Evidence-based development of the Caribbean Pharmaceutical Policy

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Abstract Health is a human Right. Access to essential medicines, is a prerequisite for realizing that right. Facing challenges for ensuring sustained access quality medicines at affordable prices, CARICOM Ministers of Health, in 2004, established the Technical Advisory Group (TAG) on the matter.

The objective of this paper is to describe the development of the Caribbean Pharmaceutical Policy (CPP) and present its content. Due its extent, only the medicines regulation part is detailed.

The Regional Assessment on medicines regulation and Patent and Related Issues in CARICOM and Dominican Republic and the Pharmaceutical Situation in the Caribbean, provided evidence for the development of the CPP. Caribbean Cooperation in Health III is the main political framework.

Based on the main problems identified, such as the challenges to ensure safety and quality of medicines provided and high expenditure, TAG prepared the CPP and submitted it to stakeholder's consultations and approval. The CPP and its governance and implementation mechanisms were approved

by the 21st COHSOD in April 2011 for guiding Caribbean countries to ensure: access, quality and rational use of medicines. It is a framework for collaborative action and strengthening of national policies.

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Keywords: Caribbean, Caribbean Cooperation in Health, Pharmaceutical Policies

Introduction

Health is a human Right. Access to health care, which includes access to essential medicines, is a prerequisite for realizing that right[i]. It is part of the governance and steering role of the state to ensure the fulfilment of its right. Medicines, vaccines and technologies are one of the six building blocks of the well-functioning health systems, proposed by WHO[ii].

Access to medicines is guaranteed through the development and implementation of pharmaceutical policies, integrated with health policies, addressing primary determinants in product selection, pricing and financing, as well as regulation, organization of the provision system and rational use[iii].

In order to be beneficial, medicines need to be safe, effective and of quality - otherwise funds will be wasted, the populations' health will be put at risk and confidence in the health systems can be jeopardized. National medicines expenditure, as a proportion of total health expenditure, currently ranges from 7% to 66% worldwide. The proportion is higher in developing countries (24%-66%) than in developed countries (7%-30%)[iv].

The Caribbean Community (CARICOM)[13] was established in 1972[v]. The Principal Organs are The Conference of Heads of Government (and its Bureau) and The Community Council of Ministers (The Community Council). They are assisted by four 'Organs', including The Council for Human and Social Development (COHSOD)[vi]. Subjected to the provisions of Article 12 (Functions and Powers of the Conference) of the Revised Treaty of Chaguaramas, COHSOD shall be responsible for the promotion of human and social development in the Community. The mandate of COHSOD includes*: "promote the improvement of health, including the development and organisation of efficient and affordable health services in the Community"*[vii]. The CARICOM Ministers responsible for Health also have a Caucus, just before the PAHO/WHO Directive Council. In

[13] CARICOM comprises 15 Country Members, namely: Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica , Montserrat, Saint Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname and Trinidad and Tobago and five Associate Members: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands.

Health issues, the COHSOD is assisted by the Chief Medical Officers, who meet periodically prior to the COHSOD meetings.

Faced with an HIV/AIDS epidemic, an increasing burden of non-communicable chronic diseases which require sustained access to adequate quality medicines at affordable prices, Ministers of Health, at the 10th Meeting of the Council for Human and Social Development (COHSOD), in April 2004, established the Technical Advisory Group (TAG) on Trade Related Intellectual Property Rights. A "Regional Assessment of Drug Regulatory and Registration Systems" [viii] and a "Regional Assessment on Patent and Related Issues and Access to Medicines"[ix] in the CARICOM countries and Dominican Republic by Health Research for Action (HERA) were commissioned by CARICOM Secretariat as part of the mandate of the TAG, financed by PANCAP/World Bank with Technical Support of PAHO/WHO. Besides these studies, PAHO/WHO published the "Pharmaceutical Situation in the Caribbean Countries"[x] – as summary of the answers of the WHO Level I Survey (structure and process) in 2007, of 13 participating Caribbean countries.

The Caribbean Pharmaceutical Policy was developed based on the findings of the abovementioned studies and framed by the international and regional mandates, including the Caribbean Cooperation in Health III (CCH III)[xi], Port of Spain Declaration[xii] and the PAHO/WHO Sub-regional Cooperation Strategy for the Caribbean: 2010-2015[xiii]. The CCH III represents a mechanism to unite Caribbean Nations in a common goal to improve health and wellbeing, as well as develop the productive potentials of the people. It comprises of eight priorities, amongst which Health Systems Strengthening, for responding effectively to the needs of the Caribbean People, that includes the access to safe, affordable and effective medicines. 'Support 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.

Objective

The objective of this paper is to describe the development of the Caribbean Pharmaceutical Policy (CPP).

Methodology

This is a descriptive study of the Caribbean Pharmaceutical Policy (CPP) development. The main reference for its process was the use of the guideline developed by WHO[3]. The results are presented in terms of process and content of the CPP. Due to its extent, only the part related to medicines regulation is presented in detail.

The process included the development of a Policy Paper, a preparation of a draft document, which was submitted for consultation to the different stakeholders and presented for approval to the Policy Making organs of CARICOM.

Results

In the results, the process of development and the content of the policy are presented. The CPP is based on the problems identified and priority proposed by the three abovementioned surveys.

Problems identified and priorities established

The main problems in the sector identified in the Caribbean include the deficiency or lack of mechanisms to ensure the safety and quality of the medicines provided to the population besides the high expenditure, approximately US$ 20 per capita/year compared with the region of the Americas of US$ 10 per capita/year.

According to PAHO/WHO (1), in 2003, only four countries mentioned that they had legal provisions for a Medicines Regulatory Authority (MRA) and the establishment of a MRA. In 2007, this number had increased to eleven (85%). According to the CARICOM report on Drug Regulatory Assessment, none of the existing legislations is fully comprehensive. Even though progress can be observed with regards to several individual components of the regulatory structure, it is a priority to strengthen the institutional capacity of MRAs, in particular, their technical capacity. This is important to ensure performance of several essential functions of medicines regulation, such as registration or marketing authorization (MA), inspection and licensing of facilities and personnel and marketing surveillance and Pharmacovigilance. In this regard, a sub-regional regulatory framework and a Network among the MRAs for improving harmonization and integration efforts as well as collaboration among them are proposed.

According to the CARICOM report (2), seven of the countries under study have privately owned pharmaceutical manufacturing plants producing multi-source (generic) products only, with export capacity in four of these countries. Private sector pharmaceutical importers and/or wholesalers are operating in 14 of the 16 countries, while all countries under study have private retail pharmacies (ranging from 1 in Montserrat to 2,812 in the Dominican Republic). It is necessary to establish a comprehensive regulatory framework considering this multitude of stakeholders and actors.

Development Process

1. Policy Paper:

The Policy Paper was developed including: a) A *situation analysis* based on the review of existing international recommendations, mandates, health context and identification of main issues in the pharmaceutical sector based on the abovementioned exploratory studies, including two surveys commissioned by CARICOM and the one developed by PAHO/WHO; b) the *Policy Outline* with the proposed structure and content; c) the *governance mechanisms*, with responsibilities, technical and financial viability. The Policy Paper was presented and approved during the 18th Meeting of the CMOs held in Port-of-Spain, Trinidad and Tobago from April 19th to 20th, 2010.

2. Consultation with Stakeholders:

Development of a draft Caribbean Pharmaceutical Policy (1st version) submitted to stakeholders' consultation during the Workshop, held in Barbados, July 6th – 7th 2010. After consolidation of contributions, it was circulated to CARICOM countries and Dominican Republic for another review, systematization of contributions and issuing of a second version (August/September -2010). The document was again circulated to CARICOM countries and Dominican Republic and the sub-regional institutions for a final review, systematization of contributions and issuing of a third version (November/2010 to January/2011);

3. Submission to Ministers of Health for approval

The 2nd draft Policy document was presented to the 19th CAUCUS of CARICOM Ministers

responsible for Health, who referred to the 21st COHSOD for a decision. The 3rd version of the Policy and the governing mechanisms were approved in principle by the 19th CMOs Meeting and approved by 21th COHSOD (Health) in April 2011.

The Policy

The CPP goal is: "To guide Caribbean countries to ensure: access, quality and rational use. It is guided by the main principle of access to medicines as a Human Right, the values and principles of Public Health and the renewed Primary Health Care strategy. The seven objectives are organized in the following strategic areas: Pharmaceutical Policy Scope; Regulatory Framework; Access; and Rational Use of Medicines.

Mechanisms for Implementation: An implementation plan is under development with indicators for monitoring and evaluation. It is proposed an oversight mechanism with the Expanded Technical Advisory Group on Pharmaceutical Policy (TECHPHARM), with shared responsibilities with the national authorities and regional institutions, CARICOM Secretariat and PAHO/WHO.

Conclusions

The CPP was developed using the existing evidence and it represents the necessary framework for collaborative action and includes the development of several networks and regional platforms of work that are already under development. Considering that most of the Caribbean countries are Small Islands Developing States and there are several constraints for development of the activities on their own, there is willingness for collaboration expressed at both the technical and political levels that can facilitate the CPP implementation.

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