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Regionalization as an approach to regulatory systems strengthening: a case study in CARICOM member states

Charles Preston,[1] *Harinder S. Chahal,*[2] *Analia Porrás,*[1] *Lucette Cargill,*[3] *Maryam Hinds,*[4] *Babatunde Olowokure,*[5] *Rudolph Cummings,*[6] *and James Hospedales*[5]

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ABSTRACT *Improving basic capacities for regulation of medicines and health technologies through regulatory systems strengthening is particularly challenging in resource-constrained settings. "Regionalization"—an approach in which countries with common histories, cultural values, languages, and economic conditions work together to establish more efficient systems—may be one answer. This report describes the Caribbean Regulatory System (CRS), a regionalization initiative being implemented in the mostly small countries of the Caribbean Community and Common Market (CARICOM). This initiative is an innovative effort to strengthen regulatory systems in the Caribbean, where capacity is limited compared to other subregions of the Americas. The initiative's concept and design includes a number of features and steps intended to enhance sustainability in resource-constrained contexts. The latter include 1) leveraging existing platforms for centralized cooperation, governance, and infrastructure; 2) strengthening regulatory capacities with the largest potential public health impact; 3) incorporating policies that promote reliance on reference authorities; 4) changing the system to encourage industry to market their products in CARICOM (e.g., using a centralized portal of entry to reduce regulatory burdens); and 5) building human resource capacity. If implemented properly, the CRS will be self-sustaining through user fees. The experience and lessons learned thus far in implementing this initiative, described in this report, can serve as a case study for the development of similar regulatory strengthening initiatives in resource-constrained environments.*

Key words International cooperation; legislation, pharmacy; Barbados; Guyana; Jamaica; Trinidad and Tobago; West Indies.

Current worldwide efforts to strengthen basic capacities for regulating medicines and health technologies are an important trend in the field of health systems strengthening. For example, at the 2014 World Health Assembly (WHA), World Health Organization (WHO) member states adopted a resolution on regulatory systems strengthening (1) in response to a dizzying array of new regulatory challenges. These include the globalization of manufacturing and supply chains, the threats posed by falsified and substandard medicines (FSMs), worsening antimicrobial resistance, and the need for governments to increase access to essential medicines, among others.

[1] Pan American Health Organization, Washington, District of Columbia, United States of America. Send correspondence to: charlesmarshallpreston@gmail.com
[2] Department of Clinical Pharmacy, University of California, San Francisco, California, United States of America.
[3] Caribbean Public Health Agency, Kingston, Jamaica.
[4] Barbados Drug Service, Bridgetown, Barbados.
[5] Caribbean Public Health Agency, Port of Spain, Trinidad and Tobago.
[6] Caribbean Community and Common Market, Georgetown, Guyana.

Resource[7]-constrained countries face particular difficulties in strengthening their regulatory systems. In some countries, a regulatory system may consist of only a small number of people and may not perform all recommended functions. In contrast, well-resourced systems might employ thousands of staff and carry out all functions on their own (3). A central question for many is how to build and establish systems with basic regulatory capacities that meet public health needs and at the same time ensure their sustainability.

Regionalization may be one answer. A regionalized approach is one in which regional entities (e.g., countries or organizations) with similar characteristics (e.g., histories, cultural values, languages, economic conditions, etc.) combine their resources, harmonize disparate rules and processes, and/or rely on and share common information and policies to establish a collective regulatory system that is stronger and more efficient than what would be feasible individually. The world is beginning to coalesce around this approach, as reflected in WHA resolution 67.20 (2014), which urges member countries to engage in regional networks and cites "the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious, and affordable medical products" (1). The East Africa Community (EAC) African Medicines Regulatory Harmonisation Programme (AMRH) (4) and regional initiatives in Southeast Asia (5) are some examples of these efforts. Regional regulatory approaches are also used in the European Union and Gulf Cooperation Council, but many of the nations involved in those initiatives are high-income and thus have a different purpose and resource context than resource-constrained settings (6, 7).

This report describes the Caribbean Regulatory System (CRS)—a regionalization initiative currently being implemented in the mostly small countries of the Caribbean Community and Common Market (CARICOM) (8). To the best of the authors' knowledge this research is the first to document the CRS concept and design and thus can serve as a case study for the development of similar regulatory strengthening initiatives in resource-constrained environments.

Status of regulatory capacity in CARICOM

Strong regulatory systems for medicine and health technology improve public health because they ensure safe, high-quality, and efficacious products for consumers. These checks and balances are established through the implementation of various processes, including granting marketing authorization, inspecting manufacturing facilities, monitoring adverse events, sampling products at borders, tracking products in the supply chain, and overseeing elements of clinical trial activity. However, delays or "bottlenecks" in these regulatory processes due to a lack of resources or other causes can diminish or eliminate the system's efficiency or objectives (e.g., a backlog of products for marketing authorization could result in decreased access to life-saving therapies) or even cause harm to health. For example, the failure of medical product regulatory systems to provide strong oversight and enforcement can result in death or injury. Three examples of the latter outcome include 1) antimalarial drugs in West and Central Africa in which only 2% of the ingredients were active, 2) contaminated cardiac medicine in South Asia that caused more than 200 deaths, and 3) the failure of quality control in acetaminophen production in Haiti (9–11). These types of problems tend to affect systems that are underdeveloped. According to WHO, only about 20% of its member countries have a well-functioning regulatory authority, while 50% have variable regulatory quality, and 30% have very limited or no capacity at all (12).

The Americas region is trying to address these gaps through regulatory systems strengthening efforts. Although much progress has been made, significant challenges remain. Along with other stakeholders, the regional office of WHO for the Americas, the Pan American Health Organization (PAHO), has developed key capacity-building initiatives for its member countries, including the National Regulatory Authorities of Regional Reference (NRAs/RR), as mandated by PAHO Directing Council resolution CD50.R9 (Strengthening National Regulatory Authorities for Medicines and Biologicals), and the Pan American Network for Drug Regulatory Harmonization (PANDRH) (13). PAHO has also developed a set of 20 basic indicators for regulatory capacity. Analysis of basic indicator data shows that much of the region (Central America and Latin Caribbean, North America, and South America subregions) has achieved 90% or more of them (Figure 1) (14).

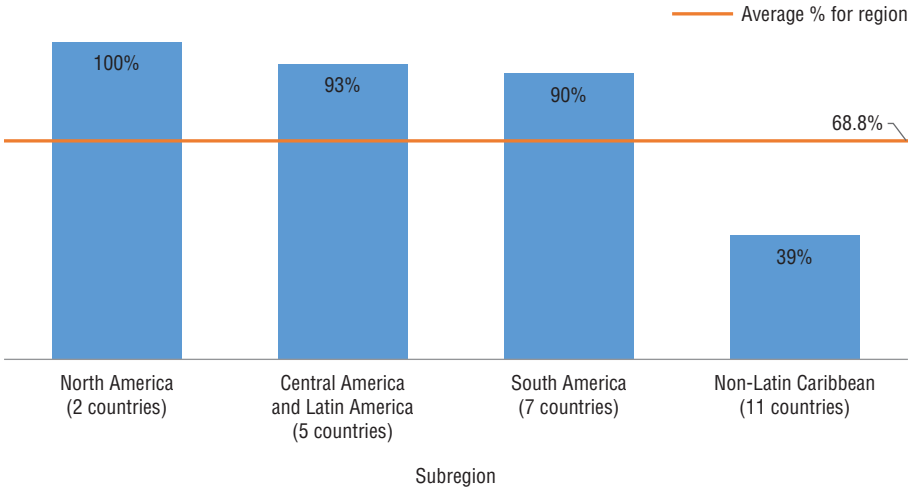
However, the Non-Latin Caribbean lags significantly behind in this capacity (14), having only implemented 39% of the basic indicators (Figure 1) (14). Specifically, basic indicator data show poor capacity in core functions, including marketing authorization, pharmacovigilance, and post-market surveillance, among other areas (Table 1). For example, only 55% have a legal provision requiring marketing authorization of pharmaceutical products (also known as "registration"), and an internal PAHO analysis found that full implementation of marketing authorization procedures for generic medicines ranges from 0 to 25% in some Caribbean countries.[8] In addition, only 27% have legal provisions that provide for pharmacovigilance activities as part of the NRA mandate, and only 36% have a database of adverse drug reactions (for post-market surveillance). None of the countries surveyed have a crisis communication strategy to respond to regulatory emergencies.

The reasons for low regulatory capacity in CARICOM are complex, but resource constraints likely play a significant role. CARICOM member states' populations are some of the smallest in the world; six of the independent countries have less than 250 000 people, and 10 have less than 1 million people (15). Their economies are also relatively small. Although the gross national income (GNI) per capita measure places five member states in the high-income category, the largest GNI in CARICOM—that of Trinidad and Tobago—is 107th out of the 214 economies ranked by the World Bank (16). In addition to the high-income countries, CARICOM has seven upper-middle-income countries, one lower- middle-income country, and one low-income country (15). Restricted health spending may also be a reason for low regulatory capacity. Data from WHO show that average national spending on health in CARICOM countries is more

[7] The World Bank defines resources as "the machines, workers, money, land, raw materials, and other things that a country can use to produce goods and services and to make its economy grow" (2).

[8] Morais Vicente Lima J. Marketing authorization (registration) of medicines—a comparison study conducted in the Caribbean. Unpublished report. Washington: PAHO; 2013.

FIGURE 1. Average % of each of the 20 PAHO[a] basic indicators for regulatory capacity achieved by 25 selected countries, by subregion, Americas region, 2014



Source: Data from (14).
[a] PAHO: Pan American Health Organization.

TABLE 1. Average percentage (%) of each of the 20 PAHO[a] basic indicators for regulatory capacity achieved across CARICOM[b] member states,[c] Caribbean region, 2014

Basic regulatory indicator	Average % achieved
1. Legal provisions establish the functions/responsibilities of the National Regulatory Authorities (NRAs)	64
2. The NRA has a website	27
3. The NRA participates in harmonization/collaboration initiatives	91
4. The NRA uses a digital information management system to keep and recover all information related to product licensing, registration, inspections, etc.	36
5. Legal provisions require marketing authorization (registration) for all pharmaceutical products sold	55
6. Legal provisions require the NRA to make information about registered pharmaceutical products publicly available with defined periodicity	18
7. Legal provisions require publication of the Summaries of Product Characteristics (SPCs) of registered pharmaceuticals	0
8. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	82
9. Local manufacturers are inspected to supervise the implementation of good manufacturing practices (GMPs)	36
10. Legal provisions require authorization to import medicines	73
11. Legal provisions allow the sampling of imported products for testing	64
12. Legal provisions require manufacturers to be licensed	73
13. Legal provisions exist for controlling the pharmaceutical market	45
14. A laboratory exists in the country for quality control testing	36
15. Legal provisions require NRA authorization for clinical trials	0
16. Legal provisions require the approval of an ethics committee/institutional review board for the clinical trial to be performed	9
17. Legal provisions require sponsor investigator to comply with good clinical practices (GCPs)	0
18. Legal provisions provide for pharmacovigilance activities as part of the NRA mandate	27
19. A national adverse drug reactions (ADRs) database exists in the country	36
20. A routine and crisis communication strategy exists	0

Source: Data from (14).
[a] PAHO: Pan American Health Organization.
[b] CARICOM: Caribbean Community and Common Market.
[c] Antigua and Barbuda, Barbados, Dominica, Grenada, Guyana, Jamaica, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago.

consistent with averages for low- and middle-income countries, with an average[9] of 6.18% of gross domestic product (similar to the average for low- and middle-income countries of 5.4% and 5.8% respectively, and lower than the 12.2% average for high-income countries (15)). This may make it difficult to prioritize complex public health functions such as regulation, even though the need is great. Accordingly, national medicines regulatory authorities exist in only about half of the Caribbean countries surveyed.[10] Some CARICOM countries rely on procurement systems for quality assurance, while in others there is no regulatory control (17).

Other factors may contribute to low regulatory capacity as well. For example, there is little medicine and health technology manufacturing in CARICOM member states, and where it does exist, it is mainly focused on producing formulations and repackaging of dosage forms.[10] With low manufacturing production, countries may have fewer incentives to develop robust systems for regulation.

Policy action in response to current situation

Policy-makers in CARICOM member states have taken a number of steps to reverse the current limitations in the regulatory environment. In 2011, the minister-level policy-making body for health, the Council for Human and Social Development (COHSOD), approved the Caribbean Pharmaceutical Policy, which set the goal of implementing a regional framework for medicines regulation (18). Progress has been steady and includes the 2013 multi-stakeholder–authored "road map" to develop the CRS.[11] The road map proposed operationalizing the CRS as a regulatory unit in CARICOM's regional public health agency, the Caribbean Public Health Agency (CARPHA). It also called for the CRS to concentrate its initial efforts on registration[12] of

[9] Does not include Montserrat (an overseas British territory) because no data were available.
[10] Pan American Health Organization. Pharmaceutical situation in the Caribbean. Factbook on monitoring indicators 2011–2012. Unpublished report. Washington: PAHO; 2013.
[11] Ivama A. Sub-regional regulatory framework for medicines and health technologies: concept paper and roadmap. Unpublished report. Washington: Pan American Health Organization; 2013.
[12] From a regulatory standpoint, the term "registration" is synonymous with "marketing authorization," but only a sovereign country can authorize products for marketing. Therefore the CRS can only "register" products.

generic medicines from WHO's Essential Medicines List (EML), and clarified that the CRS will not replace regulatory authorities but will provide an overarching layer of support to respond to the highest-priority regional regulatory needs. A follow-on study examined the various ways a centralized system could undertake registration, including making registration recommendations to member states that can then be taken up as marketing authorizations.[8] Subsequent consultations of stakeholders, including the committee of technical representatives created to oversee implementation of the pharmaceutical policy (known as TECHPHARM), finalized these recommendations, along with additional implementation principles, which culminated in COHSOD's formal approval of the CRS pilot in September 2014.

CRS pilot and discussion of important design elements

The CRS pilot is designed to address CARICOM's most important regulatory needs, and to do so in resource-constrained contexts like those found in the small and very small member states that do not permit each one to have a full regulatory system. In broad terms, the CRS concept leverages existing platforms for centralized cooperation, governance, and infrastructure; prioritizes the strengthening of the regulatory capacities that are expected to have the largest public health impact; enhances efficiencies that will enable a sustainable enterprise, including the incorporation of policies related to reliance on reference authorities; incentivizes industry to market their products in CARICOM; and at the same time builds human resource regulatory capacity in the region. Specifically, the CRS pilot proposes that a small number of staff 1) be organized as a regulatory unit at CARPHA headquarters in Trinidad and Tobago and 2) conduct abbreviated registrations of priority generic medicines. These registrations will then be recommended to the member states. The CRS will only register medicines that have already been approved by one or more PAHO-assessed NRAs/RR[13] and/or the European Medicines Agency (EMA). CRS staff will be mentored by NRA/RR employees. The pilot will also focus on implementing any necessary legal or policy frameworks to facilitate rapid marketing authorization of CRS recommendations in member states. These policy choices are discussed in more detail below.

Organizational structure: CARICOM and CARPHA as centralized platforms for cooperation, governance, and infrastructure

The CRS organizational structure includes a number of features intended to increase regulatory efficiencies in a resource-constrained environment. In many instances, they are similar to those of regional initiatives elsewhere in the world. For example, one common feature of both the CRS and the AMRH is that both are centered in regional economic communities. The resulting groups of nations tend to have similar economic, political, and social interests and are thus well primed for regulatory cooperation. These economic communities also typically have systems for governance, as CARICOM does. CARPHA was chosen to house the CRS for a number of reasons, including the fact that it has a regional public health mandate as well as the infrastructure and broad public health expertise to provide in-kind support to a regulatory unit. CARPHA is the amalgamation of five previously existing regional health institutions, including the Caribbean Regional Drug Testing Laboratory in Jamaica, and is headquartered in Trinidad and Tobago. It has a staff of approximately 104 people and its budget is primarily derived from annual quota contributions paid by member states, supplemented by grants and projects from regional and international development partners. CARPHA also has experience leveraging benefits of the regional concept in other areas of public health, including shared reference laboratory services in CARPHA; shared outbreak investigation team capacity; shared training; and shared subregional surveillance.

The choice to dedicate full-time staff to a regulatory unit in CARPHA is also consequential because it could help improve continuity and timeliness of regulatory processes. This is in contrast to other regional initiatives, where groups of national regulators are convened to review applications on a periodic basis. The risk of the latter type of design is that the regulatory process can become cumbersome and slow, as travel and other logistics must be coordinated for multiple individuals with competing responsibilities, and this may affect how many decisions can be made and the pace of the decision-making.[14]

Operational focus: registration of priority generic medicines already approved by a reference authority

The policy decision to focus CRS activities on registration fulfills both public health and efficiency considerations. In its guidance to countries on how to develop regulatory functions, WHO states that "the first duty of a … regulatory authority is to register pharmaceutical products, thus defining the pharmaceutical market in the country" (19). The registration phase provides a public health benefit because it ensures the safety, quality, and efficacy of a given product through a dossier review (a review of the clinical and quality information submitted by a company). It also provides an efficiency benefit because it is a regulatory function that can be accomplished through reliance on the work of reference authorities, such as NRAs/RR. Using their work means the dossier review can be abbreviated, as much of the review would not need repeating unless it relates to local context specific information, such as how product stability is affected by tropical climates. The corresponding decrease in staff and time resources required can enable a shift of attention to other regulatory priorities, including those functions that are not as easily leveraged, such as monitoring products for adverse events in local markets (i.e., pharmacovigilance and post-market surveillance).

The policy decision to focus on registration of generic medicines has a public health and efficiency rationale

[13] Those in Argentina, Brazil, Canada, Colombia, Cuba, Mexico, and the United States.

[14] Al-Rubaie MH. Evaluation of the regulatory review process of the GCC Centralised Procedure: development of a model for improving the approval process [unpublished thesis]. Cardiff: Cardiff University; 2013. Available from: http://orca.cf.ac.uk/58554/

as well. Generic medicines increase competition among manufacturers, causing prices to decrease, and in turn, improving access. From an efficiency standpoint, generic medicines are less complex to review than new chemical entities, and thus require fewer resources (e.g., in staffing and technical knowledge). Much of the required regulatory science is evaluation of bioequivalence (assessing the generic product for its similarity to the reference product). Regulatory work for new chemical entities, including the evaluation of animal and clinical trials data, is not needed because it has already been done for the reference product. For these reasons, in part, and with some exceptions, WHO recommends that resource-constrained settings do not register new chemical entities (19).

The policy decision to refine the CRS focus to priority medicines is also rooted in public health and efficiency principles. Stakeholders have identified noncommunicable disease (NCD) medicines as high-priority, consistent with a regional political commitment known as the Port of Spain Declaration (20). To develop the actual list of priority medicines, the CRS will survey CARICOM member states on a periodic basis and request that they consider burden of disease, availability, affordability, and any regulatory challenges for products, such as shortages or backlogs. The WHO EML will be used as a starting point because it factors in the minimum medicine needs for a basic health care system, including current and future public health relevance, as well as the potential for safe and cost-effective treatment (21). Other medicines eligible for the CRS priority list will include those prequalified by WHO, which targets HIV, TB, malaria, and reproductive health. From an efficiency standpoint, use of a priority medicines list will ensure that the regulatory resources available via the CRS are allocated to only the highest-priority medicine needs of CARICOM.

Sustainability: incentivizing industry to pay user fees and building a professional regulatory workforce

One of the most important promises of the CRS is that it will be self-sustainable, and many of the policy efficiencies discussed above should help it achieve this goal. However, irrespective of the system's efficiency, some resources will be required. The dedicated staffing model chosen by the CRS will require financing for technical officers. However, CARPHA does not have the budgetary flexibility to pay these additional staff. Therefore, alternative financing models must be considered. One commonly used approach is assessing user fees (fees paid by a company for the regulatory review of the application required to market a given product). In order for the schema to work, the applicant must have an incentive to pay the fee. The CRS is designed with this purpose in mind. Because the CRS will be centrally located and will make registration recommendations to all CARICOM member states, industry can use it as single point of entry to CARICOM's markets, which have a combined population of approximately 17.5 million people. The success of this model will depend on the establishment of policy and legal frameworks to facilitate rapid uptake of CRS registrations as marketing authorizations in the member states, and efforts are under way to establish CARPHA's legal authority. The user fee structure should be designed to cover the costs of staff at CARPHA and include mechanisms that ensure reliable funding streams if application numbers vary from year to year. In the meantime (before the user fee system is up and running), financing will be required to capitalize the initiative.

The sustainability of the CRS also depends on the teamwork and collaboration of key stakeholders, including CARICOM and CARPHA, in the implementing roles, and PAHO, in the technical support role. External partners are essential for CRS success as well, in their provision of financing and in-kind support, as well as training and mentorship. Various NRAs/RR from Argentina, Brazil, Canada, Colombia, Cuba, Mexico, and the United States have already provided support, or have pledged to do so in the future. Some of the NRAs/RR have committed to making technical staff available to train and mentor CRS personnel, and to guide them through the abbreviated registration procedure. This will help provide a solution to the important problem of how to ensure technical competency of employees, which research has shown to be a key challenge in resource-constrained settings (3). In addition to mentorship by reference authorities, regulators could benefit from education and training in core competencies (3). PAHO/WHO are currently in the process of developing a fundamental set of competencies and curricula for regulators that the CRS can leverage. Related issues, such as recruitment and retention of staff, could potentially be addressed by forming partnerships with local schools of pharmacy, which could help chart career paths for future regulatory professionals.

Monitoring and evaluation

PAHO's 20 basic indicators for regulatory capacity can be used to benchmark improvements in CARICOM's regulatory environment. Although the indicators were designed for a single national authority rather than a regional system, they can be adapted to the regional context. The adaptation process for a number of the indicators will be carried out as the CRS further establishes its own legal status, begins to register products, and implements a pharmacovigilance and post-market surveillance system. However, some of the indicators (e.g., those for inspection and those related to the clinical trials) are beyond the scope of the initiative's current concept and design. Therefore, stakeholders estimate the CRS can help CARICOM achieve 70% of PAHO's 20 basic regulatory capacity indicators—a level of achievement that would almost double the current regulatory capacity.

Feasibility of exporting CRS model elsewhere

The CRS case study can serve as a model for other parts of the world considering regionalized approach to strengthening regulatory systems. One lesson learned from CARICOM experience is that regionalization initiatives are complex. The CRS pilot builds on years of work by a diverse group of participants who have 1) gathered evidence on regulatory capacity challenges, 2) developed and implemented pharmaceutical policies conducive to initiative goals, 3) leveraged existing platforms of CARICOM and CARPHA, and 4) obtained political agreement on an implementation plan. Thinking by PAHO/WHO on how to establish regulatory systems in resource-constrained settings has also been critical, because it

helped to provide a rationale for prioritization of basic regulatory functions (22, 23). Other groups of nations contemplating regional initiatives should consider how key features of the CRS example might be applicable to their context.

Conclusions

The minister-level decision to pilot the CRS is the result of a confluence of factors giving rise to the use of regionalization as an approach to strengthen regulatory systems in resource-constrained environments. Although data are needed to validate the CRS' outcomes, multiple benefits are anticipated, including: 1) improved access to safe, effective, and high-quality essential medicines; 2) improved market control of these products; 3) improved efficiencies in allocation of resources to regulatory activities; 4) reduced regulatory burdens for industry; and 5) improved human resource capacity in regulation. In short, the strengthened regulatory environment will be better for people, governments, and businesses. However, meeting the needs of this improved environment (developing a robust regulatory workforce, establishing appropriate legal and policy frameworks between the CRS and CARICOM member states, and securing financial sustainability) will be challenging. Nevertheless, stakeholders will move forward because there is great desire to bring stronger and more efficient regulation to CARICOM. Lessons learned from this case study may encourage other regions facing similar challenges to consider a regional approach as well.

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RESUMEN

La regionalización como medio para fortalecer los sistemas de reglamentación: estudio de caso en los estados miembros del CARICOM

El mejoramiento de la capacidad básica para la reglamentación farmacológica mediante el fortalecimiento de los sistemas de reglamentación plantea un reto especialmente difícil en contextos de escasos recursos. Una posible solución radica en la "regionalización", proceso según el cual países con un mismo legado histórico, cultural y lingüístico y con situaciones económicas semejantes colaboran entre sí con objeto de establecer sistemas más eficientes. En el presente informe se describe el Sistema de Reglamentación del Caribe (SRC), iniciativa de regionalización que se está poniendo en marcha en los países de la Comunidad y el Mercado Común del Caribe (CARICOM), pequeños en su mayoría. La iniciativa representa una medida innovadora por fortalecer los sistemas de reglamentación en el Caribe, donde la capacidad existente es más modesta que en otras subregiones de las Américas. En el concepto y diseño de la iniciativa hay elementos y pasos destinados a fomentar la sostenibilidad en contextos de escasos recursos. Estos consisten en aprovechar las plataformas ya existentes para la cooperación, gobernación e infraestructura centralizadas; fortalecer las capacidades de reglamentación que puedan tener la mayor incidencia sobre la salud pública; incorporar políticas que fomenten la confianza en los organismos de reglamentación; modificar el sistema para alentar a la industria a comercializar sus productos en el CARICOM (por ejemplo, utilizando un punto de entrada centralizado para aligerar las cargas reglamentarias); y fortalecer la capacidad en materia de recursos humanos. Si se pone en práctica adecuadamente, el SRC se financiará a sí mismo con las cuotas de los usuarios. La experiencia y las enseñanzas extraídas hasta el momento con la puesta en marcha de esta iniciativa, que se describen en el presente informe, pueden ser útiles como estudio de caso para la formulación de iniciativas afines orientadas a fortalecer la capacidad de reglamentación en entornos de pocos recursos.

Palabras clave Cooperación internacional; legislación farmacéutica; Barbados; Guyana; Jamaica; Trinidad y Tobago; Indias Occidentales.