source: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

RATIONAL USE OF MEDICINES

Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

[Source: <http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf>]

REGULATIONS

The second stage of the legislative process (the first stage being legislation; see above). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation.

[Source: <http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf>]

STANDARD TREATMENT GUIDELINES (STGs)

STGs summarise recommended treatments for commonly occurring conditions. They should represent a consensus on what is regarded as the most appropriate treatment for each condition. The aim of providing such information is that treatments become standardised throughout a health system and that prescribing for the conditions covered is rationalised. Widespread adoption and application of standardised treatments also make it possible to use these, together with morbidity and patient attendance data, as a basis for quantification of drug requirements. STGs are useful to prescribers as ready reference texts for consultation during the course of daily clinical work and also as resource materials for basic and in-service prescriber training.

[Source: <http://apps.who.int/medicine-docs/pdf/whozip24e/whozip24e.pdf>]

TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to strike a balance between the long-term social objective of providing incentives for future inventions and creations and the short-term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement. The balance works in three ways:

- Invention and creativity in themselves should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.
- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids “reinventing the wheel”.
- The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves to import pharmaceuticals made under compulsory license. In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it.

[Source: [http:// www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]

TRADITIONAL MEDICINE (TM)

Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses.

Herbal medicines: plant-derived material or preparations with therapeutic or other human health benefits that contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal origin may also be present.

Complementary/alternative medicine (CAM): often refers to a broad set of health care practices that are not part of a country’s own tradition and are not integrated into the dominant health care system. Other terms sometimes used to describe these health care practices include “natural medicine”, “nonconventional medicine” and “holistic medicine”.

[Source: <http://apps.who.int/medicinedocs/en/d/Js7916e/3.html>]

ANNEX V. Development of the Caribbean Pharmaceutical Policy

In April 2004, the Technical Advisory Group (TAG) on Trade-Related Intellectual Property Rights was established. A regional assessment of drug regulatory and registration systems and a regional assessment of patent and related issues and access to medicines in the CARICOM countries and the Dominican Republic by Health Research for Action (HERA) were commissioned by the CARICOM Secretariat as part of the mandate of TAG. The assessments were financed by the Pan Caribbean Partnership against HIV and AIDS (PANCAP) and the World Bank, with technical support from PAHO/WHO. In addition to these studies, PAHO/WHO published *Pharmaceutical Situation in the Caribbean Countries*, a summary of the results of the 2007 WHO Level I Survey among the 13 participating Caribbean countries.

The Caribbean Pharmaceutical Policy (CPP) was developed based on the findings of the just-mentioned studies and framed by international and regional mandates such as the Caribbean Cooperation in Health Initiative, Phase III (CCH III); the Declaration of Port of Spain; and the PAHO/WHO Sub-regional Cooperation Strategy for the Caribbean: 2010–2015. The CCH III is a mechanism designed to improve the health and well-being of the people of the Caribbean and to develop their productive potential. It comprises eight priorities, among which is health systems strengthening, which aims at responding effectively to the needs of the Caribbean people and includes access to safe, affordable and effective medicines. Supporting the design and implementation of a Caribbean Pharmaceutical Policy is one of the areas of joint collaborative action in the CCH III to achieve this goal.

The Development of the CPP

The development process and the content of the policy are described below. The CPP is based on the problems identified and the priorities proposed in the three above-mentioned surveys.

1) Policy Paper:

A policy paper was developed that included:

- b) A situation analysis that included a review of existing international recommendations, mandates, and health contexts and identification of primary issues in the pharmaceutical sector based on the above-mentioned exploratory studies;
- c) A policy outline with the proposed structure and content; and
- d) Governance mechanisms, including responsibilities and technical and financial viability.

The policy paper was presented to and approved by the CARICOM Chief Medical Officers (CMOs) during their Eighteenth Meeting, held in Port of Spain, Trinidad and Tobago, on 19–20 April 2010.

2) Consultation with stakeholders:

A draft Caribbean Pharmaceutical Policy (first version) was developed and submitted for stakeholders' consideration during a workshop held in Barbados on 6–7 July 2010. After consolidation of their contributions, it was circulated to CARICOM countries and the Dominican Republic for another review, systematisation of contributions and revision,

resulting in the issuing of a second version (August/September 2010). The document was again circulated to CARICOM countries, the Dominican Republic and the sub-regional institutions for final review and systematisation of contributions (November 2010 to January 2011), and a third version was issued.

3) *Submission to Ministers of Health for approval*

The second draft policy document was presented to the Nineteenth Meeting of the Caucus of CARICOM Health Ministers, who referred it to the Twenty-First Meeting of COHSOD for a decision. The third version of the policy and the governing mechanisms were approved, in principle, at the Nineteenth Meeting of CMOs, who recommended it to COHSOD. It was approved at the Twenty-First Meeting of COHSOD in April 2011.

Conclusions

The CPP was developed using the existing evidence. It represents the necessary framework for collaborative action and includes several networks and regional platforms of work that are already under development.

Considering that most of the Caribbean countries are Small Island Developing States and that there are several constraints for development of activities on their own, a willingness to collaborate has been expressed at both the technical and political levels, which can facilitate the implementation of the CPP.

References

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4. PAHO. Informe del Grupo de Trabajo 2005. Los aspectos de los derechos de propiedad intelectual relacionados con el comercio (ADPIC) y el acceso a medicamentos. Santo Domingo, República Dominicana, 4-6 de abril, 2005. Available at: [http://www.paho.org/Spanish/AD/FCH/AI/Derechos_de_propiedad_intelectual_\(ADPIC\).pdf](http://www.paho.org/Spanish/AD/FCH/AI/Derechos_de_propiedad_intelectual_(ADPIC).pdf)

ANNEX VI. Outline of the Implementation Plan for the Caribbean Pharmaceutical Policy

Some of the priority areas identified for the Caribbean Pharmaceutical Policy are outlined in the following table. The content should be expanded and completed to represent the implementation plan for the CPP.

WHAT	WHEN	WHO	REMARKS
Sub-regional platform for medicines regulation	After establishment of policy	TECHPHARM	Regional policy functions include: <ul style="list-style-type: none"> ▪ registration of medicines ▪ importation of medicines ▪ procurement <ul style="list-style-type: none"> a) If product is not registered, under which conditions would you procure it? b) How will government procure?
Essential medicines list for the Caribbean, including medicines for paediatric use	2011	TECHPHARM	Includes creation of a subcommittee
Development of the framework for the establishment and integration of the existing collaborative networks in the pharmaceutical sector	2011	TECHPHARM	Includes establishment of a steering committee and legal mechanisms
Harmonisation of procurement and importation requirements and establishment of a pool negotiation mechanism for medicines in the Caribbean	2012	TECHPHARM	Includes strengthening of CARIPROSUM and collaboration among countries

ANNEX VII. Terms of Reference - CARICOM Expanded Technical Advisory Committee on Pharmaceutical Policy (TECHPHARM)

BACKGROUND

Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living life in dignity. Access to health care, which includes access to essential medicines, is a prerequisite for realising that right. However, the growing incidence and prevalence of chronic diseases is a threat to the Region's health and a considerable strain on health budgets. Public health costs for care, treatment and support are rising faster than general inflation.

The Region's geography and its small and open economies compound the fiscal situation. Both of these realities spell increased vulnerability to the negative impacts of natural disasters and crises in international markets. Meeting health care guarantees and sustaining health gains are serious challenges.

In response, the Region continues to forge areas for collective action. Under the mantra "Investing in Health for Sustainable Development", the Member States of the Caribbean Community (CARICOM) have developed a framework called the Caribbean Cooperation in Health Initiative (CCH). Now in its third phase, this initiative's mission is to improve the health and well-being of the people of the Caribbean and, by extension, develop their productive potential and the competitive advantage of the Region.

A prominent priority area is the strengthening of health systems whose activities include the development and implementation of a Caribbean Pharmaceutical Policy. This platform will guide the actions of governments in the quest to ensure that essential medicines are available, affordable and accessible to all people who have a legitimate need.

DEVELOPMENTS

In 2004, the Tenth Meeting of the Council for Human and Social Development (COHSOD) mandated the establishment of a Technical Advisory Group (TAG) to address major health challenges related to intellectual property rights (IPRs), particularly access to medicines, and to provide advice to CARICOM governing bodies. TAG members include representatives of regional health and related institutions such as the Caribbean Regional Negotiating Machinery, CRDTL, OECS/PPS and PAHO/WHO, as well as technical officials from the governments of Barbados, Jamaica, Suriname and Trinidad and Tobago. The group has been meeting periodically for the last four years under the coordination of the CARICOM Secretariat and with administrative and technical support from PAHO/WHO.

As TAG set about the task of formulating a pharmaceutical policy for the Caribbean, certain developments in the interface between public health and global trade rules necessitated a rethinking of its original scope.

A pharmaceutical policy should not focus solely on access to and rational use of safe, cost-effective and quality essential medicines. The inherent tension between public health imperatives

and intellectual property rights related to product innovation can impede the Region's access to affordable medicines of assured quality. Therefore, policy provisions must be included to account for trade rules and their impact on public health.

Innovation needs and access imperatives have made it necessary to reformulate the TAG mandate and to review its functioning and interaction with CARICOM institutions and Member States.

Accordingly, in September 2009, at the Eighteenth Meeting of the Caucus of CARICOM Health Ministers in Washington, D.C., the ministers considered the Regional Strategic Framework of PAHO/WHO in supporting *an accelerated approach to a series of projects related to improving quality of life, partnership in pharmaceutical policies, intellectual property rights, strengthening the functions of the Health sector, among others.*

The Caucus also urged that *there be coordinated collaboration between the CMOs, the CARICOM Health Desk and PAHO on the issue.* Consequently, a draft proposal for the Caribbean Pharmaceutical Policy was presented at the Eighteenth Meeting of Chief Medical Officers (CMOs) on 19 May 2010.

Based on lessons learned in the Caribbean, the successful experiences in other sub-regions, and the direction of the Caucus of CARICOM Health Ministers, it is proposed that the scope of the current functioning of TAG be extended to the Expanded Technical Advisory Committee on Pharmaceutical Policy (TECHPHARM). This technical advisory body will continue the process of holistic policy development, implementation, monitoring and evaluation.

On 5–7 July 2010, the TECHPHARM proposal was reviewed and accepted by a joint meeting of TAG and a representative group of CMOs, with the participation of a consultant from the EU, the principal founder of the policy development process. The proposal will be submitted to COHSOD.

OBJECTIVES

General Objective

To improve access to assured quality, safe and cost-effective medicines, and promote their rational use in the Caribbean.

Specific Objectives

To guide the development, implementation and assessment of the Caribbean Pharmaceutical Policy; and

To advise CARICOM governing bodies and support Member States in policy-related activities.

SPECIFIC RESPONSIBILITIES

TECHPHARM will formulate, implement and evaluate a work plan including, but not limited to, the following functions:

- Act as an advisory body to the CARICOM Secretariat and Member States in matters related to pharmaceutical policies;
- Present a proposal for the Caribbean Pharmaceutical Policy, along with an implementation plan and mechanisms to monitor its implementation;
- Develop a sub-regional framework for the regulation of medicines and health technologies based on the Pan American Network for Drug Regulatory Harmonization (PANDRH), WHO frameworks and other relevant recommendations and contribute to national capacity-building;
- Develop and implement mechanisms for pooled negotiation and price monitoring of medicines integrated with other sub-regional and regional initiatives;
- Support CARICOM Member States in implementing TRIPS, ensuring that the full extent of TRIPS flexibilities (including the successful management of intellectual property rights) is acknowledged and implemented;
- Develop and implement a Caribbean Working Plan based on the regional perspective regarding the Global Strategy on Public Health, Innovation and Intellectual Property and the negotiation of international trade agreements, regulations and dispositions that might affect access to affordable and adequate pharmaceutical products to address public health needs; and
- Develop and implement a Caribbean Pharmaceutical Observatory (an information clearinghouse).

PROCEDURES

TECHPHARM will have a coordinator who will be responsible for monitoring policy outcomes and informing the CARICOM Secretariat and related governing bodies, including COHSOD, on the committee's scope of work. The coordinator will also ensure that a constant link with PAHO/WHO and other possible technical partners is maintained, in order to assess progress and challenges in executing the work plan. The coordinator will be selected by the members every three years and supported by the respective Ministry of Health (MOH).

Decisions taken at each meeting should be based on consensus. The report of each meeting must be agreed upon and signed by all present members in acknowledgment of adherence to the meeting's decisions. Documents will be sent to absent members, who will be asked to provide comments.

TECHPHARM will assess the progress of the implementation of the policy in an annual report to the Ministers of Health, embedded in reporting mechanisms of the CMOs regarding CCH III implementation. COHSOD will provide the necessary political support and guidance for implementing the agreements and recommendations of technical documents.

TECHPHARM can establish ad hoc working sub-groups for technical issues when required.

TECHPHARM will hold face-to-face meetings twice a year and use other mechanisms for additional meetings as required (e.g., Elluminate).

TECHPHARM is responsible for articulating the different collaborative networks and sub-groups and for integrating their work into the scope of the Caribbean Pharmaceutical Policy.

MEMBERS

TECHPHARM is composed of 10 members and respective alternates, namely:

- Three representatives of the Ministry of Health chosen from the following Member Countries: Bahamas, Barbados, Belize, Jamaica, Haiti, Guyana, Suriname and Trinidad and Tobago;
- Two representatives of the OECS countries;
- One representative of the UK Overseas Territories;
- One representative of CRDTL or CARPHA;
- One representative of PAHO/WHO;
- One representative of the academic institutions in the region; and
- One representative of the CARICOM Secretariat.

The alternate representative for each Member Country should ideally be from a different country than the incumbent member. The country and academic institutions' representatives and alternates should rotate every three years.

Institutions with pharmacy programmes and relevant health professions will choose a representative. Once the network of institutions with pharmacy programmes is established, that agency will nominate the representative.

All of the CARICOM Member States will be invited to nominate a focal point to act as interlocutor between TECHPHARM and the MOH.

Other sub-regional organisations or experts may participate, upon request. Cuba, the Dominican Republic and overseas territories of France, the Netherlands, the United Kingdom and the United States of America, as well as Caribbean academic institutions, are invited to nominate focal points as observers who will collaborate with TECHPHARM.

After the CARPHA implementation transition period, CRDTL will be replaced by a CARPHA representative with expertise related to medicines regulatory functions.

Profile of the Members

The representatives of Member Countries and academia who will be selected are required to have professional expertise and work experience in the area of medicines. They should not have any linkage with the pharmaceutical industry or any conflict of interest. In respect of that, a statement declaring no conflict of interest should be signed by each member. The member selected must be committed to the principles of public health, as defined by TECHPHARM.

Nomination occurs through COHSOD, based on proposals from Member States, and rotation takes place on a two-thirds basis.

TECHPHARM should establish a code of conduct that is agreed upon and signed by its members and alternates.

Coordinator

One of the country members will be nominated to serve the coordinator on a rotation basis, with another country acting as an alternate.

Secretariat

PAHO/WHO will support the secretariat until an official mechanism can be established (e.g., CARPHA). It will work in close collaboration with the CARICOM Secretariat and the coordinating country. It is recommended that a full-time staff be dedicated to the work of the secretariat.

FUNDING

It is proposed that PAHO/WHO continue to provide technical and financial support, in addition to other funds that will be identified by TECHPHARM and the CARICOM Secretariat. TECHPHARM should seek additional funding resources as well, supported by PAHO/WHO and the CARICOM Secretariat.

Countries are encouraged to provide budgetary support to TECHPHARM.

WAY FORWARD

A request has been made for the CARICOM Secretariat to present the proposal to the CARICOM Ministers of Health (at the COHSOD meeting or the meeting of the Caucus of CARICOM Health Ministers) for TECHPHARM to be approved as a sub-committee of COHSOD.

ANNEX VIII. Roadmap for Development of the Pharmaceutical Policy

WHAT	WHEN	WHO	REMARKS
Appointment of small working group (SWG)	In process	PAHO and CARICOM staff	
CPP documentation: 1) Review existing policy documents and determine policy framework 2) Develop a glossary of terms 3) Identify gaps in the CPP document and address these gaps 4) Reformat the document so that it is reader-friendly 5) Create a draft document 6) Send the document to CARICOM	Draft by August 15, 2010	Small working group	Documentation completed
Circulation for comments among stakeholders	15–30 August 2010	CARICOM and PAHO/WHO	In collaboration with the Caribbean Association of Pharmacists; process completed
Submission of the policy and the TECHPHARM proposal to the Caucus of CARICOM Health Ministers for approval	25–26 September 2010	CARICOM	The technical staff involved with the development of the CPP will be responsible for briefing their respective CMOs and ministers and advocating for its approval
Development of the implementation plan	September 2010	TECHPHARM	
Support for collaborative activities among schools in providing technical assistance/collaboration	December 2010	TECHPHARM	
Identification of financial support, submission of proposals for financing of sub-regional structures		TECHPHARM	

