RESEARCH REPORT

"Mapping of the Productive Capacity of Medicines; Medicines Policies of Regional Blocs: UNASUR, MERCOSUR, CAN, CARICOM and ALBA, and mapping of bilateral cooperation in production and/or purchase of medicines in countries of South America"

Consultant Researcher: Thiago Botelho Azeredo

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Instituto Suramericano de Gobierno en Salud
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Rio de Janeiro

May 2014

UNASUR iSAGS Instituto Suramericano de Gobierno en Salud

UNASUR Unión de Naciones Suramericanas

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Research report on the "Mapping of the Productive Capacity of Medicines; Medicines Policies of Regional Blocs: UNASUR, MERCOSUR, CAN, CARICOM and ALBA, and mapping of bilateral cooperation in production and/ or purchase of medicines in countries of South America"

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The opinions expressed in this document are those of the author and do not necessarily reflect the official policy or position of the Organization.

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Summary

Background 6
Justification 7
Introduction 9
Objectives 10
General Objective 10
Specific Objectives 10
Scope and focus of the research 10
Methodology 11
Results and Discussion 12
Medicines Policies of the Blocs 12
Member countries and document signatories of the Blocs 12
Stated objectives and main strategies 14
Bilateral cooperation 21
Limitations of the study 24
Final Considerations 25
Bibliography 26

Tables and Matrices

Table 1. Signatory countries of selected documents 12

Table 2. Components of a NMP according to the WHO and their link to key policy objectives 14

Table 3. Objectives stated on Medicines Policy Documents 15

Table 4. Strategic areas covered: contents and main guidelines 17

Matrix Table 1. Number of cooperation agreements/project according to countries that provided information on cooperation and respective cooperating countries 21

Matrix Table 2. Number of cooperation agreements/projects according to countries that provided information on cooperation and area of cooperation 23

Annexes

Annex 1 – Information on bilateral cooperation obtained from websites of cooperation agencies 28

BRAZIL → 15 projects 28

ARGENTINA→ 8 projects 34

URUGUAY → 6 projects 36

CHILE → 6 projects 38

Annex 2 – Information on bilateral cooperation on medicines as per the REDESUR-ORIS map. 39

Background

The project entitled "Mapping of the Productive Capacity of Medicines and Health Supplies – medicines policies of Regional Blocs: Union of South American Nations (UNASUR), Southern Common Market (MERCOSUR), Andean Community (CAN), Caribbean Community (CARICOM) and Bolivarian Alliance for the Peoples of Our America (ALBA), and mapping of bilateral cooperation in production and/or purchase of medicines between countries of South America" is part of the 2013 Annual Operating Plan of the South American Institute of Government in Health (ISAGS) and of the South American Health Council's Technical Group on Universal Access to Medicines. The Health Ministers who took part in the VII Meeting of the UNASUR Health Council expressly approved both initiatives, on September 6th, 2012.

The Project foresaw three specific tasks: 1 – Mapping the productive capacity of medicines of public, including military, and privately owned laboratories (included by the Technical Group on Universal Access to Medicines); 2 – Mapping of the medicines policies of Regional Blocs such as UNASUR, MERCOSUR, CARICOM, ALBA and CAN; 3 – Mapping of bilateral cooperation on medicines.

For the sake of clarification, we inform that the undertaking of the above-mentioned Project took longer than expected and especially hindered the realization of the first task – mapping the productive capacity of public and privately owned laboratories – which, has yet to be carried out due to administrative difficulties and excessive activities of UNASUR.

This task required the 12 member countries to approve the use of resources from the Common Initiatives Fund and the subsequent financial transfer from UNASUR's General Secretariat to ISAGS.

However, the approval of the transfer of resources from the Common Initiatives Funds, required to fulfill ISAGS' 2013 Annual Operating Plan, was only officially recorded in the minutes of the 8th Health Council Meeting, held on March 20, 2014, in Suriname. Thus, only thereafter were we be able to proceed, in collaboration with the Technical Group on Access to Medicines, to conduct field research activities.

This report includes, therefore, research results from the two other tasks proposed by ISAGS' 2013 Annual Operating Plan: the mapping of the medicines policies of selected Regional Blocs such as UNASUR, MERCOSUR, CAN, CARICOM and ALBA, and the mapping of bilateral agreements in production and/or purchase of medicines in countries of South America.

Justification

The emergence of economic, social and political fluxes and mobilizations have led to the rise of new forms of territorial organization, which have sparked new discussions on regional, national and global concepts. From this scenario stem questions and reflections regarding themes whose developments have immediate repercussions and long-term regional integration processes.

The regional issue is linked not only to the tangible reality, which displays continuous contrasts and paradoxes in the form of national-cultural singularities, but also in the form of the homogenization of globalization. The regional aspect needs to be discussed on many levels: regional survival in a world of moving boundaries; bringing together individuals, policies and powers; debating regional policies, initiatives of physical integration and tackling asymmetries in integration experiences.

The main objective of this part of the research is to examine the similarities and differences between the distinct regional experiences, by presenting a diagnosis of the Regional Blocs in order to provide for a more ample debate regarding the complexity of regional issues and of medicines policies within the Blocs.

A diagnosis of the medicines policies of certain selected Regional Blocs such as UNASUR, MERCOSUR, CAN, CARICOM and ALBA – always making use of already consolidated information regarding the sub-regional progress in implementing referred scattered information to the current capacities of UNASUR member countries – may serve to enhance strategic decisions regarding medicine production and consequently improve care in health systems.

This can also help to ensure that government entities will be able to gather information to identify regional/local strategic policies to strengthen countries of the Bloc and to facilitate the decision-making process in production policies.

Understanding the building blocks of a medicines policy that enables the coordination of incentives and stimuli to advance regional productive sovereignty, to strengthen the Bloc and to produce effective, quality and safe medicines, is also part of this research.

A topic that also contributes to strengthen the Bloc is that of bilateral cooperation agreements, which can be characterized as temporary interventions destined to promote qualitative and/or structural changes in a specific socioeconomic context, be it to solve and/or minimize specific problems identified within that context, be it to explore opportunities and new paradigms of development of technical capacities of institutions or individuals. Likewise, it could be aimed at gaining technical knowledge and improving purposive action of public and private institutions, as well as developing interventions in predetermined geographical areas.

Bilateral cooperation can also serve to improve professional staff and technical infrastructure, to learn internal processes and elaborate and implement better action strategy plans, in order to improve the chances of formulating and executing public projects or projects that involve partnerships with the private sector and not the government. Thus, contributing to generate measurable impacts on social, economic, and environmental indicators, among other advances.

The above-mentioned arguments justify and emphasize the need to consolidate information on bilateral agreements and cooperation on production and/or purchase of medicines in member

countries of UNASUR, so that government entities will be able to gather information to identify regional/local strategic policies, thus strengthening the Bloc countries and facilitating political decision-making regarding the production of medicines.

It was deemed important to make use of the already consolidated information regarding the sub-regional progress in implementing referred information to the current medicine production capacities within UNASUR member countries. Thus pushing forward strategic decisions regarding the production of medicines and improving care in health systems.

Introduction

Growing concerns regarding access to medicines and their adequate use have led many so-called developing nations to formulate national policies and regulations destined to increase purchasing power, supply, safety and the rational use of medicines (RATANAWIJITRASIN et al., 2001; HOEBERT et al., 2013).

The political process linked to the pharmaceutical arena is very complex and is dominated, according Almarsdóttir e Traulsen (2006), by three political inputs: public health policies, health care policies and industrial policies. Bermudez et al. (1999) state that national medicines policies involve very complex relationships, as they incorporate different fields that can be treated as health policies, but are also related to economic, scientific, technological and industrial policies, among others.

One can ascertain that the pharmaceutical policies arena deals with (often) conflicting objectives, such as: maximizing access to medicines; ensuring the quality of medicinal products; minimizing costs related to the use of medicines and of health services; promoting the rational use of medicines through appropriate use by health professionals; safeguard jobs; ensure a strong economy, etc. For this reason, governments do not follow a single agenda, which opens the policy-making process to discussion and debate. It is worth noting that often a single policy document may contain elements that present contradictions within their definition.

The strategy of formulating a single, integrating document that would serve as a guiding framework for the different actions and initiatives in pharmaceutical policies in a country, under the name of National Medicines Policy (NMP), followed a specific trajectory. The 28th World Health Assembly (WHA), held in 1975, indicated that the World Health Organization (WHO) should support member countries in developing and implementing national medicines policies to ensure equitable access of the population to essential medicines, a recommendation subsequently reinforced in the 49th WHA (1996). In the view of the Assembly, the implementation of rational medicine use (RMU), of regulatory and quality control activities, as well as the periodic assessment of progress in these areas, are equally important.

According to a WHO document (WHO, 2006c), of the 140 countries that responded to the survey, 108 have an (official or proposed) document on a National Medicines Policy – NMP (62 of which were updated within the 10 years prior to the survey), 64 are currently implementing policy plans and 73 have their policy and implementation plans integrated into general health plans.

Regarding Latin America, surveys indicate that in 1999, of the 18 countries that responded to the question regarding NMP, only four reported having an official document, while the others reported having drafts, although six reported having implementation plans for their policies (official or proposed) (WHO, 2006b). In 2003, the scenario seems to have changed: of the 25 countries that responded to this question, 16 had NMP (nine official documents and six proposals) and 10 claimed to have implemented their policies (WHO, 2006a).

Bigdeli et al (2012) emphasize that the elaboration of intervention proposals intended to improve access to medicines, with the purpose of structuring health systems, should come from a concept of access that includes the understanding of determinants that goes beyond the strict activities of the health sector in each country. It is important to analyze international policies and activities in order to understand access to medicines. Emmerick et al (2013) point out the lack of research focusing on access to medicines in Latin America and the Caribbean that include this level of analysis.

Objectives

General Objective

Carry out the descriptive mapping of medicines policies of Regional Blocs: UNASUR, MERCOSUR, CAN, CARICOM and ALBA, and mapping of bilateral cooperation in production and/or purchase of medicines in UNASUR member countries.

Specific Objectives

1. Gathering information on the structure and history of the formation of selected Regional Blocs (UNASUR, MERCOSUR, CAN, CARICOM and ALBA), with emphasis on their performance in the Health sector to contextualize policies and agreements involving the purchase or production of medicines.
2. Mapping of normative acts approved by the official decision-making structures of such Blocs that constitute general Medicines Policies or affect the cooperation of member countries, specifically in terms of purchasing, regulation or production of medicines;
3. Mapping of documents concerning bilateral cooperation agreements on the purchase, regulation or production of medicines between countries of South America and search of projects related to such agreements;
4. Elaboration of a comparison matrix and analysis of documents of Medicines Policies within the Blocs contemplating, whenever applicable, the diagnosis of the situation regarding the policy or decision: declared objectives; themes covered; specified implementation operators or agents; decision flows or projected resources;
5. Elaboration of a decision matrix of the bilateral agreements and cooperation projects on medicines between countries of South America including: theme and object of the agreement (regulation, purchase, training of human resources, etc.); declared objective; scope and duration of the agreement.

Scope and focus of the research

The present work focused on the identification and comparative description of documents that formalize medicines policies in the above-mentioned Regional Blocs and of bilateral cooperation agreements on medicines involving UNASUR member countries. In this sense, the proposed methodological design sought to increase the chances of response regarding the existence of documents and their acquirement in order to make an analysis possible. Information about the implementation and resources available to these projects are not the focus of the study and may be included occasionally.

Information related to the main objectives of the research was obtained chiefly from primary sources – policy documents, terms of cooperation – while information on other relevant issues was obtained from secondary sources – scientific articles, reports and information available on the internet. Information on initiatives tied to the health sector were prioritized, and included information on industrial policy whenever a relevant link was determined.

Methodology

This was an exploratory, descriptive and analytical study of the normative acts that describe the South-South health cooperation activities on medicines in the Americas.

It was necessary to build a theoretic reference and historic contextualization of the existing initiatives in the region to enable the delimitation of analytical categories of interest. Thus, a search using bibliographic databases (Scielo and Medline) was performed on the following terms: South-South cooperation; health policies; regional integration; medicines (DeCS = Pharmaceutical Preparations); industrial policy; South America, UNASUR, MERCOSUR, CAN, CARICOM and ALBA; and its combinations. This is not a systematic review. To raise information relevant to the understanding of the historical formation of blocs, their performance in the health sector and finding consistent analytical categories to guide the analysis of findings, were sought review articles on the topics and authors with the highest number of publications.

In order to identify and obtain the documents of interest to the study, some strategies were employed:

1. Search of the official websites of the Regional Blocs;
2. Search of the official websites of international cooperation agencies of the countries of South America;[1, 2]
3. Search of the websites of governmental and non-governmental organizations that operate in the field;
4. Search of the Database of cooperation agreements of the International Advisory Network and of International Cooperation in Health of UNASUR's Council of Ministers – REDESSUL – ORIS.[3]

1 Websites listed by the Pan American Health organization.
Available at: <http://www.paho.org/sscoop/?page_id=1048&lang=es>

2 The report of the Ibero-American General Secretariat (SEGIB, 2012) identifies key countries that offer and receive cooperation. This identification can be used to increase the chances of finding the largest number of cooperation agreements and projects underway in the region.

3 The methodology originally proposed involved an electronic survey of a network of key informants linked to international health cooperation of the countries in the region, with the possibility of carrying out interviews. In a meeting with ISAGS research coordinators, it was determined that we should emphasize the search for publicly accessible documents on the Internet and negotiate access to that database (received in March 2014).

Results and Discussion

Medicines Policies of the Blocs

A search of the official websites of these five Regional Blocs, revealed, without exception, that they all had normative decisions related to medicines. However, only MERCOSUR, CAN and CARICOM have documents with normative decisions on Medicines Policies: 1) Agreement RMS/ Mercosur # 05/00, December 2000 – Medicines Policy of MERCOSUR (**PMM**) (MERCOSUR, 2000; Brasil, 2009); 2) Resolution REMSAA XXX/455, March 2009 – Andean Medicines Policy (**PAM**) (ORAS-CONHU, 2009); 3) Caribbean Pharmaceutical Policy (**CPP**) (PAHO, 2013). UNASUR **Resolution 9**, of 24 November 2009, of the Health Council (UNASUR, 2009) and ALBA establish an action plan for the health sector that includes two initiatives aimed at producing medicines (ALBA-TCP, s/d).

It was possible to locate and have access to digitized versions of four of these documents: PMM – MERCOSUR, PAM – CAN, Resolution 9 – UNASUR and CPP – CARICOM (listed in the document section of this report). ALBA's decision was found on the ALBA-TCP website, but the digitized document was not available – therefore, we used information from the website.

Member countries and document signatories of the Blocs

Table 1, below, displays the list of countries that were signatories of medicines policies and other normative decisions mentioned above. It becomes evident that the adherence to such policies is not necessarily restricted to countries that are members of these Blocs. Chile and Bolivia, for example, are signatories of MERCOSUR'S Medicines Policy although they are not part of the Bloc; the Andean Medicines Policy, signed by the Andean Health Organization – Hipolito Unanue (The agency of the Andean Integration System and intergovernmental body set up by the Health Ministries of Bolivia, Colombia, Chile, Ecuador, Peru and Venezuela, in order to promote health as a means for integration, develop coordinated efforts to address common problems and assist governments in ensuring the Right to Health), includes countries that are not part of the Andean Community (Chile and Venezuela); and Resolution 9 of UNASUR's Health Council does not include signatures from every member country. However, it is understood that every country has agreed to its contents.

Table 1. Signatory countries of selected documents

PMM	PAM	CPP	UNASUL Resolution 9	ALBA-TCP	# of documents signed by each country
Argentina			Argentina		2
Brazil			Brazil		2
Paraguay			Paraguay		2
Uruguay			Uruguay***		2
Bolivia*	Bolivia		Bolivia	Bolivia	4
Chile*	Chile*		Chile		3
Venezuela**	Venezuela*		Venezuela	Venezuela	4
	Colombia		Colombia		2

PMM	PAM	CPP	UNASUL Resolution 9	ALBA-TCP	# of documents signed by each country
	Ecuador		Ecuador	Ecuador	3
	Peru		Peru		2
		Suriname	Suriname***		2
		Guyana	Guyana***		2
		Dominica		Dominica	2
		Saint Vincent and the Grenadines		San Vincent and the Grenadines	2
		Antigua and Barbuda		Antigua and Barbuda	2
		Saint Lucia		Saint Lucia	2
				Cuba	1
				Nicaragua	1
		Bahamas			1
		Barbados			1
		Belize			1
		Grenada			1
		Haiti			1
		Jamaica			1
		Montserrat			1
		Saint Kitts and Nevis			1
		Trinidad and Tobago			1

*Not a member of the Bloc signing the document.
**Joined the Bloc after signing the document.
***Members of the Bloc that do not appear among the signatories of the document.
Source: Own elaboration.

It is important to highlight the existing overlaps among the signatories of the various documents. Most of the countries listed are signatories of at least two normative decisions. Venezuela and Bolivia signed four of five documents, while Chile and Ecuador adhered to three. Almost half of the PMM signatories are also signatories to PAM, and all signatories that signed at least one of these two documents are members of UNASUR.

By bringing together South American countries, UNASUR intersects with the other Blocs surveyed and may lead to closer ties between members of MERCOSUR and CAN with CARICOM, as it already includes two members from that community of nations. On the other hand, ALBA could represent another means of Caribbean – South American medicines integration, by bringing together different countries of the Caribbean and South American countries that signed the most Multilateral Medicines Policies in the region.

Stated objectives and main strategies

As described earlier, three (MERCOSUR, CAN and CARICOM) of the five Blocs analyzed have a National Medicines Policy formally laid out in a single document (PMM, PAM and CPP).

An important point regarding the WHO proposal on the adoption of a Medicines Policy is that such a document should constitute a complete and coherent integration framework. Furthermore, the document should balance the different goals and objectives of each participant and allow them to perform a specific role in order to achieve one or more of the policies' general objectives (OMS, 2002). Hoebert et al (2013) point out that the lack of a general integrating framework for medicines policies is unsatisfactory from a public health perspective, as the dispersion of objectives and strategic action plans through different normative acts result in policies that are often contradictory or self-defeating. Table 2 below summarizes the distinct components recommended by the WHO for medicines policies and their correlation with proposed general objectives.

Table 2. Components of a NMP according to the WHO and their link to key policy objectives

Components	Objectives		
	Access	Quality	Rational Use
Selection of essential medicines	X	(X)	X
Affordability	X		
Financing of medicines	X		
Supply Systems	X		(X)
Regulation and quality assurance		X	X
Rational Use			X
Research	X	X	X
Human Resources	X	X	X
Monitoring and evaluation	X	X	X

X = direct link; (X) = indirect link.
Source: WHO (2002).

The objectives stated in the three National Medicines Policies analyzed are described in Table 3 (page 15). The table includes the following three topics: ensuring equitable access to medicines, especially to those deemed essential in responding to the health needs of the population; ensuring quality, safety and efficacy of medicines in circulation; and promoting the rational use of medicines. Additionally, PMM and PAM include as a stated objective the selective promotion and fostering of the pharmaceutical sector in order to meet the health needs of the population of member-countries.

Resolution 09/2009 of UNASUR's Health Council (UNASUR, 2009) does not explicitly establish an individual goal per se. However, it includes in its considerations the fact that medicines are essential for enabling the human right to health and the need to develop a productive health complex in order to meet the demands of National Health Systems.

ALBA has among its founding documents, a general agreement on principles and commitments (ALBA-TCP - *Alianza Bolivariana para los Pueblos de Nuestra America – Tratado de Comercio de los Pueblos*) related to the construction of the bloc, which includes a trade

treaty involving member countries. As part of the actions delineated for regional integration, the agreement foresees the establishment of supranational (*grannacionais*) companies in several areas considered strategic for regional development. With respect to medicines, it proposes the creation of a distribution company that should supply 25% of the demand of member-countries, according to their public health needs. Additionally, a regulatory agency should be instituted to guarantee the quality, efficacy and safety of the products manufactured by the supranational (*grannacional*) medicines distribution company.

Table 3. Objectives stated on Medicines Policy Documents

Medicines Policy of MERCOSUR (PMM)	(...) seek to improve Government action, especially with respect to the four topics identified as essential for the region's countries in terms of medicines: (...) a) Increase the population's access to medicines, considering the needs of different social groups; b) Ensure the quality, safety and efficacy of medicines in circulation in the region; c) Promote a culture of rational use of medicines; d) Create an environment of research and development that improves the countries' technological knowhow within the sector (MERCOSUR, 2000, Annex, item 1 - Purpose and Objectives)
Andean Medicines Policy (PAM)	(...) to guide and strengthen the health management of the countries of the Andean sub-region by improving health activities and protection related to medicines, by defining regional strategies and prioritizing basic principles such as access, quality, rational use, and fostering research and development in the pharmaceutical sector, with the aim of meeting the public health needs of the Andean sub-region. (...) Ensure that the population of the Andean sub-region has access to effective, safe and quality medicines, promoting their rational use and guaranteeing equitable access to essential medicines. (ORAS-CONHU, 2009, p. 8-9)[1]
Caribbean Pharmaceutical Policy (CPP)	(...) 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. (PAHO, CARICOM, 2013, p.x)

Source: Own elaboration.

The objectives expressed in the medicines policies documents unfold into areas of strategic action, for which guidelines are defined. The main contents of the guidelines set for each of the strategic areas are presented in Table 4: 1) Access/Universal Access; 2) Quality, efficacy and safety/regulation; 3) Rational use; 4) Research and development.

Although UNASUR's and ALBA's normative decisions on medicines do not constitute policy documents (according to WHO definitions) and do not include in their structure the statement of guidelines organized into strategic areas, it was possible to classify their proposals according to thematic areas derived from other documents by means of approximation.

4 Esta política tiene como propósito orientar y fortalecer la gestión sanitaria de los países de La Subregión Andina hacia el mejoramiento de las acciones de salud y protección, relacionadas con el medicamento, definiendo estrategias regionales y priorizando aspectos básicos tales como el acceso, la calidad, el uso racional y el impulso a la investigación y desarrollo en El sector farmacéutico, con la finalidad de atender las necesidades de salud pública de la Subregión Andina. (...) Lograr que la población de la Subregión Andina cuente con medicamentos eficaces, seguros y de calidad, promoviendo su uso racional y garantizando el acceso equitativo a medicamentos esenciales. (ORAS-CONHU, 2009, p. 8-9)

All documents propose actions destined to promote *access to medicines* Table 4, page 17. Consequently, the directive to establish a list of medicines that are vital to meet the regions' health needs, through activities of selection of medicines and the adoption of the concept of essential WHO-recommended medication, is recurrent in these documents.

The recognition of high prices (and high costs) as barriers to access results in frequent propositions of establishing certain mechanisms, such as: 1) Price control and regulation; 2) Joint negotiations with industry; 3) Increased transparency, disclosure and sharing of information on pricing in the region; 4) Adoption of generic names in management processes and in promoting the production of generics; 5) Improving the quality and training in government procurement.

In parallel, great emphasis is placed on the importance of establishing sustainable financing mechanisms, including greater coverage by private health plans, and, primarily on guaranteeing public resources for medicines.

The need for managing intellectual property in favor of public health is highlighted in four of five of the previously mentioned documents. Patents are recognized as barriers to access, which point to the need for impact studies and the importance of incorporating the flexibilities of the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) in national patent laws.

Item eight (8) of UNASUR Resolution 09/2009[5] underlines that the definition of access to medicines as an item of public interest, which provides for the issuance of compulsory licenses as a means to overcoming existing barriers, should be recognized as an advance in the region's access strategies.

Distribution mechanisms and reliable supply logistics, with the incorporation of best quality management techniques, are considered important. In addition, promoting production, especially of generics, and strengthening industrial sectors of interest to health are considered strategic. Such promotion should include the transfer of technologies and the use of installed capacity in the region.

5 "8 Reconocer los avances de la región en las estrategias de acceso, en particular al Gobierno de Ecuador, por declarar de interés público el acceso a las medicinas utilizadas para el tratamiento de enfermedades que afectan a la población, propiciando la emisión de licencias obligatorias como instrumento para superar las barreras existentes." (UNASUR, 2009, p.2)

Table 4. Strategic areas covered: contents and main guidelines.[6]

Access / Universal Access	
PMM	1) **Selection of medicines**: institution of a common list of essential medicines (LEM), adoption of WHO essentiality criteria and creating a Therapeutic Formulary. 2) **Affordability**: price control, generics legislation, price database, government procurement (legislation and management training) and negotiation with industry. 3) **Sustainable financing**: public funding (percentage of the health budget), management of medicines, include coverage by private plans and financing alternatives. 4) **Distribution and supply systems**: public-private mix, Best Practices in Pharmacy (BPP), HR education and training, and planning the distribution of establishments. 5) **Patents**: studies of their impact on access, alternatives to national laws and relaxation of requirements in case of high relevance to health.
PAM	1) **Selection of medicines:** essential medicines (equitable access without discrimination, to enable prioritization) and national and regional LEMs. 2) **Generic medicines**: use of generic name (DCI); increased supply, lower prices and purchasing efficiency. 3) **Market transparency, monitoring and intervention**: price rationalization based on production costs, monitoring of prices, generation and exchange of information. 4) **Management and distribution**: optimization and transparency; price negotiation; joint purchases of essentials (high cost priority). 5) **Production**: promotion and prioritization of essentials; technology transfer, development of the pharmaceutical and biotech industries; partnerships for generics production. 6) **Financing**: recognize access as a universal right, with increased coverage and guaranteed financing. 7) **Patents**: balance between stimulus to innovation and the needs of public health; studies of their impact on access; prioritize health interests. 8) **Update of sanitary regulations**: harmonization and requirements should not imply lack of access. 9) **Pharmaceutical services**: implementation of supply networks, Pharmaceutical Care.
CPP	Collaboration between National Pharmaceutical Systems, mechanisms for joint negotiation and purchases: strengthening of CARIPROSUM (Caribbean Regional Network of Pharmaceutical Procurement and Supply Management Authorities) and harmonization of supply systems; sub-regional platform for joint negotiations; policies for cost reduction strategies (generics, price regulation and financing mechanisms); patent examination systems with a pro public health approach and changes in national patent laws (incorporate TRIPS flexibilities according to the DOHA declaration).
UNASUR Resolution 9	Promote integrated policies to assure access to essential medicines, vaccines and other health technologies; development of the Health production complex (strategic niches and installed capacity); promote the management of intellectual property from a public health perspective (favoring access and promoting innovation); incorporate and use TRIPS flexibilities (Doha and the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property); Technical Group on Universal Access to Medicines (TG UAM); recognize advances (Ecuador) – access to medicines as public interest, allowing for compulsory licensing.
ALBA-TCP	Creation of a supranational (*grannacional*) pharmaceutical products distribution and sales company: develop fair trade in medicines that favors public health systems of member countries; trigger pharmaceutical product distribution mechanisms according to the particularities of each country in order to supply 25% of demand.

6 This table presents common or recurring topics of the different documents analyzed.

Quality, efficacy and safety / Regulation	
PMM	Strengthening the regulatory role of the State: define norms and supervision; granting of authorizations and registrations (gauging therapeutic advantages). Priority to essential medicines: harmonization of sanitary regulations; Good practices in production and control; Good laboratory practices, quality standards for Pharmaceutical Services; HR training.
PAM	Surveillance and control of all medicine production stages; post-sale control; assurance of unbiased, complete, impartial information; quality standards for pharmaceutical production, establishments and products; Good practices; Sub regional quality surveillance system; Pharmacovigilance: fostering technical capacity of National Regulatory Authorities (NRA); HR education and training; cooperation for information exchange; harmonization of norms according to international standards.
CPP	Development of a common medicines regulatory framework; sub regional platform for the regulation of medicines; proposed legislation for essential regulatory functions; Medicines Regulatory Network; Pharmacovigilance Network in collaboration with the Pan American Network for Drug Regulatory Harmonization (PANDRH); strengthening of the Regional Laboratory for Medicines Testing; ethics and conduct codes for health professionals; strengthening of national regulatory authorities, quality standards and national quality control laboratories.
UNASUR Resolution 9	
ALBA-TCP	Creating a Center for Medicines Regulation for ALBA (ALBAMED): develop and implement a single, centralized and harmonized system for sanitary registration of the medicines sold by ALBA's medicines import, export and distribution company; pre and post sales components to guarantee the quality, efficacy and safety as part of ALBA's new medicine selection – purchase – distribution system.
Rational use	
PMM	Improvement of prescription and dispensing; prescription norms; continued consumer education activities; health education curriculum reform; Pharmaceutical Care; Pharmacovigilance Good Manufacturing Practices (GMP); promotion and publicity control (ethical agenda); LEM, Therapeutic Formularies and clinical protocols.
PAM	1) **Regulation**: definition of OTC, required prescription or special control; risk-benefit assessment for authorization and selection; update transparency norms; 2) **Selection**: adopt essentiality criteria (WHO); Pharmacy and Therapy Committees; permanent revision of LEM; 3) **Education**: education of health professionals, strengthening of Medicines Information Centers (MIC); 4) **Prescription**; 5) **Dispensing**: use of DCI; norms for prescription and dispensing, protocols; Pharmaceutical Care; GMP; social function of pharmacies; 6) **Publicity and promotion**: regulation, control and surveillance (ethical agenda); development and access to independent information; 7) **Consumer Information**; 8) **Pharmacovigilance**: integration in public health policies; complimentary to the actions of each National Regulatory Authority (NRA); creation and implementation of a Sub Regional System of Pharmacovigilance.
CPP	Lists the sub regional model of essential medicines, Therapeutic Formulary; develop regionally harmonized clinical protocols; regional medicines information center, integration of current national information centers; support national capabilities for selection and use of medicines; promote the protection of access to medicines and rational use in communities.
UNASUR Resolution 9	
ALBA-TCP	

Research and development	
PMM	Definition of regional priorities: foster the production of generics included in LEM (including raw materials); investigation of innovative molecules and their industrial technological development; harness the potential of the region's fauna and flora, study of traditional medicine; R&D funds for essential raw materials and overlooked diseases.
PAM	Use WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008); transfer of technology and development of the pharmaceutical and biotech industries; identify low-supply EMs (essential medicines), establish partnerships for the production of generic versions; strive to guide R&D to fill the gaps in research on health problems that affect the region; harness the potential of the region's fauna and flora, study of traditional medicine; Guide of Good Clinical Practices and ethical standards in research.
CPP	
Resolução 9 UNASUL	Mechanisms for R&D based on regional needs; Assessment of Innovation and Incorporation of Technologies (technological and economic evaluation – comparative studies); harmonized position on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, including mechanisms for fostering R&D directed to the region's health needs.
ALBA-TCP	

Source: Own elaboration.

Assuring the quality, safety and efficacy of medicines comprises the general objective of the second most frequent strategic area, present in four of the five documents analyzed (Table 4).

The content of the propositions regarding the quality assurance of pharmaceutical products point to a strengthening of the role and capacity of the State in regulating, supervising and controlling the entire distribution chain of medicines – from pre-sales procedures such as business operation authorizations and concession of product registrations to the post-sales monitoring and the establishment of integrated pharmacovigilance systems.

The harmonization of sanitary regulations is often recommended via mechanisms of international cooperation – such as the establishment of regulations and multilateral regulatory entities, quality control and warranty – and the adoption of international quality criteria and standards (Good Manufacturing, Laboratory and Control Practices). Strengthening the regulatory capacity of national authorities and investing in the technical training of personnel are required in order to accomplish these goals and directives.

With respect to *the rational use of medicines*, a strategic area present in three of the five documents, the policies advocate the establishment of norms and parameters for the prescription and dispensing of medicines. The strategy of selection of medicines is revisited and reinforced through the definition of national and regional Lists of Essential Medicines (LEM), in addition to the elaboration of Therapeutic Formularies, Clinical Protocols and Therapeutic Guidelines for the directing prescription and dispensing activities.

Activities related to education, be it of professionals, through the reform of curricula, be it of the community, are both mentioned. Equally cited are the generation of information, the strengthening and integration of medicines information centers and ethical guidelines for the regulation of advertising and promotion of medicines, whether aimed at the population or health professionals (Table 4).

In contrast to the OMS proposal, which lists R&D (Research and Development) as a component of a medicines policy, the two documents that include such components (PMM and

PAM) give it equal status to other strategic area objectives (access, quality and rational use of medicines). This denotes that the set of guidelines related to *research and development* is of strategic importance for achieving the objectives set out in the policies, namely: meet the health demands (with respect to medicines) of the population. Aside from PMM and PAM, Resolution 9 of UNASUR's Health Council contains articles aimed at fostering Research and Development in the pharmaceutical sector (Table 4).

The fostering and promotion of research and technological and industrial development activities should, according to the documents, be carried out in order to selectively induce the development of capacities (investigative, production and innovative). Such selectivity signifies a prioritization of the particular health needs of the region, such as overlooked diseases, high-cost medicines, essential medicines and generics with low availability, in order to supply and provide sustainability to health systems.

Finally, innovation itself and the incorporation of technologies should be evaluated by way of comparative studies (evaluation of health technologies), and decision-making should be guided by taking into account both criteria that indicate technical advantages and economic criteria.

Blocs surveyed

There were documents directed at pharmaceutical sector policies in all Blocs surveyed. The objectives stated within the documents are geared towards meeting (with medicines) the health needs of the population. The most frequent operational objectives, which organize strategies and advocate coordinated courses of action, include the *promotion of access to medicines, their rational use and assurance of safety, efficacy and quality*. Additionally, fostering pharmaceutical *research and development* is described as an essential fundamental goal to overcoming the state of industrial and technological dependence prevalent in the region, in order to meet the demands of the health systems of the countries in the region and the specific health needs of their populations.

Bilateral Cooperation

Thirty-seven (37) bilateral cooperation agreements or projects on medicines were identified as a result of a search conducted on the websites of international cooperation agencies from Argentina (8 agreements), Brazil (15 agreements), Mexico (2 agreements), Uruguay (6 agreements) and Chile (6 agreements). According to the Report on South-South Cooperation in Ibero-America (SEGIB, 2012)[7], these countries were among the main providers of international cooperation in 2011. Annex 1 of this document includes the reproduction (or summary) of information regarding cooperation agreements obtained from website searches.

Matrix Table 1 below presents the distribution of cooperation agreements or projects according to the countries that provided the information on cooperation and the respective cooperating countries.

Matrix Table 1. Number of cooperation agreements/project according to countries that provided information on cooperation and respective cooperating countries.

Cooperating countries	Countries that provided information on cooperation					
	Argentina	Brazil	Chile	Uruguay	Mexico	Total
South America						**15**
Argentina			1			1
Bolivia	1					1
Brazil	1		1	4		6
Colombia	1					1
Ecuador	1	1				2
Paraguay	1		2			3
Uruguay	1					1
Central America and Caribbean					**10**	
Cuba		3	2			5
Honduras					1	1
Dominican Republic	1	1				2
Central America*					1	1
CARICOM*	1					1
Africa						**8**
Mozambique		5				5
Nigeria		3				3
Others						**2**
Korea				1		1
Israel				1		1
Not informed		2				2
TOTAL	**8**	**15**	**6**	**6**	2	37

*All the countries in the region or Bloc (CARICOM) are reported as cooperating.
Source: Own elaboration.

7 No information regarding bilateral cooperation on medicines was found on the websites of the other countries that were subjects of this work, with the exception of the website of Cuba's cooperation agency. However, due to the Cuban website's very high number of references to the subject, which were provided in the form of news, it was impossible to filter and precisely select information pertaining to cooperation agreements on medicines.

The distribution of projects and agreements points to South America[8] as the main region for cooperating countries (15 projects), followed by Central America and the Caribbean (10). Outside the Americas, African countries (Mozambique and Nigeria) prevailed as cooperating nations according to the documents examined. Brazil, Cuba and Mozambique were mentioned the most as cooperating countries, as shown on Matrix Table 1.

There is great difficulty in obtaining detailed information from websites. The way information is organized varies by website and not many documents related to agreements and projects were found. The website of the Cooperation Agency of Chile[9] was the only one to provide copies of cooperation agreements. Information is only generally available in the form of abstracts or notices informing the existence of projects and their themes and, in some instances, also their nature and duration. Annex 1 lists the information that was uncovered.

Evidence of the absence of publicly accessible information is found on Matrix Table 1, where Brazil is indicated as a cooperating country according to information provided by the websites of Argentina, Chile and Uruguay, but there is no corresponding reference to such projects on the Brazilian website. The same occurs for projects listed between Chile and Argentina and between Argentina and Uruguay.

In order to expand the search for cooperation agreements, a search was made on the Database of cooperation agreements of the International Advisory Network and of International Cooperation in Health of UNASUR's Council of Ministers – REDESSUL – ORIS. This database contains information on experiences and ability to offer cooperation in health, according to experience, country and offering institution – it provides a descriptive summary of the experience and lists the countries that received cooperation in specified areas. However, the database does not provide details about the terms of cooperation agreements or projects, nor does it single them out. Therefore, it is impossible to quantify agreements or projects. There are 89 experiences listed, of which five involve matters related to medicines. Annex 2 reproduces database information related to these five experiences.

Argentina, Brazil and Uruguay are the countries that offer cooperation in areas (experiences) related to medicines. Bolivia, Colombia, Ecuador, Paraguay, Dominican Republic, Uruguay, Cape Verde and other African countries[10] (sic) are listed as countries that received cooperation related to medicines.

Although the scope of the research carried out in this project differs depending on whether one examines websites or the content of the REDESSUL-ORIS Database, both alternatives point to similar country profiles in providing and receiving bilateral health cooperation on medicines.

Regarding the content of the agreements, the majority of those surveyed on websites are concentrated into few areas:

1. Activities related to technical cooperation and training, exchange of experiences and definitions of common standards aimed at strengthening the regulatory capabilities of health authorizes in cooperating countries – for example, involving regulatory agencies: National Health Surveillance Agency (ANVISA, Brazil), ANMAT (Argentina), INVAMA (Colombia), CECMED (CUBA), among others;

8 Although this study focuses on bilateral cooperation among countries within the region, agreements or projects realized with other world regions were included whenever found.

9 Documents relating to agreements that mention medicines-related activities were organized and delivered with this report.

10 Probably agreements with Mozambique and Nigeria, found on the website of the Brazilian Cooperation Agency.

2. Activities related to feasibility studies, presentation and specification of projects, training for the production of medicines pertaining to the implementation of an antiretroviral factory – activities carried out mainly between Brazil (FIOCRUZ) and Mozambique;
3. General health cooperation agreements, listing different cooperation areas, including issues related to medicines – this was the main type of agreement found in Chile and Uruguay.

Matrix Table 2. Number of cooperation agreements/projects according to countries that provided information on cooperation and area of cooperation

Area of cooperation	Countries that provided information on cooperation					
	Argentina	Brazil	Chile	Uruguay	Mexico	Total
Strengthening of Authorities Regulation of Medicines	8	7	1	3		19
Production of Medicines		7				7
General health cooperation agreements			4	3		7
Other		1	1		2	4
TOTAL	8	15	6	6	2	37

Source: Own elaboration.

A similar result was obtained by analyzing the contents of the experiences listed in the REDESSUL-ORIS database (Annex 2). Of the five experiences listed, three are related to the strengthening the regulatory capabilities of health authorities and one is related to the production of medicines by the public sector for the national health system (referred to the experience of cooperation between Brazil and African countries). One area of cooperation that had not been found previously relates to technical assistance in health economics involving Argentina and Uruguay as providers, and Paraguay and Ecuador as recipients of cooperation.

Limitations of the study

First, one should consider that the search for documents that ratify agreements does not indicate that foreseen activities have been implemented, nor have been conducted according to set objectives. This caution is especially important for documents that establish general guidelines, recommendations or strategies – such as the Medicines Policies documents and general health cooperation agreements.

Such an investigation could be effected by researching funding streams and the allocation of resources in surveyed areas, identifying who carried out proposed activities and monitoring routines, reports or activity progress reports, project details derived from normative decisions, among others – which is outside the scope of this study.

As previously reported, there was great difficulty in obtaining information relating to bilateral cooperation agreements from publicly available primary sources on the internet. The type of available information varied in terms of organization, scope and detail. From information in the form of news or general descriptions, as in the case of Mexico and Cuba, to categorized descriptions, which include the duration of the project, such as those available on the website of the Brazilian Cooperation Agency, to the availability of scanned original documents, as in the case of Chile. Moreover, this variability generated difficulty in establishing a predefined and homogeneous scope of research – information was not always available and could result in the exclusion of part of the already scarce agreements or projects.

Regarding the nature and content of the agreements, due to the non-exhaustive nature of the search and great difficulties in obtaining complete information, one should take great care in the interpretation of quantitative analyses. There is neither certainty concerning the magnitude of the universe of the study, nor about the significance of the sample of documents or data obtained. Thus, a qualitative interpretation of results should be favored, such as areas where there are reported initiatives or experience in health cooperation on medicines and, therefore, opportunity for cooperation.

Final Considerations

All of the Regional Blocs surveyed (MERCOSUR, UNASUR, CAN, CARICOM and ALBA) possess health guidelines or strategies pertaining to issues related to medicines. This translates to all countries in the region being signatories of at least one multilateral agreement on the issue.

The analysis of the contents of these documents points to a strong convergence towards the general objectives recommended by the WHO for organizing the pharmaceutical sector for the sake of public health and the strengthening of national health systems. In other words, promoting universal / equitable access to medicines; ensuring their quality, efficacy and safety; and promoting the rational use of these inputs. These objectives are present in documents covering all countries of South America and the Caribbean (CARICOM members). Bilateral or multilateral cooperation activities in these areas rely on the legitimacy of these documents and represent opportunities for joint action.

A fourth area of activity for pharmaceutical policy – fostering research and development – is present in most of the documents and conveys multilateral commitments by most countries in South America.

There is an overlap or intersection of signatory countries of different documents with similar objectives. Although this may indicate redundant or disperse efforts, financing streams and agents that share the same purpose, it may also represent an opportunity to generate synergies and broader coordinated or combined activities on behalf of common objectives.

Of the areas defined as strategic and vital, the one that garnered the most bilateral cooperation initiatives pertains to guaranteeing the quality of products in circulation through the strengthening of the regulatory capabilities of health authorities.

Initiatives more closely linked to access, such as fostering the public production of medicines, are reflected by bilateral cooperation initiatives outside the region – projects to set up antiretroviral drug factories in Mozambique (and Nigeria in earlier stages), carried out in cooperation with Fiocruz.

Although difficulties and limitations were many, they do not seem to be, however, specific to this study. The Report on South-South Cooperation in Ibero-America (SEGIB, 2012) points out its own limitations because of the bias and incompleteness of its data, despite specific efforts, through a program of strengthening of South-South cooperation, for generating, standardizing and using indicators for guiding data collection and analysis.[11] Efforts to obtain and organize information on cooperation via REDESSUL-ORIS, despite the inadequacy and limited scope of the data, seem to strive to overcome such difficulties, which is very positive.

11 The report informs "Whether they used several **Indicators for South-South Cooperation.** Its more ample objective consists in delving into issues such as **visibility**, improving **strategic management and planning,** as well as a possible **evaluation**. The gathering of data related to project costs or their approval dates, beginning and end of activities, enabled the start of such measurements. The most significant limitation when interpreting results was caused by data that, despite efforts, continued to be biased and incomplete". (SEGIB, 2012, p.7 – highlights on the original document)

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Annex 1 – Information on bilateral cooperation obtained from websites of cooperation agencies

BRAZIL → 15 projects	
Cooperation area: Health	
1. BRA/04/044-S010	Techno-Economic Feasibility Study on the Installation of a Medicines Plant in Mozambique for the Production of Antiretroviral Drugs and Others.
	Objective: the project aims to elaborate a study on the technical feasibility of installing an antiretroviral medicines plant in Mozambique
	Type: South-South Cooperation
	Status: concluded
	Start date: July 15, 2005
	End date: August 15, 2007
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: Ministry of Health (Brazil) - MH
2. BRA/04/044-A063	Training in health surveillance of medicines.
	Objective:
	Type: South-South Cooperation
	Status: concluded
	Start date: September 11, 2006
	End date: September 30, 2006
	Sector: Health
	Subsector: Health Surveillance
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa
3. BRA/04/044-A087	Mission to Specify Technical Cooperation in Health (Antiretroviral Drugs).
	Objective: this isolated activity aims to present to the Nigerian health authorities a proposed technical cooperation project entitled “Training in Production Technology of Antiretroviral Drugs” as well as finalizing the details of the contract between Far-Manguinhos and the “Maniab” laboratory of Nigeria for the transfer of medicines production technology.
	Type: South-South Cooperation
	Status: concluded
	Start date: November 13, 2006
	End date: December 13, 2006
	Sector: Health
	Subsector: STD/AIDS
	Accountable Brazilian Partner Institutions: Ministry of Health (Brazil) - MH

BRAZIL → 15 projects	
Cooperation area: Health	
4. BRA/04/044-A198	Technical Study on the Installation of an Antiretroviral Drugs Plant and Others in Mozambique.
	Objective: to conduct a brief diagnosis of the status of AIDS in Mozambique; survey of foreign aid for HIV / AIDS; use of antiretroviral therapy (ART); drug production plant; alternatives for local production of other necessary inputs; costs of machinery for production of medicines; profile and number of personnel required for operation of the plant; identifying the training needs of staff; outline of preliminary construction plans; assessment of the feasibility study; and identifying potential international cooperation for the construction of the plant.
	Type: South-South Cooperation
	Status: concluded
	Start date: February 26, 2008
	End date: April 26, 2008
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: Oswaldo Cruz Foundation - FIOCRUZ/MH
5. BRA/04/044-S106	Institutional strengthening in health surveillance of medicines.
	Objective: The project aims to transfer to the Cuban government the techniques adopted by ANVISA related to pharmacoeconomics, combating counterfeit drugs, bioequivalence analysis and inspections of clinical research centers and of radiopharmaceuticals, in order to strengthen CECMED as a Medicines Regulatory Authority. Given the significant trade in medicines between Brazil and Cuba, the project, which obtained five different results, was of particular importance in bringing together the working methods of both regulatory institutions and in allowing the two countries to market imported pharmaceuticals more quickly.
	Type: South-South Cooperation
	Status: concluded
	Start date: March 31, 2008
	End date: March 31, 2010
	Sector: Health
	Subsector: Health Surveillance
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa
6. BRA/98/004-A056	Technical Mission to specify the Project of Installing an Antiretroviral Drugs Plant and Others in Mozambique.
	Objective: provide further details for the final proposal of the plant installation project by offering technical support to the staff or the Ministry of Health of Mozambique regarding the transfer of technology for the production of medicines between Far-Manguinhos and the Mozambican counterpart. I.e., human resources training, technology transfer schedule, quality control and warranty, adjustment of physical plant layout and develop components of the medicines plant installation project. These actions resulted in the project entitled “Training in the Production of Antiretroviral Drugs”.

BRAZIL → 15 projects	
Cooperation area: Health	
6. BRA/98/004-A056	Type: South-South Cooperation
	Status: concluded
	Start date: August 15, 2008
	End date: October 15, 2008
	Sector: Health
	Subsector: DST/AIDS
	Accountable Brazilian Partner Institutions: Oswaldo Cruz Foundation - FIOCRUZ/MH || Pharmaceutical Technology Institute - Far-Manguinhos || Ministry of Health (Brazil) - MH
7. BRA/04/044-S117	Training in the Production of Antiretroviral Drugs.
	Objective: the project is part of the process of installing an antiretroviral drug plant in Mozambique, under the responsibility of Fiocruz. It aims to train and provide expertise to the Mozambican professionals who will work in the production of antiretroviral drugs and other pharmaceutical products for fighting the country's major epidemics at the above-mentioned plant.
	Type: South-South Cooperation
	Status: under execution
	Start date: September 29, 2008
	End date: April 30, 2014
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: Oswaldo Cruz Foundation - FIOCRUZ/MH
8. BRA/04/044-S136	Institutional Strengthening of Mozambique's Medicines Regulatory Agency as a regulatory agent of the pharmaceuticals sector.
	Objective: the Ministry of Health of Mozambique, in light of the installation of an antiretroviral drug plant, intends to develop an effective legal framework for the pharmaceutical area, in order to regulate the public and private markets for medicines, vaccines and other biological products, according to WHO recommendations. Therefore, Mozambique is creating, with the support of Brazil, a medicines regulatory agency endowed with technical and financial capabilities so as to ensure the availability of safe, good-quality and affordable products for the entire population. The Mozambican government will be trained in techniques for promoting and protecting the health of the population through the sanitary control of the production and sale of products and services subject to sanitary surveillance, including their physical environments, processes, inputs and technologies. It also aims to strengthen institutionally the medicines regulatory agency of Mozambique as the sector's regulator, by developing human resources and sharing information and experiences.
	Type: South-South Cooperation
	Status: concluded
	Start date: October 17, 2008
	End date: February 02, 2012

BRAZIL → 15 projects	
Cooperation area: Health	
8. BRA/04/044-S136	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa
9. BRA/04/043-A279	"Generic Medicines Exploratory Mission."
	Objective:
	Type: South-South Cooperation
	Status: concluded
	Start date: June 10, 2009
	End date: July 10, 2009
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: Ministry of Health (Brazil) - MH
10. BRA/04/044-S225	Supporting the Strengthening of the Dominican Health Authority Regarding Medicines Registration, Pharmacovigilance and Health Inspections.
	Objective: the project aims to strengthen institutionally the health regulatory authority through training and the exchange of laws, information and experiences with respect to medicines, pharmacovigilance, food inspection and toxicology.
	Type: South-South Cooperation
	Status: under execution
	Start date: July 09, 2010
	End date: July 09, 2014
	Sector: Health
	Subsector: Health Education
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa
11. BRA/04/044-S324	Technical Support for Strengthening Pre and Post Medicines Sales Regulatory Activities in Ecuador.
	Objective: to support the implementation of the pharmacovigilance system for public health policies in Ecuador for proactively monitoring the use of medicines in the post-sales phase and to strengthen the process of medicines registration and pharmaceutical inspections at pre-sales phase.
	Type: South-South Cooperation
	Status: under execution
	Start date: March 25, 2011
	End date: March 25, 2014
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa

BRAZIL → 15 projects	
Cooperation area: Health	
12. BRA/04/044-S351	Establishing Reference Substances for the Quality Control of Medicines.
	Objective: through the exchange of experiences between the health authorities of Brazil and Cuba for establishing and monitoring reference substances used in quality control of medicines, the project aims to improve the quality, safety and efficacy of medicines, following the basic guidelines recommended by the World Health Organization - WHO.
	Type: South-South Cooperation
	Status: under execution
	Start date: December 14, 2011
	End date: December 14, 2013
	Sector: Health
	Subsector: Medicines
	Accountable Brazilian Partner Institutions: Oswaldo Cruz Foundation - FIOCRUZ/MS
13. BRA/04/044-S215	Institutional Strengthening of Cecmed and Anvisa in Health Surveillance.
	Objective: the project aims to strengthen the institutions responsible for health surveillance and control of medicines in Cuba and Brazil. Consequently, this cooperation will contribute to greater access to quality and effective medicines in both countries and, subsequently, to improve the public health of both populations.
	Type: South-South Cooperation
	Status: under execution
	Start date: June 21, 2010
	End date: June 04, 2013
	Sector: Health
	Subsector: Health Surveillance
	Accountable Brazilian Partner Institutions: National Health Surveillance Agency - Anvisa
	Cooperation area: Industry and Commerce
14. BRA/04/044-A110	Mission to Negotiate the Project of Technical Training for the Production of Antiretroviral Drugs.
	Objective: this isolated activity was aimed at specifying and finalizing the proposal of the technical cooperation project whose objective is to train Nigerian human resources to produce and develop antiretroviral drugs in their country.
	Type: South-South Cooperation
	Status: concluded
	Start date: March 10, 2007
	End date: April 10, 2007
	Sector: Industry and Commerce
	Subsector: Pharmaceutical Industry

BRAZIL → 15 projects	
Cooperation area: Health	
15. BRA/04/044-A087	Mission to Specify Technical Cooperation in Health (Antiretroviral Medicines).
	Objective: this isolated activity aims to present to the Nigerian health authorities a proposed technical cooperation project entitled "Training in Production Technology of Antiretroviral Drugs" as well as finalizing the details of the contract between Far-Manguinhos and the "Maniab" laboratory of Nigeria for the transfer of medicines production technology.
	Type: South-South Cooperation
	Status: concluded
	Start date: November 13, 2006
	End date: December 13, 2006
	Sector: Industry and Commerce
	Subsector: Pharmaceutical Industry
	Accountable Brazilian Partner Institutions: Ministry of Health (Brazil) - MH

ARGENTINA → 8 projects	
Cooperation area: Science and Technology (no projects were found)	
1. 6167 - CARICOM/PAHO	Strengthening Quality Control of Medicines Laboratories of CARICOM.
	This project aims to contribute to strengthening the health system in the Caribbean, by developing the capabilities of professionals working in the quality control of medicines. Anglophone Caribbean countries have been traditionally importers and receivers of medical substances manufactured in other regions under very different quality standards. To contribute to a harmonization of practices of intra-regional control, in 1974 CARICOM countries created the Caribbean Regional Drug Testing Laboratory (CRDTL), a Jamaica-based institution, which acts as a reference laboratory where the regulatory authorities of all countries of the Bloc send their pharmaceutical products to test their quality and properties. Meanwhile, some countries have developed their own Medicines Control Laboratories as in the case of Guyana, Suriname and Trinidad, which require support to meet international requirements, especially from the WHO. Through this South-South/Triangular Cooperation, Argentine professionals from the National Administration of Medicines, Food and Medical Technology (ANMAT) provided training at the CRDTL and throughout Argentina for five professionals from Jamaica, Trinidad and Tobago, Guyana and Suriname in Good Practices in Laboratory Controls, especially controls on anti-tuberculosis drugs. The project has the support of experts from the Pan American Health Organization (PAHO), the agency responsible for the certification of national reference laboratories and that has been working for over 10 years on the harmonization and strengthening of national medicines control laboratories of the Americas. Upon completion of the project, the CRDTL will have taken a first step in the process of attaining qualification by PAHO as a regional reference laboratory, a key aspect for having their test results recognized by other laboratories throughout the region and the world.
2. 6093 -URUGUAY	Creating a Regional Pharmacopeia.
	This project is conducted in coordination with individual initiatives for South-South Cooperation with Paraguay and Brazil, to strengthen their respective medicines control authorities.
3. 6052 - ECUADOR	Technical assistance to the Ministry of Public Health of Ecuador to strengthen control standards for pre and post medicines approval.
	Ecuador has undertaken a policy of strengthening its control system for drugs that are imported or produced domestically. This has led to the creation of the National Health Authority, the entity responsible for the safety and quality of medicines. Through an exchange with Argentinean experts from the National Administration of Medicines, Food and Medical Technology (ANMAT), this project seeks to support and strengthen the system of control of pre and post registered medicines at the headquarters of the Health Ministry of Ecuador.

ARGENTINA → 8 projects	
Cooperation area: Science and Technology (no projects were found)	
4. 6030 - COLOMBIA	Strengthening the standards for pre-market surveillance (production) and post-market (distribution) of medical devices and reagents for in-vitro diagnosis.
	Medical devices and in vitro diagnostic reagents devices are products, materials or equipment used to study blood, tissues or samples of the human body. It is therefore necessary to apply strict controls to check their quality when acquired and, once used, so they do not become sources of disease and contamination. The National Institute of Food and Drug Monitoring (INVAMA) of Colombia and the National Administration of Medicines, Food and Medical Technology (ANMAT) of Argentina are the two entities responsible for carrying out such pre and post market controls.
5. 6009 - BOLIVIA	Implementation of Pharmacovigilance System.
	Pharmacovigilance systems make the control of adverse reactions to medicines possible and provide a means of evaluating their safety levels according to usage. This South-South cooperation project seeks to contribute to the implementation of a National Pharmacovigilance System in Bolivia through the training of 120 professionals from Medicines and Health Technology Unit (UNIMED) and from the National Commission of Pharmacovigilance (CNF) of the Ministry of Health and Sports of Bolivia, by experts from the National Administration of Medicines, Food and Medical Technology (ANMAT) of Argentina.
6. 5983 - BRASIL	Creating a Regional Pharmacopeia.
	The Pharmacopoeia is the official compilation of the most common types of medicines, the different preparations and medication useful for medicine and pharmacy in their various aspects, including the origin, nomenclature, preparation, identification, purity, valuation, dose and other conditions to ensure the quality and consistency of their properties. Experts from the National Administration of Medicines, Food and Medical Technology of Argentina (ANMAT) and the National Health Surveillance Agency (ANVISA) of Brazil join efforts and knowledge to form a regional pharmacopoeia that can generate more equitable access to medicines in MERCOSUR member-countries. This project is conducted in coordination with individual initiatives for South-South Cooperation with Paraguay and Uruguay to strengthen their medicines control authorities.
7. 5967 - REPUBLICA DOMINICANA	Safer medicines for the entire Caribbean.
	With the aim of contributing to the advancement of the Official Medicines Control Laboratory of the Dominican Republic, Dr. Defilló, in becoming a reference institution in the Caribbean region, in late 2010, the Directorate General of Drugs and Pharmacy of that country requested collaboration of Argentina and the Pan American Health Organization (PAHO).
8. 5665 - PARAGUAY	Strengthening technical capacity in Health Surveillance.
	Paraguay has set as a priority the reorganization, reform and strengthening of public health institutions with the objective of achieving free circulation of medicines and medical products within MERCOSUR. This South-South Cooperation project promotes training by Argentine experts from ANMAT (National Administration of Medicines, Food and Medical Technology), of Paraguayan officials and pharmacists. The courses focus on the surveillance of health products, especially in the areas of manufacturing, combating counterfeiting, pharmacovigilance and medical technology.

URUGUAI → 6 projects	
Korea and Uruguay	1. Memorandum of understanding in health signed between the Ministry of Health and Well-being of the Republic of Korea and the Ministry of Public Health of the Eastern Republic of Uruguay. Signed in Seoul on November 15, 2012, by the Ministers of Health of both countries. Its validity is of five years, renewable automatically. Priority health areas to be developed: 1. Epidemiological Surveillance 2. Access to health services for rural populations 3. Medical Technology 4. Telehealth and telemedicine 5. Access to medicines 6. Health Systems 7. Rectory 8. Human Resources 9. APS 10. Health of children and adolescents 11. Sexual and reproductive health 12. Social participation November 26, 2012.
Brazil y Uruguay	2. Memorandum of Understanding signed between the Governments of Uruguay and Brazil in the field of health. Signed in Montevideo on May 30, 2011. This document extends and continues with the mechanisms and modalities of cooperation already undertaken by the Parties under the Basic Agreement on Scientific and Technical Cooperation. Brazil appoints the ABC as the organization responsible for coordinating activities and MS. ROU designates the AUCI, the MRREE and MSP. Areas: medicines, APS, regulatory capacity, border issues, HIV-AIDS, social participation, HR, rural health, etc. 3. Supplemental Agreement to the Basic Agreement on Scientific and Technical Cooperation between the Government of the Federative Republic of Brazil and the Government of the Eastern Republic of Uruguay for the implementation of the project “Strengthening the institutional capacity of the MSP and expansion of regulatory dialogue between health Authorities in Brazil and Uruguay” signed in Montevideo on May 30, 2011.
Technical Cooperation in health between ABC and MRREE	4. Institutional Strengthening of the Secretariat of the Ministry of Public Health of Uruguay-MSP in the area of Health Surveillance. Signed in March 2007. The objective is to contribute to strengthening the Brazil-Uruguay bilateral relationship in the area of health as well as deepening the relationship of member countries of MERCOSUR. This technical assistance will be provided with the goal to contributing and strengthening the leadership of the MSP in the area of health monitoring, medications and foods. It is supported by ANVISA.

URUGUAI → 6 projects	
Israel and Uruguay	1. Agreement between Uruguay and the State of Israel on Cooperation in the area of health and medicine. Signed in Jerusalem, 29 May 2006. The goal is to encourage the exchange of information, specialists, equipment, medicines and others. Both ministries should implement plans for cooperation by mentioning the funding. a. Plan for cooperation in the field of health and medicine between the MS of the State of Israel and MSP of Uruguay for 2009-2014. Implementation of the Agreement signed in 2006. Areas of interest: health emergencies and traumas, telemedicine, health management and medical technology, biotechnology and pharmacogenetics, genetics and stem cells, research in cancer and cardiac health, implementation and evaluation of national health insurance, analysis of health quotas and their link to the incorporation of new health benefits, audits of health systems and hospital units. It is a cost-sharing arrangement. Signed on February 18, 2009 in Montevideo between the two Ministries.

CHILE → 6 projects	
1. ARGENTINA	Identification of the Standard: DTO-1552
	Publication date: December 06, 1999
	Promulgation Date: September 21, 1999
	Agency: MINISTRY OF EXTERNAL RELATIONS
	Agreement for Health Cooperation with Argentina "(...) Article 1 Scope of Cooperation: The Parties shall encourage cooperation between their competent authorities in health. The aforementioned cooperation will be undertaken in particular in the following areas: 1. Promotion, protection and recovery of health. 2. Exchange of medical technology. 3. Food and **medicines**. 4. Training of human resources. 5. Technical cooperation in health of the population of border areas." (...) "Article 3 Technical Information: The Parties shall develop a network of technical information to disseminate knowledge about medical equipment efficiency and efficacy of drugs, food control, including their process technologies and selection methods, as well as their safety and costs."
2. CUBA	Technical cooperation between countries that includes the strategic items of "essential medicines and vaccines."
3. CUBA	Technical cooperation between countries that defines the main area of interest as "the development and application of biotechnology products such as vaccines, innovative drugs," also "to coordinate multicenter binational clinical trials."
4. PARAGUAY	Technical cooperation between countries, which includes among its priority areas: "health technology with special emphasis on medical equipment, medicines, biological products, etc."
5. PARAGUAY	Protocol of intent for cooperation in health: establishes as one of the items of cooperation: "Logistics of Medicines".
6. BRASIL (Anvisa) e Chile (ISP)	Cooperation between health authorities in both countries, pertains to health surveillance of medicines.

Annex 2 – Information on bilateral cooperation on medicines as per the REDESUR-ORIS map.

Experience	Summary	Offering countries	Institution	Receiving countries
Strengthening the Regulatory Capacity of Health Products	The National Administration of Medicines, Food and Technology (ANMAT) of Argentina, is the Agency responsible for ensuring that medicines, foods and technologies available to the population possess adequate quality, safety and efficacy. For this, the oversight role of the Health Authority is prioritized, through the work of trained human resources and adequate infrastructure. The role of ANMAT is comprised of the following tasks: 1. Licensing of Operations and product approval; 2. Audit and Control; 3. Surveillance; 4. Monitoring of Advertising. ANMAT is providing cooperation on human resources education and training in countries of the region, especially with respect to: 1. Inspectors that assess compliance with Good Manufacturing Practices-GMP based on Risk Management Analysis: tools and applicability; 2. Issues of counterfeit medicines through the development of a Program to Combat Counterfeiting; 3. The implementation of Pharmacovigilance Systems that deliver timely and adequate alerts; 4. Fulfilling norms related to required studies of Bioavailability and Bioequivalence, both prospectively and retrospectively; 5. Issues of Medical Technology.	Argentina	National Administration of Medicines, Food and Medical Technology (ANMAT)- MINISTRY OF HEALTH	Bolivia, Paraguay, Colombia, Ecuador, Dominican Republic

Experience	Summary	Offering countries	Institution	Receiving countries
Technical Assistance in Health Economics	Directors of Health Economics have experience in cooperating through Horizontal Cooperation projects of the Argentine Fund for South-South and Triangular Cooperation (FO.AR). Projects are generally structured from an initial experiment where field exploration is carried out, and then the following steps are agreed upon after considering the strengths and weaknesses of each institution. The visits aim to teach representatives of the receiving country about the main lines of work of the Department of Health Economics of Argentina's daily activities, with emphasis on the analysis of the methodology used. Specifically, the following topics are discussed: 1. Prices of medicines; 2. Health expenditure and sources of financing; 3. Economic evaluation of health projects; 4. Medicines industry; 5. Intellectual property of medicines; 6. Priority sources of information and their use.	Argentina Uruguay	Board of Directors of Health Economics, Secretariat of Health Determinants and Health Relations, National Ministry of Health	Paraguay y Ecuador
Common MERCOSUR Pharmacopeia	(Forum) In order to achieve the MERCOSUR Pharmacopeia, work is carried out cooperatively to reduce asymmetries between Brazil, Paraguay, Uruguay and Argentina.	Brazil y Argentina	Anvisa – Regulating and Supervising Agency of Pharmaceutical and Food Products (ARFA) and ANMAT	Paraguay y Uruguay
Regulatory Activities in Public Health	In general, the activities are comprised of the following modalities: exchange of documents between agencies and regulations; strategy planning; discussion of proposed interventions; technical visits with in-service training on defined topics; joint discussion of proposed technical regulations; exchange of information and communication materials; impact analysis of regulatory actions and training in regulatory actions. The project involved the participation of officials from ARFA's permanent staff, as well as professionals from other institutions involved in the sector. The direct contribution of ARFA's staff in preparing and executing the project denotes the agency's level of preparation and commitment with the activities that were carried out and the effects that resulted from these activities. Because they pertain to the permanent staff, they will be able to continue to replicate acquired knowledge and to develop activities.	Brazil	Anvisa – Regulating and Supervising Agency of Pharmaceutical and Food Products (ARFA)	Cabo Verde

Experience	Summary	Offering countries	Institution	Receiving countries
Production of medicines by the public sector for the national health system	Support for national public initiatives for the production of medicines that are part of essential medicines in different health systems. This support can be provided at various stages such as research, biosynthesis, production plan designs, planning, distribution and storage. They also perform feasibility studies for the production of medicines.	Brazil	Fiocruz	Cooperation exists in some African countries