

## **Whats New 2011**

- **Annual Course on the Health Area Response to Nuclear Accidents**

With a view to training health professionals to boost the health emergency response capacity in the wake of nuclear accidents, the Annual Course on the Health Area Response to Nuclear Accidents was offered in Angra dos Reis, Brazil, from 2 to 5 December 2011.

This course, held at the Centro de Medicina de las Radiaciones Ionizantes in Angra dos Reis, was organized by the Fundação Eletronuclear de Assistência Médica (FEAM) and included speakers from national institutions of the FEAM, the Ministry of Health of Brazil, the National Nuclear Energy Commission (CNEN), the National Cancer Institute (INCA), the Institute for Radiation Protection and Dosimetry (IRD), and 70 physicians, nurses, and responders.

The program included two days of theory and a day devoted to a simulation of care for a patient contaminated with radiation from a nuclear accident. Dr. Pablo Jiménez, PAHO's Regional Adviser on Radiology and Radiation Protection, gave two presentations, The Role of PAHO in Preventing and Mitigating Nuclear Emergencies and The Fukushima Nuclear Accident, and participated in the simulation Care for a Patient with Radiation Injuries.

The main conclusions drawn from the activity were: the need to devise the national emergency medical response plan for nuclear emergencies and define the roles and responsibilities of each institution; that ANVISA should regulate the importation and use of the medicines needed to treat patients with radiation injuries, following the guidelines issued by WHO and the International Atomic Energy Agency (IAEA); and that the training and retraining activities for the health professionals that should participate in the medical response to nuclear emergencies should continue.

- **Experts meet to advise official medicine control laboratories in Suriname and Trinidad**

Within the framework of the Pan American Network for Drug Regulatory Harmonization (PANDRH) and the Amazon Malaria Initiative (AMI), a mission visited Paramaribo, Suriname and Port-of-Spain, Trinidad for a meeting on 28 and 29 November 2011.

The meeting's objectives were: to discuss the preparation of a cooperation project to boost laboratory capacity for quality assurance in the Caribbean with the national regulatory authorities (NRA), specifically in Suriname and Trinidad; to verify the information provided by the Drug Supply Company Suriname (BGVS) and the Chemistry, Food, and Drug Division (CFDD) of Trinidad in the survey for the "Study of the Current Conditions of the Official Medicine Control Laboratories in Latin America and the Caribbean;" to explore participation in the External Laboratory Quality Control Program (EQCP) in 2012 and discuss the preparation of a program for quality control of antimalarials within the framework of the AMI/RAVREDA program.

Dr. José María Parisi, PAHO's Specialist in Quality Assurance and Safety of Pharmaceuticals, was in charge of verifying the information provided by the BGVS and the CFDD in the survey for the "Study of the Current Conditions of the Official Medicine Control Laboratories in Latin America and the Caribbean." In addition, the two laboratories were added to PANDRH's list of Official Medicine Control Laboratories (OMCL).

At the conclusion of the meeting, the experts agreed to bring the quality assurance systems of the BGVS and CFDD up to the international standards for good laboratory practice; to reorganize the current facilities of the two laboratories through a technical evaluation by PAHO; to hold a training workshop with the Promoting the Quality of Medicines Program (PQM) and the U.S. Pharmacopeia (USP) on high-performance liquid chromatography and dissolution testing in Paramaribo in March 2012; to follow up the 10th stage of the EQCP, which will be held in September 2012; and to improve the quality assurance system for antimalarials, among other medicines.

- **Meeting of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH)**

On 22-23 November 2011, the PANDRH Steering Committee met at the headquarters of the Pan American Health Organization (PAHO) in Washington, D.C. The participants were representatives from CARICOM, Central America, the Andean Community, MERCOSUR, ALIFAR, and FIFARMA, who are on the Steering Committee, and PAHO, as Secretariat.

Dr. James Fitzgerald, coordinator of the Essential Medicines and Health Technologies Project (HSS/MT), opened the meeting, which was moderated by Dr. José Peña, PANDRH coordinator. The achievements and challenges and the need to adjust efforts to countries' needs and to the mandates of PAHO's 50th Directing Council in order to strengthen the National Regulatory Authorities were the issues taken up at the start of the meeting.

The purpose of the meeting was to direct PANDRH efforts toward fulfilling the recommendations of the VI Pan American Conference on Drug Regulatory

Harmonization, held in July 2011 in Brasilia, coordinating the work and avoiding duplication of efforts by establishing a strategic plan for this Network.

The most significant agreements of the meeting were:

- To create an ad hoc group to prepare a draft of the Development Plan for PANDRH grounded in flexibility, scientific rigor, and adequate representation of its members;
  - To discuss the work plans of PANDRH's technical groups at an upcoming Elluminate meeting in order to evaluate their performance and incentives and decide whether to continue or discontinue them;
  - To support the incorporation of a representative from the Regional Regulatory Authorities as an observer on the PANDRH Steering Committee;
  - To prepare an instrument for identifying the needs of the National Regulatory Authorities in order to establish an appropriate training plan;
  - To create a group, made up of members of the PANDRH Steering Committee and Secretariat, responsible for coming up with the Network's training strategy;
  - To urge countries to participate in the Regional Platform for Access and Innovation in Health Project.
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- **1st Conference on the Radiological Protection of Patients**

On 18-20 November 2011, the 1st Conference on the Radiological Protection of Patients was held in Caracas, Venezuela. Organized by the Venezuelan Society for Radiological Protection (SOVEPRA), it had a prestigious panel of national and international speakers and was attended by some 400 people, including physicians, medical physicists, and radiology, radiation therapy, and nuclear medicine technicians.

During the conference, participants discussed current issues related to the radiological protection of patients in diagnostic imaging and radiation therapy. Dr. Pablo Jiménez, Regional Adviser on Radiology and Radiological Protection at PAHO, gave the presentations "New Basic International Safety Standards: Medical Exposure" and "PAHO's Role in the Radiological Protection of Patients" and participated in the "Forum: Proposals for a National Radiology Plan for Patients in Venezuela." Ileana Fleitas, engineer and program officer for PAHO/WHO's Radiological Health Program in Cuba, gave the presentation "Radiological Protection of Patients in CAT."

At the end of the meeting, participating experts recommended that PAHO schedule activities for promoting the development and implementation of national plans for the radiological protection of patients, bearing in mind that Venezuela has been integrating important complex health technology in this field.

- **Third International Conference on Improving Use of Medicines**

With a view to improving the use of medicines in developing countries, 600 world drug experts met in Antalya, Turkey, on 14-18 November 2011.

The issues addressed at the different roundtables during the conference were: approaches to the use of medicines in low- and middle-income countries; developing strategies for the use of medicines at different levels in healthcare systems; and identifying and evaluating strategies for the appropriate use of medicines.

In addition, there were plenary sessions where the following issues were addressed, among others: the cost of, economic access to, incentives for, and the transparency and coverage of medicines; maternal and child health; care of chronic diseases, such as diabetes and high blood pressure; and mental health; AIDS and tuberculosis; and drug resistance.

The participants from 80 countries who attended this important event learned that more people in developed countries die of chronic diseases like high blood pressure, asthma, and diabetes than of infectious diseases like HIV and tuberculosis. Moreover, the participating experts underscored how important it is for governments to take more concrete action towards getting essential drugs to their people.

Representing PAHO were Dr. James Fitzgerald, Coordinator of the Essential Medicines and Health Technologies PAHO (PAHO), who presented “Affordable, Appropriate Access to High-Cost Medicines: Key Issues in Latin America;” Dr. Adriana Ivama, Subregional Advisor on Medicines in the Caribbean, who presented nine papers on the results of technical cooperation in the pharmaceutical area in the Caribbean, principal among them the one on the development of the Caribbean pharmaceutical policy; and Dr. María Cecilia Acuña, Specialist in Health Systems and Services at PAHO, who presented “Social Determinants of Access to Medicines in Three Central American Countries.”

This important conference was an opportunity for participants to learn about the results of current pharmaceutical research from around the world and the “gaps” in research to improve the use of medicines in the coming years.

The conference program and book of abstracts of the papers that were presented are available at: <http://www.inrud.org/ICIuM/Conference-Overview.cfm>. Presentations and posters will be available shortly on the conference website: <http://www.inrud.org/ICIuM/ICIUM-2011.cfm>.

Presentations:

 [Affordable, Appropriate Access to High Cost Medicines: Key Issues \(3.92 MB\)](#)

 [Social Determinants of Access to Medicines in Three Central American Countries \(667 kB\)](#)

Posters:

 [Access to and Use of Medicines in Barbados: Evidence from a Household Survey \(737.85 kB\)](#)

 [Assessment of Pharmaceutical Situation in Jamaica \(1.95 MB\)](#)

 [Assessment of Pharmaceutical Situation in Suriname \(325.08 kB\)](#)

 [Caribbean Network on Pharmaceutical Education \(80.42 kB\)](#)

 [Evidence-based development of the Caribbean Pharmaceutical Policy \(105.23 kB\)](#)

 [Partnership on Pharmaceutical Policies in The Caribbean: 2006-2009 \(322.31 kB\)](#)

 [Pharmaceutical Situation in the Caribbean as Background for Policy Development \(2.03 MB\)](#)

 [Pharmaceutical Situation in Barbados: WHO Level II Health Facilities Survey, 2010 \(456.57 kB\)](#)

 [Proposal for a Baseline Assessment for the Caribbean Pharmaceutical Policy \(258.51 kB\)](#)

- **Workshop on Quality Control in the Supply Chain (PAHO-PQM/USP-AMI/RAVREDA)**

From 8 to 11 November 2011 two consecutive meetings were held in Bogotá, Colombia, in collaboration with the Promoting the Quality of Medicines Program (PQM), the U.S. Agency for International Development (USAID), and the U.S. Pharmacopeia (USP), within the framework of the Amazon Malaria Initiative (AMI).

First, the workshop on the Three-level Approach to Drug Monitoring was held. Attended by the representatives of seven countries in the Amazon region, its purpose was to announce implementation of the three-level approach to quality control throughout the supply chain; its application in areas of high and low malaria transmission; the role of the quality control laboratories within this framework; and the guidelines for developing protocols for monitoring drug quality.

At the conclusion of the workshop, the participants and authorities representing the national malaria programs, regulatory programs, and the official drug monitoring laboratories, made a commitment to implementing the quality approach in their countries.

## Progress toward Creation of the National Medicine Quality Control

Next, on 11 November, a meeting was held to study the progress made toward creation of the National Medicine Quality Control Network; learn about experiences implementing the three-level approach; identify achievements and lessons learned in implementing the approach, and improving channels for communication between the Territorial Health Bureaus and the National Drug and Food Surveillance Institute (INVIMA).

The participants were the Territorial Health Bureaus of Colombia, the Medicine Inspection, Monitoring, and Control Coordinators, and the Public Health Laboratory Coordinators.

Also present at both meetings were Dr. José María Parisi (PAHO/WDC) and Dr. Adriana Mendoza (PAHO/COL).

- **International Meeting of Pharmacovigilance Centers**

The Annual Meeting of National Pharmacovigilance Centers was held in Dubrovnik, Croatia from 31 October to 2 November to provide an update on events related to international pharmacovigilance. A total of 180 participants from national pharmacovigilance centers around the world, the Uppsala collaborating center, and WHO were in attendance.

Work sessions were held on a variety of topics, including notification and monitoring systems; experience with insertion in public health programs, especially vaccine and HIV programs; aspects of pharmacovigilance communication; experiences in managing medication errors; and experiences with common pharmacovigilance problems. The significant progress made in the work of Uppsala and WHO in 2011, together with the countries of the Region and Collaborating Centers, was also presented.

At this meeting, significant agreements were reached for more intense collaboration, especially in training, database management, and proposals for intensive pharmacovigilance with the Region of the Americas.

- **Framework Agreement between the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Pan American Health Organization (PAHO)**

On October 26th 2011, the Director of PAHO, Dr. Mirta Roses Periago and the President of the Canadian Agency for Drugs and Technologies in Health (CADTH), Dr. Brian O' Rourke signed a Framework Agreement.

CADTH provides decision-makers in Canada with evidence, analysis, technical assistance, and recommendations they require in order to make decisions in the field of health technologies.

The agreement between CADTH and PAHO will facilitate cooperation between both organizations in order to strengthen governance and interventions in the pharmaceutical and other health technologies sector, through the use of best scientific evidence and Health Technology Assessment (HTA)

Through this agreement, the database Rx for Change will be made available in Spanish and accessible for the Region. Rx for Change was developed by the Cochrane Effective Practices and Organization of Care Group, and the Cochrane Consumer and Communication Review Group and contains information on scientific evidence to inform the design and implementation of interventions, management and use of health technologies.

In addition, the agreement proposes collaboration between CADTH and PAHO in training activities to increase regional capabilities for health technologies management and other instruments.

The present agreement will remain in effect from October 26th 2011 to December 31st 2013.

- **RAD-AID Conference on International Radiology for Developing Countries**

RAD-AID International, a nonprofit NGO founded by a team of radiologists trained at Johns Hopkins University in Baltimore, organizes an annual conference on international radiology for developing and emerging countries in order to improve global health services. The event is free of charge.

This year, the conference took place at the Johns Hopkins School of Medicine in Baltimore, Maryland on 30 October 2011. The aim was to provide an interactive forum for discussions on how to improve diagnostic imaging to promote health care internationally.

This important event brought together various nongovernmental humanitarian organizations, medical schools, government agencies, radiologists, public health

officials, technology engineers, economists, medical assistants, nurses, physicians, and business leaders.

The topics discussed during the sessions included the Economics of International Radiology: Long-term Model Building; Clinical Imaging Models and Radiology Service Strategies for the Developing World; International Education for Attendings, Residents, Technologists, and Nurses for Global Service; Technology for Radiology and Health Care in Developing Countries; and Public Health International Radiology: Radiology and Global Public Health Objectives.

As part of the session on Public Health International Radiology: Radiology and Global Public Health Objectives, Dr. Pablo Jiménez, Regional Adviser on Radiology and Radiological Health for PAHO, presented Challenges and Strategies to Improve Access to and Quality of Diagnostic Imaging Services in Latin America and the Caribbean.

For more information on the conference go to the RAD-AID web page at <http://www.rad-aid.org/default.aspx>.

- **Congress of the World Self-medication Industry (WSMI)**

The Congress of the World Self-medication Industry, held in Puerto Vallarta, Mexico from 26 to 28 October 2011, brought together industry representatives from around the world.

The topics addressed during the sessions and roundtables included the importance of self medication and its impact on public health, barriers and challenges faced by this industry, local experiences, and the distribution and promotion of OTCs (over-the-counter drugs not requiring a prescription).

Dr. José Luis Castro, PAHO's Regional Adviser on the Rational Use of Medicines, coordinated the public health impact panel and participated in the roundtable that addressed the distribution and promotion of OTCs.

- **Experts Meet to Strengthen the National Regulatory Authorities in Quality Control of Medicines and to Monitor the Quality of Cholera Medicines**

Two consecutive meetings were held in Haiti and the Dominican Republic from 24–28 October 2011 to lay the foundation for a cooperative project among regulatory authorities from the two countries for the registry, inspection, and authorization of medicines, and to strengthen the normative capacity of Haiti's national regulatory authority, specifically to control the quality of cholera medicines.

Participants at the meetings included Dr. José M. Parisi (PAHO/WDC) and Dr. Michel Klopfenstein (PROMESS/HAI). They were joined in Port-au-Prince by

Zoulikha Faraj (PAHO/HAI) and in Santo Domingo by Dahlia Castillo (PAHO/DOR).

In Haiti, the participants explored the possibility of setting up an official laboratory for the control of medicines, considering several entities (University Hospital, National Control Laboratory, School of Pharmacy, and the Bureau for Pharmaceuticals and Medicines). They agreed to work with the Dominican Republic's Official Drug Control Laboratory to design a quality control plan for medicines in Haiti. In addition, the Bureau for Pharmaceuticals and Medicines met to set up a customs control system similar to that used by national regulatory authorities for medicines in the Dominican Republic.

The activities of the participating experts included training professionals from Haiti and the Dominican Republic in the functions of the registration of medicines, best practices in manufacturing, and best practices in laboratory work; training professionals from Haiti's Essential Medicines Program (Programme de Médicaments Essentiels – PROMESS) on WHO best practices for the storage and certification of pharmaceutical products; and quality control of cholera medicines in the Dominican Republic's Official Drug Control Laboratory, with a view to establishing a control plan in the future for the Bureau for Pharmaceuticals and Medicines, and for Haiti as well.

In the Dominican Republic, the experts held various meetings and made visits to exchange information about the drug registration and import process. Dr. José María Parisi gave a presentation to the Bureau for Pharmaceuticals and Medicines in order to present the WHO program for prequalification of control laboratories for medicines.

One of the most important objectives achieved at this meeting was the agreement between the Dominican Republic's Official Medicine Control Laboratory, Dr. Defilló, and PROMESS for quality control services for cholera medicine samples, which will serve as a pilot project for future tests to be conducted in 2012.

- **Framework Agreement for Cooperation between the National Administration of Drugs, Foods, and Medical Devices (ANMAT) and the Pan American Health Organization (PAHO)**

On 17 October 2011, Dr. Mirta Roses Periago, Director of PAHO, and Dr. Carlos Alberto Chiale, Director of ANMAT, signed a framework agreement for cooperation in Buenos Aires, Argentina.

The purpose of this agreement is to set the terms for close and ongoing collaboration between the two institutions in the area of drugs and health technologies, which will be accomplished by assigning ANMAT professional staff to the PAHO/WHO Representative Office in Argentina. Each institution will also designate focal points to

make the information resulting from the implementation of this agreement available to the national and international scientific community.

Specifically, the framework agreement that was signed provides for the coordination of PAHO/WHO regional cooperation to strengthen the regulatory authorities, promote international cooperation in the regulation of drugs and health technologies, and support ANMAT participation in PAHO/WHO regional cooperation projects. These projects include the Pan American Network for Drug Regulatory Harmonization (PANDRH) and the Regional Healthcare Access and Innovation Platform, in addition to the regulatory aspects of promoting the rational use of drugs and intercountry and regional exchange on frameworks, structures, and related processes in drug regulation.

The agreement will also facilitate joint activities to coordinate and monitor technical cooperation activities in countries on drugs and medical technologies; create and implement participation mechanisms to enrich curriculum content for careers in the health professions; promote and encourage joint scientific activities; and share bibliographic and research information necessary for meeting the goals of each institution.

The agreement, which will last for two years, went into effect on 17 October 2011.

- **Third International Regulatory Forum (IRF), Health Canada**

For the purpose of supporting the mechanisms of cooperation among regulatory authorities and promotion of strengthening the regulatory capacities of the Region of the Americas, Health Canada and the Pan American Health Organization have supported the participation of representatives from 10 Latin American and Caribbean countries in the Third International Regulatory Forum, which will be held October 24th-28th, 2011 in Ottawa, Canada.

This event will include the participation of approximately 100 persons from the National Regulatory Authorities of Asia, Africa, Europe and the Region of the Americas, specifically, Argentina, Barbados, Belize, Brazil, Chile, Colombia, Costa Rica, Cuba, the United States, Haiti, Honduras, Mexico, Nicaragua, Panama, Trinidad and Tobago and Venezuela.

The Forum agenda comprises regulation of pharmaceutical products, biologicals (including vaccines) and medical devices, in the pre-and post-marketing stages.

In order to promote knowledge of important regional initiatives related to the construction of regulatory capacity, a previous event on 23 October has been organized. At this event, WHO and PAHO will present initiatives related to the network of clinical assessment of vaccines for developing countries (DCVRN), the African Vaccine Regulation Forum (AVAREF), and the initiatives to strengthen the

National Regulatory Authorities for Medicines and Health Technologies in the Region of the Americas.

For additional information on the event, see the [Health Canada website](#).

- **Brazil doubles the production of drugs to combat Chagas' disease**

Brazil. 19 October 2011.- Responding to a request from multilateral cooperation agencies, the Ministry of Health of Brazil issued a press release in which it committed to doubling the production of benznidazole, a drug used in the treatment of Chagas' disease. This action will assist patients in Argentina, Bolivia, Colombia, Paraguay, Uruguay and Venezuela.

In the press release, Brazil's Minister of Health, Dr. Alexandre Padilha, said, "The ability to provide this service was the result of cooperation between the Ministry of Health and the Lafepe and Nortec laboratories, in conjunction with ANVISA. Brazil is the only country to take up the challenge of producing technologically advanced drugs for neglected diseases."

- **Meeting between PAHO and AEMPS aims to strengthen cooperation strategies in pharmaceutical regulation**

On October 12th 2011, PAHO Assistant Director, Dr. Socorro Gross-Galiano received the Director of the Spanish Agency for Medicines and Medical Products (AEMPS) Dr. Belén Crespo Sánchez-Exnarriaga and Chief of the Director Support Unit, Dr. Ramón Palop Baixauli, at PAHO headquarters in Washington, DC, in order to explore joint activities in the area of the regulation of medicines and health technologies.

Topics discussed during the visit included: presentation of PAHO/WHO cooperation initiatives and activities with the countries in the Region of the Americas in medicines and health technologies, presentation of AEMPS perspectives and its activities with PAHO, with special focus on pharmacovigilance and training on issues related to Good Regulatory Practices.



Dr. Belén Crespo introduced the AEMPS new management model for medicines regulation for human and veterinarian use. In addition, she explained the new structural organization of the agency and challenges in legal, socio-political, and scientific areas relating to pharmaceutical regulation, among others.

Similarly, Dr. Ramón Palop Baixauli highlighted AEMPS international activities that aim to promote exchange and cooperation between Latin American countries in pharmaceutical regulation

In this context, the PAHO Medicines and Health Technologies (HSS/MT) Project Coordinator, Dr. James Fitzgerald, outlined activities being developed in medicines and health technologies within the context of the global and regional health agenda. He also mentioned the qualification of four National Regulatory Authorities (NRAs) that are considered as regional reference for PAHO and presented recent advances of the Pan American Network for Drug Regulatory Harmonization (PANDRH).

At the end of the visit, AEMPS and PAHO representatives agreed to promote cooperation in pharmacovigilance for 2012, as well as strengthen training processes and the development of platforms to promote exchange between countries within the region.

- **Regional Workshop on Patient Safety and Quality of Care**

PAHO/WHO representatives and several Ministries of Health from the region met in the Dominican Republic on October 11th-13th, 2011 to evaluate the progress of implementation of the Patient Safety and Quality Program (PSQP) in the countries of the Region of the Americas.

During the meeting the experts participating made presentations, and shared experiences related to the performance and progress of the Patient Safety and Quality Programs in their countries. Representatives from PAHO and the Ministries of Health

presented the future PSQP work agendas of the countries at the regional and subregional level.

For additional information about this news, see the [PAHO/Dominican Republic website](#).

- **First Regional Workshop on National Health Surveillance Systems in South America**

The First Regional Workshop on National Health Surveillance Systems in South America was held from 3-7 October, 2011 at the headquarters of the South American Institute of Government in Health/Union of South American Nations (ISAGS-UNASUR) in Rio de Janeiro, Brazil. Participants included representatives from Argentina, Brazil, Bolivia, Chile, Colombia, Ecuador, Paraguay, Suriname, Uruguay, and Venezuela.

The objectives of the meeting included understanding the structures and needs of the health regulatory and surveillance systems of each country; facilitating the building of pro-ISAGS cooperation and work programs on regulatory matters; and addressing subjects related to medicines, generics, and falsification.



During the first three days of the meeting, the participating countries presented their health surveillance systems. On the final two days, 6–7 October, the Focal Points of the UNASUR Technical Group on Access to Medicines met and discussed priority topics for the 2012 work plan and the regional position on fraudulent health products, to be presented soon to the World Health Organization.

The meeting was attended by PAHO staff members Dr. María Luz Pombo and Dr. Christophe Rerat. They presented the different initiatives supported by the countries of the Region of the Americas to strengthen the functions of the national regulatory authorities for medicines and biologicals. The presentation also looked at the progress that has been made and the challenges faced.

[Presentation: Fortalecimiento de las Autoridades Reguladoras Nacionales de Medicamentos y Productos Biológicos en la Región de las Americas \(2.52 MB\)](#)

Representatives of PAHO and ISAGS-UNASUR agreed on the need to complement technical cooperation activities and establish a channel of communication among the organizations in order to work synergistically and to make available and share strategic information.

The conclusions of this meeting will soon be available on the [ISAGS-UNASUR web page](#).

- **Subregional Technical Committees on Medicines and Health Technologies met in Lima, Peru**

- 13th Meeting of the Subregional Technical Committee for the Access to Medicines Policy

- 1st Meeting of the Subregional Technical Committees for the Access to Medicines and Assessment of Health Technologies (AHT) policy of the Andean Health Agency-Hipólito Unanue Agreement (ORAS-CONHU)

- 5th Assessment of the Subregional Technical Committee on Assessment of Health Technologies

Three consecutive meetings were held in Lima, Peru on October 2nd-8th, 2011 to present progress related to subjects such as Access to Generic Medicines, Pharmacovigilance, information about medical equipment, assessment of health technologies, and the participation of Andean countries in the Regional Platform of Access and Innovation for Health.

There was participation by technical representatives from Bolivia, Chile, Ecuador and Peru, the director of the General Health Services of Bolivia, subregional and national advisors in the field of medicines and health technologies from Peru, and consultants in the field of medicines and assessment of health technologies from ORAS-CONHU, as well as others. On behalf of PAHO in Washington, D.C., Dr. Analía Porrás, Dr. Alexander Lemgruber and Dr. Victoria de Urioste were also present.

Through the different documents presented, the technical committees agreed to contribute to development of the PAHO Regional Platform of Access and Information for Health by providing information related to the lists of essential medicines. In this regard, PAHO and the AHT committee will manage development of a model for information resources about medical equipment in the regional platform.

Furthermore, the committees agreed to prepare a matrix of generic strategies for each of the countries in the region using the PAHO Guide to Implementation of Generic

Medicines Strategy as reference. They also agreed to hold the continuous virtual training workshop on Pharmacovigilance and use the databases of the WHO Center for International Drug Monitoring.

- **Workshop on Promoting Change in Pharmaceutical Services in the Americas: From the New Conceptual Framework to Reality**

The workshop on “Promoting Change in Pharmaceutical Services in the Americas: From the New Conceptual Framework to Reality” was held from 3–5 October, 2011 in Montevideo, Uruguay. The Pharmaceutical Forum of the Americas (FFA) and the Association of Chemistry and Pharmacy of Uruguay (AQFU), with support from PAHO and the International Federation of Pharmacists (FIP), organized the workshop.

Workshop participants included approximately 40 professionals from different areas of Uruguay’s pharmaceutical sector, including government, universities, hospital pharmacies, and private community pharmacies, as well as FFA members from Brazil, Colombia, Costa Rica, Paraguay, Venezuela, and the United States, and members of the IFJ. Dr. Nelly Marin, Dr. José Luis Castro, and Dr. Miguel Fernández represented PAHO.

Two documents presented during the workshop are considered central to promoting change in pharmaceutical services: one on pharmaceutical services based on primary health care developed by PAHO, prepared by Dr. Nelly Marin, Regional Adviser for Pharmaceutical Policies; and the good pharmaceutical practices guides jointly updated by WHO and the IFJ and presented by Dr. Gonzalo de Souza, Secretary of Latin American Relations for the IFJ. Following the presentation of both documents, representatives from government, the pharmaceutical profession, and undergraduate and continuing education offered their points of view on the viability and challenges of the documents and submitted proposals and ideas for their future implementation.

The FFA assembly was held on 5 October. Participants ratified the decision to prioritize the actions necessary to achieve sustained development of pharmaceutical services, pharmaceutical education, and the profession’s regulatory framework, in particular good pharmaceutical practices in the Region of the Americas.

- **Meeting of the Advisory Committees for Review of Work Standards of Blood Banks in Latin America and the Caribbean**

Taking into account the significant technical and medical advances related to blood transfusion and changes in the operation of blood services in Latin America and the Caribbean, two groups of experts on this topic from the United States and Latin America and the Caribbean met in Miami, Florida from 3–8 October, 2011 to review PAHO standards currently applied in the region as related to blood services.

The participants focused on the review of the publications Standards of Work for Services of Blood and Caribbean Regional Standards for Blood Banks and Transfusion Services. The publications were compared with the requirements of the 27th edition of the Standards for Blood Banks and Transfusion Services published by the American Association of Blood Banks; and the 13th edition of the Guide to the Preparation, Use, and Quality Assurance of Blood Components published by the Council of Europe. It is important to point out that, prior to this meeting, those responsible for blood services in the member states had the opportunity to submit observations and modifications that they considered appropriate to carry out the procedures set forth in the publications.

At the end of the meeting, the participating experts presented updated versions of the two publications. In addition, they agreed that the Blood Unit of PAHO's Medicines and Health Technologies Project should send the final document to the members of the advisory committee before 21 October 2011, stipulating future publication and distribution of these documents for 2012.

- **Presentation of Progress Report: Implementation of the Global Strategy and Plan of Action on public health, innovation and intellectual property within the framework of PAHO's 51st Directing Council**

**Washington, D.C.— September 29th, 2011.** Health authorities of the Member States met for a fourth consecutive day at PAHO headquarters in Washington within the framework of its 51st Directing Council; progress reports on technical matters were among the subjects to be covered.

The Area Manager of Health Systems based on Primary Health Care (HSS), Dr. Rubén Torres, gave a presentation highlighting the progress report: Implementation of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property.

Dr. Torres emphasized that the progress report submitted to the Executive Committee in June 2011 clearly summarized the commitment to ensuring effective implementation of the intellectual property and innovation strategy.

In this regard, Dr. Torres cited some significant progress made with this strategy in the Region of the Americas, for example, the fact that integration mechanisms such as the Union of South American Nations (UNASUR), the Andean Health Agencies (ORAS) and MERCOSUR have adopted elements of the global strategy in their resolutions and opinions.

Dr. Torres also alluded to implementation of the Technology Assessment Network, its availability and effect on countries. In addition to underscoring the progress made by the Pan American Network for Drug Regulatory Harmonization, he also mentioned that four regulatory authorities of regional reference have been pre-qualified, which will strengthen the regulatory capacity for health technology.

He emphasized that the lack of price transparency can be fought with more information and referred to the future launch of an innovative platform that will make the reference prices of medicines throughout the region available to all countries.

Furthermore, and continuing with the discussion of the progress reports, Dr. Torres presented the **Regional Initiative for Transfusion Safety and Plan of Action for 2006-2010: Final evaluation.**

He indicated that this initiative seeks to reduce mortality and improve patient care in Latin America and the Caribbean through availability and equitable access to safe blood. Dr. Torres also mentioned the adoption of strategies such as planning and managing the network of national blood systems, promoting voluntary blood donation, quality assurance and the appropriate use of blood and its components.

For the report on this initiative, blood donation levels were analyzed in 35 countries and territories for the period from 2005 to 2009. The results showed an inverse relationship between the average number of blood units processed annually by the center and the total availability of blood at the national level and between the availability of blood and maternal mortality rates. The report concluded that creating more blood banks does not improve availability and timely access to blood, and thus it urged countries to promote voluntary donation through efficient management of blood systems.

At the end of the session on the progress reports, the Directing Council was asked to take note of this report and thank the members of the External Evaluation Team (Marcela Contreras, Gabriel Schmunis, Elena Franco, Marcia Otani and Ashley Duits), in addition to recommending including the Regional Plan of Action on Blood Safety for 2012-2017 in the proposed topics for meetings of the PAHO Governing Bodies in 2012.

- **Health authorities meet to discuss Antimicrobial Resistance at the meeting of the PAHO 51st Directing Council**

In order to analyze and assess the impact of antimicrobial resistance from a socioeconomic, health and epidemiological standpoint and the rational use of antimicrobials and methods of containing antimicrobial resistance, health authorities of PAHO Member States participated in a round table on September 28th, 2011 at PAHO headquarters in Washington, D.C.

Dr. Patrick Kelley of the Institute of Medicine of the National Academies of the United States provided background on the social, economic and health impact of antimicrobial resistance, the degree of antimicrobial resistance in the Region and its trends and the multifaceted approach to containing resistance to antimicrobials.

Member States had the opportunity to exchange initiatives and work plans with a view to reaching conclusions that would direct strategies and activities aimed at containing antimicrobial resistance; these exchanges took place simultaneously at three round tables.

During the “Toward a multifaceted approach to containing resistance to antimicrobials” round table, representatives from Latin America and the Caribbean highlighted the most significant issues, such as the misuse of antibiotics and emphasized the importance of applying laws to ensure safe prescription of antibiotics in order to thereby avoid their irrational use. They also mentioned strengthening regulatory bodies that handle antimicrobial medications and agreed that the steering role of governments is essential to combating antimicrobial resistance.

It is important to point out that the CD51/15, Rev. 1, Add. 1 report was presented to the Directing Council on 30 September, which refers to the importance of strengthening regulatory mechanisms and their harmonization. Countries expressed the need to prepare pharmaceutical directives and prescription guidelines for antimicrobial prescriptions at the different levels of health care (primary, secondary and community), as well as the fight against self-medication, promoting the quality of antimicrobials and regulating the distribution of free samples by the pharmaceutical industry.

Member States indicated their interest in having the Pan American Sanitary Bureau support them in consolidating and strengthening their Regulatory Authorities.

- **Policy and Regulation of Medicines and Technologies were addressed at the 20th Caucus of CARICOM Health Ministers in Washington, D.C.**

The 20th Caucus of CARICOM Health Ministers was held on September 24-25, 2011 at PAHO headquarters in Washington, D.C., where two important items related to Medicines and Health Technologies were discussed.

The first noteworthy item was that the First Progress Report of Pharmaceutical Policy in the Caribbean and the structuring of the Expanded Technical Advisory Group on Pharmaceutical Policy (TECHPHARM) were approved at the 20th Committee Meeting of CARICOM Health Ministers.

The progress report highlights the development and implementation of the Caribbean Pharmaceutical Policy, approved in April 2011 by 21st Meeting of the CARICOM Council on Human and Social Development, which in turn has been supported by PAHO/WHO. Progress has been made on the development of country pharmaceutical profiles (CPP) as a source of evidence for policy-making and a starting point for implementing the CPP in Barbados, Belize, Dominica, Haiti, Saint Vincent and the Grenadines, Trinidad and Tobago, and Suriname and its spread into six other

countries and three territories of the United Kingdom and the development of a background document for the subregional regulatory framework.

The Health Ministers also approved the structuring of TECHPHARM, which is in charge of coordinating and supervising application of the CPP. The representative countries nominated were Antigua and Barbuda, Barbados, Suriname, Trinidad and Tobago, the Pharmaceutical Procurement Service/Organization of Eastern Caribbean States (PPS/OECS) and the British Virgin Islands, in addition to the ex officio members: the Secretariat of CARICOM, PAHO/WHO, Caribbean Regional Drug Test Laboratory and the representative of the Caribbean Pharmacy Schools.

The second noteworthy item was that the 20th Caucus of CARICOM Health Ministers endorsed the proposal “Improving Radiation in Medicine and Radiological Safety: An association between the IAEA and PAHO.”



Dr. Pablo Jiménez, Regional Adviser on Radiology and Radiation Protection of the HSS/MT program, presented an overview to the Caucus of the situation in CARICOM countries, the recent technical cooperation provided and the anticipated needs for technical cooperation in the near future, as well as the requirements for governments and regulatory agencies established in the new International Basic Safety Standards (BSS). He also pointed out that no CARICOM member country has a regulatory entity for radiological safety, and that the necessary technical capability to correctly use radiation in medicine is very limited in terms of compliance with the requirements established in the BSS and in International Health Regulations.

Dr. Jane Gerardo-Abaya, Official of the Program for Management of the Department of Technical Cooperation of the International Atomic Energy Agency (IAEA), presented a general overview of the IAEA and in particular the priorities and activities of the Department of Technical Cooperation for Latin America and the Caribbean. In addition, she proposed the organization of a PAHO-CARICOM-IAEA workshop, in order to evaluate the needs of CARICOM countries for the first semester of 2012. She also expressed the IAEA’s interest in continuing to collaborate

with PAHO in order to support CARICOM countries in their effort to improve radiological safety in the region.

The Caucus thanked PAHO and the IAEA for this initiative, recognized it as one of the priorities for their region (the Caribbean) and endorsed the proposal. As a result, PAHO and IAEA will plan the next collaborative steps in response to the appeal of the CARICOM Health Ministers.

- **Experts meet to “Achieve blood self-sufficiency and safe blood products based on unpaid voluntary blood donation”**

Health authorities from WHO and PAHO participated in the meeting “Achieving blood self-sufficiency and safe blood products based on unpaid voluntary blood donation,” which was held in Geneva, Switzerland, from September 20 -23, 2011.

Based on the adoption of Resolution WHA63.12, “Availability, safety, and quality of blood products,” in May 2010 and discussion of the subject, “Blood self-sufficiency and safe blood products based on unpaid voluntary blood donation,” in the United Arab Emirates in 2011, the BTS (Blood Transfusion Safety) team of the “Essential Health Technologies” unit of WHO decided to convene a meeting of experts to review the concept and critical elements of self-sufficiency, and in order to confront the challenges, to develop strategies and identify priority actions to achieve it. A preliminary meeting of experts took place on 30 to 31 May 2011, which resulted in a reflection document.

The purpose of PAHO’s participation was to contribute to the definition of blood self-sufficiency and safe blood products and to the identification of strategies to achieve self-sufficiency at the national level; to present information and lessons learned with respect to blood self-sufficiency for transfusion based on voluntary blood donation in the Region of the Americas; and to illustrate how regional strategies work by analyzing the recent experience of Nicaragua.

A Declaration of Consensus plan on achieving blood self-sufficiency and safe blood products based on “Blood self-sufficiency and safe blood products based on unpaid voluntary blood donation” was prepared by the expert participants during the three-day meeting. In addition, the BTS team of WHO will prepare a revised version of the text to be approved by the experts before its publication as an article in an international journal.

- **National Meeting of Argentine Radiophysics Health Professionals**

On September 15-16, 2011, the National Meeting of Radiophysics Health Professionals of the Provincial Ministries of Health of Argentina took place. Professionals from 23 of the 24 provinces of the Argentine Republic participated.

The meeting was organized by the National Bureau of Health Regulation and Quality Health Care and the Ministry of Health's National Bureau of Border Registration, Taxation, and Health, coordinated by PAHO/WHO in Argentina and the HSS/MT project in Washington, D.C., which also provided cooperation.

The main objectives of the meeting included conducting a National Census of Diagnostic Imaging Services and its integration into the Argentine Integrated Health Information System (SISA), a review of compliance with current regulations in all provincial jurisdictions, the identification of gaps in the regulations and their implementation, as well as coordination and the search for synergies with other national organizations (Nuclear Regulatory Authority, ANMAT, Radiology Society of Argentina) and international entities (IAEA).

Dr. Pablo Jiménez, Regional Adviser on Radiology and Radiation Protection, presented the requirements of the new International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS), in particular the requirements for radiology services and the international consensus on nonmedical exposure of persons to radiation (screening of passengers due to a national security threat, theft, or concealed objects or drugs; screening for legal or occupational reasons, or for art or publicity; and the addition of radioactive substances to food or beverages or their frivolous use in cosmetics, jewelry, or toys).

Finally, the participants decided to strengthen regulatory infrastructures in radiological safety based on the deficiencies identified and send the revised regulations to national and provincial ministries of health.

- **Mission to improve the operations of the Strategic Fund and the Revolving Fund for Vaccine Procurement in PAHO/Venezuela**

In order to analyze the performance of the Strategic Fund and the Revolving Fund for Vaccine Procurement in procuring drugs, vaccines and strategic public health supplies and propose recommendations for improving efficiency in handling and managing regional mechanisms in the PAHO/WHO Representative Office/Venezuela, a joint mission was conducted in Caracas, Venezuela, September 12-16, 2001, in which staff from the Strategic Fund, the Revolving Fund for Vaccine Procurement, and the Procurement and Supply Management Area at PAHO Headquarters participated.

During the mission, meetings were held with technical and administrative personnel from PAHO/Venezuela. Other meetings were also held to analyze Fund operations.

Dr. Miriam Morales, Vice Minister of Public Health Networks; Dr. Alexis Guilarte, Director General of Health Programs for the Ministry of Health; Dr. Jorge Jenkins, PAHO/WHO Representative in Venezuela, and technical and administrative personnel from PAHO participated for the purpose of studying the advantages of using PAHO's regional procurement mechanisms, identifying critical areas in the procurement of vaccines and drugs and proposing action to improve supply procurement and delivery planning.

A meeting was also held with the president of the Venezuelan Institute of Social Security (IVSS), Colonel Carlos Rotondaro, and his technical staff to inform them about the Strategic Fund. A workshop was also held with staff from the PEDEVESA health area and IVSS pharmaceutical personnel on the operating principles of the Strategic Fund, procurement planning, and areas of technical cooperation. These institutions expressed interest in using this procurement mechanism in the future for scarce and hard-to-procure drugs.

The mission's objectives included a review of the structure and operation of the procurement unit in the PAHO Representative Office, the mechanisms for coordination with PAHO technical and administrative areas at all levels, and the available tools in order to identify strengths and weaknesses to meet the demand in drug procurement, which in 2011 is on the order of US\$ 15 million for purchases of antiretroviral, antitubercular, antimalarial, and other drugs.

Participating in the mission were Dr. Nora Girón for the Strategic Fund; Mónica Pereira, representing the Revolving Fund for Vaccine Procurement, and Patricia Ramos for the Procurement and Supply Management Area (PRO).

Venezuela joined the Strategic Fund in November 2010 and has been using this mechanism for the procurement of drugs and public health supplies.

- **WHO consultation on the nonclinical and preclinical evaluation of adjuvant vaccines**

With a view to summarizing the scientific information, available data, and results of previous meetings on adjuvants and identifying critical issues on which the pharmaceutical industry's views have not been received, toxicology experts and regulators, the World Health Organization (WHO), and the Center for Biologics Evaluation and Research of the United States Food and Drug Administration (CBER/FDA) jointly held an informal consultation on the nonclinical and preclinical evaluation of adjuvant vaccines on September 7-8, 2011, in Rockville, Maryland, USA.

Representatives from the national regulatory authorities (NRAs) of Brazil, Canada, the European Medicines Agency, the United States, Indonesia, and Japan, as well as manufacturers from developed and developing countries, and WHO and PAHO consultants participated in this consultation.

As a result of this event, the preparation of a draft WHO guide for the nonclinical and preclinical evaluation of adjuvant vaccines began. In addition, the results of this consultation will be presented to the WHO Expert Committee on Biological Standardization (ECBS) in Geneva, Switzerland, in October 2011, in the hope that the Committee will express its support for the development of this guide.

- **Second Regional Meeting on Implementation of the International Health Regulations (IHR) in the Americas**

On September 1 -2, 2011, the Second Regional Meeting on Implementation of the International Health Regulations (IHR) in the Americas was held in Cancún, Mexico. Representatives from 36 countries of the Region of the Americas participated.

The meeting's objectives were: to update the implementation status of the IHR and define critical points where sharing experiences is necessary; create IHR-related intersectoral advocacy opportunities; and facilitate institutionalization of the IHR's functions by mobilizing sustainable resources, both domestic and external.

Given the relevance of radionuclear risks for both national IHR action plans and the management of public health events, one of the invitees was Dr. Pablo Jiménez, Regional Adviser to the HSS/MT Radiology and Radiation Protection Program, who presented "Radionuclear Aspects: Prevention and Response."

In addition to presenting the international requirements in this area and the Region's situation in this regard, Dr. Jiménez stressed that nuclear accidents and emergencies can occur in any country and location and underscored the need to implement the International Standards and establish and/or strengthen the Regulatory Authorities.

Dr. Jiménez also emphasized that the countries must have preparation and response plans to deal with existing threats. These plans must strengthen medical response capacity in the Region, and the countries must identify their capacities for improving domestic and international coordination for events of this type.

- **Presentation of the study "Research Priorities on Access to Medicines in Latin America and the Caribbean"**

In a two-day visit to PAHO headquarters in Washington on August 30th and 31st, 2011, Dr. Vera Lucia Luiza, Investigator and Coordinator of the Center for Pharmaceutical Policy of the Sérgio Arouca National School of Public Health–Oswaldo Cruz Foundation (NAF/ENSP/FIOCRUZ), the PAHO/WHO Collaborating Center on Pharmaceutical Policy, presented the findings of the study "Research Priorities on Access to Medications in Latin America and the Caribbean" to the HSS/MT project team.

The study was recently conducted in the region by Brazil's National School of Public Health / PAHO Collaborating Center on Pharmaceutical Policy. This project is part of

a global initiative to promote evidence-based decision-making on health policies and systems.

The importance of evidence-based decision-making is underscored as a priority in the WHO Medicines Strategy 2008-2013 and the PAHO Strategic Plan 2008-2012.

### Research Methodology

Four countries were visited, 77 scientific articles and 33 gray literature documents reviewed, and 35 key stakeholders interviewed electronically. The methodology applied made it possible to identify what the region is doing in this area and its priorities, based on the sources reviewed.

This study concludes that the region has the potential to conduct research on health policies and systems and underscores the importance of group work, as the degree of capacity and development among groups varies widely in the region. It also shows that health research agendas either are not formalized or not easy to distribute and access.

- **III Meeting of the Expert Committee on Pharmaceutical Policy**

The team of PAHO's Essential Medicines and Health Technologies Project met August 23-25, 2011, with a group of pharmaceutical policy experts from Argentina, Brazil, Colombia, Spain, and Mexico. The purpose of the meeting was to assist PAHO in revising and adapting the current WHO guide, *How to Develop and Implement a National Drug Policy*, published in 2002, for use in the Americas. Another aim was to identify gaps and strategic lines for implementing pharmaceutical policy in the Region.

The expert group began the meeting on Tuesday, 23 August, at PAHO Headquarters in Washington, D.C. Dr. James Fitzgerald, Essential Medicines and Health Technologies (HSS/MT) Project Coordinator, opened the proceedings. He referred to the priority guidelines of the Medicines project to promote primary health care, mentioning the development and implementation of pharmaceutical policies as part of national health plans.

Next, Dr. Nelly Marin, Regional Adviser on Pharmaceutical Policies and coordinator of this initiative, summarized the progress made in the area of pharmaceutical policy during earlier meetings in Argentina and Colombia and discussed the meeting's agenda and methodology.

The following academics, all members of PAHO/WHO Collaborating Centers, described the context, formulation, implementation, and evaluation of pharmaceutical policies in the Region of the Americas: Dr. Veronika Wirtz, professor and researcher at the National Institute of Public Health in Mexico; Dr. Catalina de la Puente, investigator at ISALUD University in Argentina; Dr. Claudia Osorio de Castro,

investigator at the Oswaldo Cruz Foundation (FIOCRUZ) in Brazil; Dr. Rubén Darío Gómez, professor at the University of Antioquia School of Public Health in Medellín, Colombia; and Dr. Jaime Espín, professor at the Andalusian School of Public Health in Spain.

Afterwards, there was an interactive dialogue with the HSS/MT team, in which each professional offered his views on the most important guidelines to follow to achieve the effective implementation of pharmaceutical policies. As a result of the dialogue, the expert participants agreed to devise a roadmap to finalize the proposal, which will be discussed with the ministries of health and governments of each country.

- **Meeting to promote activities between PAHO and Brazil's National Health Surveillance Agency (ANVISA) on Quality of Care and Patient Safety (QCPS)**

Dr. Malhi Cho, QCPS Adviser from the Medicines and Health Technologies (HSS/MT) Project, participated in a meeting in Brazil with ANVISA and attended the II Hemobrás Workshop August 22-24, 2011.

On the first day of the visit, Dr. Cho had the opportunity to meet with ANVISA's Health Services Quality Management and Monitoring and Surveillance Management team. The parties discussed strengthening cooperative work between Brazil and PAHO's QCPS program, such as those to promote activities undertaken by ANVISA's quality management and monitoring team; to revisit and strengthen joint PAHO-ANVISA efforts on notification systems and the study of research on outpatient care; and to support ANVISA's desire to become a PAHO/WHO Collaborating Center.

Dr. Dirceu Barbano, ANVISA's Director-President, asked his Quality Management team to take the necessary steps to become a Collaborating Center and to work with PAHO on the QCPS program at the regional and national levels.

The participating experts concluded that the meeting had served to resume work between PAHO and ANVISA that had been suspended and to program joint cooperative efforts.

- **Meeting between PAHO Representatives and the Hemobrás Team**

Representatives from PAHO/WHO and the Hemobrás team met on 23 and 24 August to coordinate blood policies and the production of blood products. Representing Hemobrás were its Technical Director, Dr. Luiz Amorim, and Chief of Staff, Dr. Heloísa Machado. WHO was represented by Dr. Ana Padilla and PAHO by Drs. Malhi Cho and Christophe Rerat.

The main topics addressed in the II Hemobrás Workshop were good practices, quality management, human resources management, audits, error management, and notification systems.

Meetings were held with the President of Hemobrás, Dr. Romulo Maciel Filho, to discuss matters of interest in cooperation with PAHO. In meetings with Dr. João Paulo Baccara Araújo, Blood and Components Manager (GESAC), the parties discussed the regulations governing voluntary blood donation in Brazil and the possibility of achieving 100% voluntary donations.

The participants agreed that this meeting represented an important step toward strengthening areas of cooperation between Hemobrás and PAHO in the region.

- **Launch of the Regional Virtual Course on Evaluation and Improvement of the Quality of Patient Care and Safety**



The Program on Quality of Care and Patient Safety of the Essential Medicines and Health Technologies Project (HSS/MT) has designed a Regional Virtual Course on Evaluating and Improving the Quality of Care and Patient Safety, to be offered through the PAHO Virtual Public Health Campus (VPHC). The official launch was held on August 18th, 2011.

The general objective of the course is to learn about and deepen understanding of the principles of quality in the health services, as well as prepare participants to be able to apply the concepts and methods of continuous improvement in their organizations. The participants are expected to be able to make decisions and prepare project and intervention options that can be used in their work environments.

This course has been developed thanks to the contributions of respected experts in the field of quality in the Region from Argentina, Colombia, Mexico, and Costa Rica. It is designed to impart knowledge about the conceptual and methodological underpinnings for quality improvement, as well as their practical application in all areas of the participants' organizations.

It is important to emphasize that this is a course with tutors in which 60 participants from 17 countries of the Region are registered.

Duration of course: 4 August - 8 December.

## **GENERAL OBJECTIVES**

1. Analyze the different concepts related to the quality of care and how they have evolved throughout history in sectors other than the health sector.

2. Design projects for quality improvement through the use of quality tools.
3. Reflect on the conceptual underpinnings and state of the art in patient safety.
4. Identify the various international models of quality and their application in health organizations.

Documents (Spanish):

 [Curso Virtual Regional de Evaluación y Mejora de la Calidad de la Asistencia y Seguridad del Paciente \(117.75 kB\)](#)

 [Sesión Inaugural del Curso \(2.17 MB\)](#)

- **Journalism Award Winners Focus on Drug Resistance in Latin America**

**Washington, D.C., August 17, 2011 (PAHO/WHO)** - Three journalists whose reports examine the underlying causes of antimicrobial resistance in Latin America won the 2011 Latin American Health Journalism Awards, sponsored by the Pan American Health Organization/World Health Organization (PAHO/WHO), Red-Salud, the Communication Initiative, and the Imaginary Foundation.

This year's contest honored journalistic reports that effectively explain the threat of growing resistance to antibiotics and other antimicrobial drugs and that analyze the most important causes of this resistance, with a focus on Latin America. The contest was launched on World Health Day 2011 and was intended to support its call for greater awareness of and action to combat the problem of antimicrobial resistance.

The winners of the 2011 Latin American Health Journalism Awards are:

**First prize: Pedro Lipcovich**, of Argentina, for "Revenge of the Germs," published in *Página/12*. Lipcovich's article examines trends in antimicrobial resistance in Latin America, especially in Argentina. He examines causes, including sales of antibiotics without prescriptions and inappropriate use by consumers, and reports on outbreaks of multi-resistant microbes in health centers. The article also cites partial but encouraging results of efforts by Argentina's health system to prevent resistance to drugs for HIV/AIDS and tuberculosis. The author is editor of the newspaper and serves as professor of journalism at the University of Jujuy.

**Second prize: Nicolas Maldonado**, of Argentina, for "Antibiotics: More than Half Prescribed are Unnecessary," published in *El Día*. The article reports what area

doctors themselves believe are the factors that contribute to antimicrobial resistance in the province of Buenos Aires. The author is an investigative reporter who focuses on health issues, scientific activity, and the environment.

**Third prize: Yetel Ricaño Noguera**, of Cuba, for her story “Antimicrobial Resistance: Behaviors that Harm, Troubles that Condemn,” published by Tiempo 21, the digital edition of Radio Victoria. Ricaño reports that in Cuba, free and accessible health services make it possible to request, start and stop treatment with antibiotics to an extent that creates undue reliance on these drugs. Ricaño writes online, manages social networks, and edits the English version of Tiempo 21.

The full texts of the articles and comments from the judges are available in Spanish at the [Red-Salud](#) [site](#).

The Latin American Health Journalism Awards seek to encourage Latin American journalists to increase the quality and coverage of health issues in the media. This year, 22 articles from some of the region’s major newspapers, magazines and websites qualified for the contest.

World Health Day 2011, celebrated on April 7, was dedicated to raising awareness of the problem of antimicrobial resistance, building commitment to finding common solutions, and promoting the implementation of policies and practices to prevent and contain antimicrobial resistance.

For more information see:

- [World Health Day 2011](#) (PAHO)
- [Red-Salud](#) (Spanish only)

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- **Pre-Evaluation Meeting of the Costa Rica Drug and Biologicals Regulatory Authority**



Representatives and officials from PAHO and the Ministry of Health of Costa Rica met in San José, Costa Rica from July 26th -29th, 2011, for a preevaluation of the Drug and Biologicals Regulatory Authority in that country.

During the meeting, the staff from the Costa Rican regulatory authority were trained in the procedures and use of the tool for the qualification of national drug and biologicals regulatory authorities used by PAHO for the naming of Regional Reference Regulatory Authorities. The participants also identified the current strengths and weaknesses of their regulatory authority.

The participants agreed to develop a strategic plan to strengthen national regulatory capacity. PAHO will provide the technical cooperation necessary for implementing the strategic plan.

- **Experts from the Drug Regulatory Authorities of Central America and the Dominican Republic participate in the Workshop on the Evaluation and Regulation of Biological and Biotechnology Medicines**



From 18 to 22 July 2011 the Workshop on the Evaluation and Regulation of biological and biotechnology drugs was held Antigua, Guatemala for the regulatory authorities of Central America and the Dominican Republic.

Workshop participants consisted of staff from the Ministry of Health of Costa Rica, El Salvador, Guatemala, Honduras, Panama, and the Dominican Republic responsible for evaluating and registering biological and biotechnology drugs. Consultants Juana Rodriguez, José Peña, and María Luz Pombo participated on behalf of PAHO.

The objectives of the workshop were to strengthen the regulatory capacity of the Central American countries and the Dominican Republic in terms of the evaluation and regulation of biologicals and biotechnology products; promote the sharing of experiences among the national regulatory authorities of the Region, disseminate the WHO recommendations on the principal functions in the regulation of medicines of biological origin, and promote the participation of the Central American countries and the Dominican Republic in harmonizing the regulation of biotechnology products through more active participation in PANDRH.

Nine practice-based workshops were held on the functions of a regulatory agency for biologicals, following the recommendations of the World Health Organization (sanitary registry, control, lot release, authorization and audit of clinical trials, inspection of good manufacturing practices, and post-marketing surveillance of biologicals).

The participants identified the strengths and challenges that they face at the regional level in implementing mechanisms for the regulation and evaluation of biological medicinal products. They also agreed to include the possibility of developing a Central American proposal for standards in the regulation of biological products.

- **Pharmaceutical Quality Control Laboratory in the Region of the Americas Considered an International Reference for United Nations Agencies**

July 14th, 2011—The Official Pharmaceutical Quality Control Laboratory of Belo Horizonte, Brazil has been prequalified by the World Health Organization (WHO) to serve as an international reference laboratory for United Nations agencies.

The Octavio Magalhaes Institute (IOM), which is part of the Ezequiel Dias Foundation (FUNED) of Belo Horizonte, Minas Gerais, Brazil, has satisfactorily completed all stages of the WHO prequalification program and has been added to the reference list of pharmaceutical quality control laboratories that WHO provides to United Nations agencies.

Four official control laboratories in our Region have now obtained this status. The Belo Horizonte laboratory now joins the official laboratories of Bolivia (CONCAMYT), Peru (CNCC), and Uruguay (CCCM) on the list.

International reference laboratories play an important role in monitoring the quality of pharmaceuticals procured through international organizations such as WHO, the PAHO Strategic Fund, the Global Fund, UNAIDS, UNICEF, the Red Cross, and the Clinton Foundation.

Obtaining WHO prequalification is a harmonized objective of all pharmaceutical control laboratories in the Region. The Medicines and Health Technologies Project (HSS/MT) of the Pan American Health Organization (PAHO/WHO) has been working for over 10 years to strengthen these laboratories.

Prequalification of the four laboratories in the Region of the Americas, as well as other laboratories throughout the world, is essential for ensuring access to medicines that meet uniform standards of quality, safety, and efficacy, especially for diseases that are a principal cause of concern for WHO, as are HIV/AIDS, malaria, and tuberculosis.

Prequalification of this laboratory was achieved in part through joint activities with PAHO in evaluating the laboratory's performance and technical support from the Pan American Network for Drug Regulatory Harmonization (PANDRH).

- **New Manual Available for Diagnostic Imaging in the Community**

The Pan American Health Organization (PAHO), in collaboration with Rotary District 6440, is making available online a new manual on diagnostic imaging for clinics and small hospitals. The online publication of the manual is tied to a pilot diagnostic imaging project in Guatemala being carried out jointly by the Ministry of Health of Guatemala, PAHO and Rotary Districts 4250 from Guatemala and 6440 from Northern Illinois.

The new manual has sections on site selection and survey, radiation safety, site preparation, film processing, digital alternatives and ultrasound. The manual includes general X-ray systems with a focus on the digital World Health Imaging System for Radiology (WHIS-RAD) an international standard supported by PAHO and WHO.

This manual is being made available online to support a pilot project in Guatemala involving the installation of a digital WHIS-RAD that employs Computed Radiography (CR) for digital processing. The Guatemalan project envisions placing 29 additional digital systems in Guatemala similar to the pilot site and will provide a base of experience for similar installations in Latin America and the Caribbean, and around the world. The project is jointly supported by Guatemala's Ministry of Health, PAHO, Rotary District 6440 and Rotary District 4250 from Guatemala.

The manual is authored by Dr. Phillip E.S Palmer and Dr. Gerald Hanson who worked for PAHO and WHO in the past in radiology and radiologic safety. Click [here](#) to read more.

- **Closure of the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH)**



The VI PANDRH Conference in Brasilia, attended by over 300 representatives of health regulatory authorities from 26 countries of the Hemisphere, professional associations, the pharmaceutical industry, civil society, and PAHO experts, came to a close on Friday, July 8, with the approval of a strategic orientations document. The main recommendations, which fall within the framework of PAHO Resolution CD50.R9, Strengthening National Regulatory Authorities for Medicines and Biologicals, are aimed at developing more effective cooperation among countries to guarantee, inter alia, the adoption and implementation of the different technical documents produced by the NRA.

After PANDRH's 14 years of operation, the authorities and experts agreed that it was time for the Network to take stock of its experiences and consider the direction its new priorities should take.

The recommendations contained in the document approved emphasize cooperation centered on measurable, high-impact results, a high-profile, greater collaboration among the different NRA, the preparation of a training and institutional development plan, and the prioritization of differentiated activities. The principal needs are: implementing the different regulatory functions and addressing the wide range of national contexts in the Region of the Americas. The new cooperation process will be coordinated by PAHO in a manner that is always inclusive.

Finally, an effort will be made to work in even more synergistically to link the work with other regional regulatory initiatives, strengthening mechanisms for communication and information management among the NRA to facilitate decision-making process.

- **Opening of the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH)**

Last Wednesday, July 6th, 2011, the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) opened at the headquarters of Brazil's National Health Surveillance Agency (ANVISA) in Brasília. The theme of the Conference was Strengthening National Regulatory Authorities in the Context of Health Systems.

The Conference opened in the presence of high national public health authorities and PAHO officials, with over 300 participants from 26 countries of the Americas in attendance. This conference was an important venue for national authorities, experts, and representatives of the pharmaceutical industry and PAHO/WHO to share their views about regulatory issues of great import in public health, searching for strategies to advance drug regulatory harmonization in the Region of the Americas.

The topics addressed on the 1st day of the Conference included the role of PANDRH as coordinator of international cooperation, PAHO's recognition of national regulatory reference authorities (ANMAT-Argentina, ANVISA-Brazil, INVIMA-Colombia, and CECMED-Cuba), implementation of the PANDRH guidelines in the subregions, and innovative activities of the national regulatory agencies (NRA) in surveillance or treatment compliance, as well as the papers and other documents produced by the PANDRH Working Groups on Good Laboratory Practices, Biotechnology Products, Drug Registration, and Counterfeit Drugs. In addition, Dr. Isabela Ribeiro, Coordinator of the DNDI (Drugs for Neglected Diseases Initiative) in Brazil, gave a presentation on the challenges in regulation and neglected diseases.

The plenary Sessions were retransmitted by videocast and are available online at the following link: [www.saude.gov.br/emtemporeal](http://www.saude.gov.br/emtemporeal)

- **Preparations Continue for the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH)**

The VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) will be held in Brasilia, Brazil, from July 6-8, 2011. This important meeting, whose theme is Strengthening National Regulatory Authorities in the Context of Health Systems, will be held at the headquarters of the National Health Surveillance Agency (ANVISA).

This Conference offers PAHO Representatives, national authorities, and global experts a valuable opportunity to share opinions about issues that have a significant health impact as they search for strategies that will make it possible to advance drug regulatory harmonization in the Region of the Americas.

The specific topics that will be addressed are the strengthening of national regulatory authorities, international cooperation, implementation of the CPANDRH guidelines in the subregions, nanotechnology, biotechnology products, drug surveillance, and the rational use of drugs.

Attached please find the agenda, documents, and logistics for this meeting.

- [PANDRH website](#)
- [ANVISA website](#)

- **PAHO AND ANVISA Agree to Strengthen Important Aspects of Cooperation**

With the object of analyzing important aspects of cooperation between PAHO and the National Health Surveillance Agency (ANVISA), the Director of PAHO, Dr. Mirta Roses Periago, and the Director of ANVISA, Dr. Dirceu Barbano, met on Monday, June 27th, 2011 at PAHO Headquarters in Washington, D.C. to discuss such matters as the regulation of biologicals, international health surveillance, quality in care, and patient safety.

Dr. Barbano noted that PAHO's selection of ANVISA as co-organizer of the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) is highly significant, since the event constitutes recognition for ANVISA's role as the health products surveillance institution. The discussions included a proposal that ANVISA become a PAHO/WHO Collaborating Center and exploration of the possibility of establishing the Regional Observatory on Quality and Patient Safety in Brazil.

The VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) will be held in Brasilia, Brazil, from 6 to 8 July 2011 to promote the harmonization of

pharmaceutical regulations, which cover all aspects related to the quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the member countries of the Hemisphere. Dr. James Fitzgerald and Dr. Malhi Cho participated as representatives of the Essential Medicines and Health Technologies Project (HSS/MT).

- **Dr. Caroline Chang of ORAS-UN Meets with PAHO Experts to Discuss the Possibility of Joint Action on Medicines**

On June 29th, 2011, Dr. Caroline Chang, Executive Director of the Andean Health Agency–Hipólito Unanue Agreement (ORAS-CONHU); Dr. Ricardo Cañizares, Deputy Director of ORAS-CONHU; and several experts from the Pan American Health Organization, among them Dr. Nelly Marín Jaramillo, Regional Adviser on Pharmaceutical Policy, and Dr. José Luís Castro, Adviser on the Rational Use of Medicines, met to discuss activities in the field of pharmaceuticals of interest to that Agency.

Information on the operational aspects of the procurement processes under way for the Andean Subregion through the Strategic Fund (SF) was updated and explained, and it was reiterated that PAHO procures only strategic health supplies found on the list of the SF.

Other matters of interest brought up by Dr. Chang were: the importance of exploring the possibility of creating an effective financing fund that would permit subsidized drug procurement, especially for expensive products; the feasibility of the public-sector manufacture of medicines and strategies to achieve it; ORAS-PAHO coordination in joint cooperation activities, such as offering training in medicines surveillance and pharmaceutical services and sharing information at the next Pan American Conference on Drug Regulatory Harmonization on any agreements reached.

- **Launch of the Network for Health Technology Assessment (REDE TSA)**

Brazil.- Saturday, June 25<sup>th</sup>, 2011. Within the framework of the Annual HTAi Meeting in Rio de Janeiro, Brazil, the Network for Health Technology Assessment for the Americas, (REDE TSA) was launched. At PAHO's urging, eleven countries of the Region (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Paraguay, Peru, and Uruguay) agreed to launch REDE TSA in which subregional integration blocs (MERCOSUR, the Andean Region), PAHO/WHO collaborating centers (CENETEC, University of Ottawa, IEB), and experts in health technology assessment (HTA) and public health (IECS) would be represented.

The Network's mission will be to promote and strengthen HTA through regional exchanges, and to serve as a tool that supports decision-making regarding the incorporation, dissemination, and use of technologies, while taking into account the

contexts of the health systems at the country level, thereby expanding equitable access.

The Network was launched during a formal ceremony led and supported by Brazilian authorities, HTAi, representatives from other countries, and PAHO. The REDETSA launch was recognized as a major milestone in improving the efficiency and equity of health systems in the Region during the official opening of HTAi in Rio. REDETSA defined its own work agenda, taking into account the prior accomplishments of subregional mechanisms and member countries in the network, which will help guide and make medium- and long-term activities more dynamic.

- **PAHO Executive Committee Discusses Implementation of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property**

The Executive Committee of the Pan American Health Organization (PAHO) met for the third consecutive day of deliberations on Wednesday, June 22<sup>nd</sup>, 2011. One of the subjects discussed was Implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. Dr. James Fitzgerald, Coordinator of the Project on Medicines and Health Technologies (HSS/MT) of PAHO, began his remarks by mentioning the technical cooperation activities carried out with the countries as part of this strategy.

In addition, Dr. Fitzgerald emphasized that the countries of the Region of the Americas have taken part in developing an access, innovation, and intellectual property strategy at the international level and emphasized that the project has made advances in the joint purchases of essential drugs using the Strategic Fund. He also mentioned the importance of strategic cooperation, transparency, and exchange of information on drug prices among countries.

Dr. Fitzgerald highlighted that the Regional Proposal on the Rational Use of Medicines was launched in April 2011 during World Health Day, and that the Network for Health Technology Assessment in the Americas was formed in 2010, which will make it possible to strengthen capacities and exchange resources, thereby achieving consensus at the regional level on the selection and use of these inputs.

Other initiatives mentioned included: technology transfer to prepare flu vaccines in the Region of the Americas, creation of a regional platform for health access and innovation, and preparation of an intellectual property conceptual framework applied in 12 countries.

In turn, representatives from Argentina, Mexico, Peru, and Venezuela emphasized their commitment to continue working hard on the right to and access to and rational use and quality of essential drugs for the most vulnerable populations, and voiced their continued concern that manufacturing companies refuse to offer medicines at accessible costs.

In closing, the Director of PAHO, Dr. Mirta Roses Periago, expressed the commitment and mechanisms the countries need to implement to have a positive impact on joint price negotiations and emphasized the importance of involving the academic field and the universities in national production.

- **Designation of CONAMED as a PAHO/WHO Collaborating Center on Quality of Care and Patient Safety**

Mexico, June 2011. The National Commissioner of the Comisión de Arbitraje de Médico (CONAMED) or National Medical Arbitration Commission, Germán Fajardo Dolci, and the PAHO/WHO representative in Mexico, Dr. Philippe Lamy, reached an agreement in June 2010 to begin work together to designate CONAMED as a World Health Organization Collaborating Center.

The result of these efforts was successful, and, after the requirements had been met, the WHO Director-General, Dr. Margaret Chan, approved in June 2011 the designation of CONAMED as a Collaborating Center on Quality of Care and Patient Safety. The terms of reference and work program agreed upon with CONAMED in its capacity as a Collaborating Center focus on two interventions:

The first is to collaborate with WHO/PAHO in order to develop and use systems for notification and registry of incidents in health institutions for purposes of patient safety as well as research and education, in accordance with Resolution WHA 55.18 of 2002, by means of the following actions:

- Design tools to facilitate registry of safety incidents, based on the International Classification for Patient Safety;
- Disseminate the knowledge gained from using these tools in the incident notification systems for the purposes of learning and research;
- Design methodologies to use the information generated through notification of incidents for the purposes of learning and implementation of safe practices;

The second is to share with PAHO/WHO member countries mediation techniques in order to settle disputes between patients and service providers, for the purpose of improving the quality of care and patient safety, in accordance with Resolution CSP.27R10 of 2007:

- Develop and apply dispute settlement techniques between patients and service providers in order to improve the quality of care and patient safety;
- Generate knowledge about the factors that contribute to disputes in medical care, the impact of these disputes on patients, economic consequences, and the epidemiological profile, in order to formulate recommendations to help improve the quality of care and patient safety;
- Disseminate knowledge and training on the use of mediation techniques in settling disputes between patients and health care providers, in order to prevent conflict and improve quality of care and patient safety.

Since its creation in 1996, CONAMED has been in ongoing collaboration with PAHO/WHO, within the framework of the agreements of the Meeting of Ministers of Health of Central America and the Dominican Republic (RESSCAD), the Central American Integration System (SICA), the Council of Central American Health Ministers (COMISCA), the Puebla-Panama Plan, and other technical cooperation projects among countries. Within this framework, CONAMED has provided advisory services and conducted technical exchanges with the Ministries of Health of Argentina, Costa Rica, Chile, Guatemala, and Peru, among others.

The designation of CONAMED as a Collaborating Center enriches the network of specialized centers whose mission is to look for appropriate and effective mechanisms to improve the quality of care and patient safety, which is so necessary today in the health systems of the Region of the Americas.

- **Essential Medicines and Health Technologies Project Team receives PAHO Outstanding Team Award**

This June 17th the Pan American Health Organization (PAHO) will hold its Staff Awards Ceremony. The Outstanding Team Award will be conferred at this ceremony. The Essentials Medicines and Health Technologies Project, like other teams, has been recognized with this award.

For many years, the HSS/MT Project has provided technical cooperation to the Latin American and Caribbean countries to support access to quality health technologies and medicines to ensure their rational use.

In addition, the HSS/MT's team of specialists has promoted and developed strategies for cooperation with the countries of the Region for the development, implementation, and evaluation of policies and tools to improve supply systems, develop regulations and standards that promote the efficient use of medicines for the neediest populations, and strengthen regulatory capacity in the countries.

- **VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH)**

The VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) will take place in Brasilia, Brazil July 6-8, 2011.

The official link for PANDRH website is: [www.paho.org/pandrh](http://www.paho.org/pandrh)

On PANDRH website you can find:

- Definition of the Pan American Network for Drug Regulatory Harmonization and documents of previous conferences
- Information about the VI Conference: Agenda, Preliminary Program and Logistics
- Public Consultations elaborated by PANDRH Working Groups
- Publications

- **Nicaragua is Second Latin American Country to Achieve 100% Voluntary Blood Donation**

Washington , D.C., 14 June 2011 (PAHO/WHO)-Nicaragua has accomplished what only one other Latin American country-Cuba-has achieved: a blood supply based 100 percent on voluntary, altruistic blood donors. Today, on World Blood Donor Day 2011, the Pan American Health Organization/World Health Organization (PAHO/WHO) cited Nicaragua as a model to follow.

"We know from evidence that voluntary, altruistic and repeated blood donation is the best way for countries to ensure a safe and sufficient blood supply," said PAHO Director Dr. Mirta Roses. "Nicaragua's experience is an inspiration for other countries working toward this goal."

In Latin America and the Caribbean, only one in three blood units is collected from voluntary, altruistic donors. The remainder comes almost entirely through "family replacement" donations, in which family members or friends are recruited to donate blood before a patient undergoes a medical procedure.

PAHO/WHO data show that blood-borne pathogens such as HIV and hepatitis are much more common in blood from paid and replacement donors than in blood from purely altruistic donors. Research suggests this is because paid and family donors are less likely to admit risky behaviors than people whose only motivation is to provide "the gift of life."

Worldwide, the number of countries that obtain 100 percent of their blood supplies from voluntary, altruistic donors increased by 50 percent between 2002 and 2008, according to WHO. In Latin America, however, only two of 20 countries have been able to secure enough altruistic donations to maintain a steady and sufficient blood supply.

Nicaragua's achievement was the result of a six-year effort by the Ministry of Health and the National Red Cross to strengthen, consolidate and increase the safety of the country's National Blood Service, using €5.9 million in support from the Grand Duchy of Luxembourg. A reorganization effort reduced the number of blood banks from 26 to only two, plus three collection centers, while a mass communication campaign helped increase voluntary donations from fewer than 40,000 units in 2005 to nearly 75,000 units in 2010.

Today, Nicaragua's two blood banks provide fully screened blood and blood products to more than 60 health units across the country.

"This achievement would be remarkable even in a larger, wealthier country," noted Dr. José Ramiro Cruz, PAHO's top expert on safe blood supplies. "That a small country, with only 6 million people, could succeed in this way shows that it should be possible for others to follow suit."

Countries throughout Latin America and the Caribbean are working with support from PAHO/WHO, IFRC, the International Society of Blood Transfusion (ISBT), and the International Federation of Blood Donor Organizations (IFBDO) to increase the safety and sufficiency of blood supplies through screening and increased voluntary, altruistic blood donation.

Noteworthy achievements by other countries of the Region include:

- Canada, Cuba, the Cayman Islands, the Netherlands Antilles, Suriname, and the United States all rely entirely on voluntary, altruistic donors for their blood supplies.
- Argentina, which is hosting the global launch of this year's World Blood Donor Day, has increased voluntary blood donations from 6 percent in 2007 to 28 percent in 2010 and has set a target of reaching 1 million voluntary donors by the end of 2011.
- Over 99.9 percent of blood units collected in Latin America and the Caribbean are screened for HIV, hepatitis B and C, and syphilis. Some 96.5 percent of units are screened for *t. cruzi*, the parasite that causes Chagas' disease.
- In Latin America and the Caribbean, some 9 million people donated blood in 2010.

World Blood Donor Day, observed each year on June 14, recognizes people around the world whose voluntary donations help ensure sufficient, safe and equitable

supplies. Their contributions are essential to ensuring that every patient has access to blood when he or she needs it.

"We cannot just recruit blood donors," said Dr. Cruz. "We also must provide them with quality and caring treatment to ensure that they remain healthy and continue to give blood voluntarily for many years to come."

PAHO was established in 1902 and is the world's oldest public health organization. It works with all the countries of the Americas to improve the health and quality of life of their peoples, and also serves as the Regional Office for the Americas of the World Health Organization (WHO).

Links:

- [World Blood Donor Day 2011 \(PAHO/WHO\)](#)
- [Argentina hosts the global launch of World Blood Donor Day](#)
- [PAHO/WHO Blood Services website](#)
- ["Gift Blood is the Safest Blood," Perspectives in Health magazine](#)

- **Consultation on the Guide to Pharmaceutical Services in Primary Health Care**

Washington, DC.- June 2011. The Pharmaceutical Services (PS) Based on Primary Health Care (PHC) initiative began in late 2008 as one of the activities promoted by the Pan American Health Organization (PAHO) to strengthen health systems in the Americas. (Click [here](#) to read the document in Spanish)

As part of this initiative, a draft Guide to Pharmaceutical Services in Primary Health Care was prepared with a new individual-, family-, and community-centered approach in which medicine is one of the essential elements, but not the only one.

The purpose of this Guide is to provide orientation to the countries of the Region on implementation of PHC-based pharmaceutical services. It can be used by the ministries and departmental or state health secretariats, academia, and NGOs, as well as all civil society organizations that are working in the field of PHC with the renewed vision proposed by PAHO/WHO. Persons interested in participating in the consultation can access the site

<http://www.surveymonkey.com/s/PLG5RKB>, complete the survey, and then click on “ready” to send it.

Consultation period: until 30 July 2011.

- **President Chinchilla of Costa Rica Visits PAHO**

Washington, D.C., May 20<sup>th</sup>, 2011 (PAHO/WHO) - President Laura Chinchilla Miranda of Costa Rica visited the Pan American Health Organization/World Health Organization (PAHO/WHO) on May 19, accompanied by a delegation of Costa Rican diplomats and government officials, to exchange ideas on technical cooperation related to biotechnology investments.

In meetings with PAHO/WHO Assistant Director Dr. Socorro Gross, PAHO/WHO Deputy Director Dr. Jon Andrus, and technical experts from the Organization, President Chinchilla thanked PAHO/WHO for its cooperation and expertise-sharing with Costa Rica, particularly in areas such as social protection.

Please click [here](#) to read more.

- **Meeting of the Strategic Fund Working Group**

On May 12<sup>th</sup>, 2011, a meeting of the Strategic Fund (SF) Working Group was held, attended by specialists from the Essential Medicines and Health Technologies Project (HSS/MT) and PAHO/WHO subregional advisers, as well as several experts and technical staff.

SF Coordinator Dr. Nora Girón Aguilar reported on the achievements of the Strategic Fund and the challenges that it faces, outlining the 2011 Work Plan. She also mentioned the technical cooperation provided to the Member States in the formulation and execution of policies to increase equitable access to quality essential drugs, diagnostic media, and other supplies for the prevention and treatment of HIV/AIDS, tuberculosis, and malaria.

In his intervention, Dr. Malek Sbih explained the communication strategy to be implemented to encourage the countries of the Americas to use the Strategic Fund for drug procurement through PAHO. He also noted the importance of developing and continually updating a database with complete information on all products that can be procured through the Strategic Fund and its suppliers.

Dr. Victoria de Urioste, Andean Subregional Adviser on Essential Medicines and Health Technologies, discussed the price observatory of the Andean Community of Nations, noting the advantages that it offers in terms of reducing the cost of drug procurement. She also presented the proposal for procuring diagnostic reagents through the Strategic Fund, based on a single generic list and quality criteria for the reagents.

The participants agreed to meet quarterly to discuss the progress made on the Strategic Fund.

- **Global Annual Campaign to Improve Hand Hygiene**

On May 5th 2011, World Hand Hygiene Day was observed. Many countries in Latin America, the Caribbean, and the rest of the world affirmed their commitment to improving quality and patient safety through campaigns to raise awareness about improving hand hygiene. The SAVE LIVES: Clean your Hands Initiative was launched by the WHO Patient Safety Program as a part of the Clean Care is Safer Care Program.

The PAHO website, specifically the page of the Quality of Care and Patient Safety unit of the HSS/MT project, contains informative material, posters, and videos on this important event. Click [here](#) to see the page.

- For more information on WHO activities, visit:

<http://www.who.int/gpsc/5may/background/es/index.html>

<http://www.who.int/gpsc/5may/es/index.html>

- **Meeting of the PANDRH Steering Committee.** Bogotá, Colombia, April 28th - 29th, 2011

This meeting was attended by representatives from ALIFAR, ALBA, INVIMA, MERCOSUR, PAHO, and other organizations. The focus of the VI Conference will be the role of the authorities in the health systems with bodies for round table discussions. A agenda has been approved calling for the creation of several panels, the holding of workshops, and presentations by the working groups on important emerging issues and new regulatory agency projects.

The specific issues that will be taken up by conference include strengthening of the NRA, international cooperation, implementation of the PANDRH guidelines in the subregions, information systems, communication, transparency, and future challenges for PANDRH.

In addition, on April 29<sup>th</sup>, INVIMA and MPS authorities met to discuss the accreditation processes of the aforementioned NRA, their importance, the challenges for Colombia, and WHO prequalification of pharmaceutical control laboratories under the United Nations Program

The participants recommended holding the next meeting before 2012 at INVIMA's Pharmaceutical Control Laboratory to verify compliance with good laboratory practices and evaluate the request for WHO prequalification.

- **Pan American Health Organization: Triangular Cooperation for Pharmaceutical Quality Control**

The “South-South Opportunity” website published an notice on April 28<sup>th</sup>, 2011 explaining that under the memorandum of understanding signed between the Argentine Government, through the Argentine Horizontal Cooperation Fund (FO-AR), and PAHO/WHO, technical personnel from Argentina’s National Institute of Medicines (INAME/ANMAT) will train health personnel from the Dominican Republic to improve pharmaceutical quality control and buttress the regulatory functions of that country’s health authority.

The item explains that the technical cooperation project is designed to improve the work of the Dominican drug regulatory authority in the quality management system, which analyzes active pharmaceutical ingredients to demonstrate that reliable results are obtained.

In addition, it will help this agency to obtain WHO prequalification as a reference laboratory, which will give Caribbean countries that request its services better access to quality products approved for drug procurement by international bodies.

For the news published on the PAHO-Argentina website click [here](#) (Spanish only)

South-South Oportunity click [here](#) (Spanish only)

- **1st Thematic Workshop on the Regulation of Analysis Laboratories involved in Health Surveillance.** Brasilia, Brazil, April 25th-26th, 2011

This workshop was attended by experts from different departments of ANVISA and PAHO/WHO Representatives and enabled the participants to discuss the regulation of analysis laboratories involved in health surveillance and the role of Brazil’s REBLAS.

The meeting was also attended by representatives from international organizations (OECD, FDA, PAHO/WHO, and EMA) as well as national entities (Inmetro, Brazilian Pharmacopeia, INCQS, CGLAB, and a public laboratory) with experience in the implementation of guidelines for good laboratory practice in the regulation of analysis laboratories.

Dr. José María Parisi, PAHO Specialist in Quality Assurance and Safety of Pharmaceuticals, discussed the objectives and function of the institution, the objective and scope of WHO Good Practices for Pharmaceutical Quality Control Laboratories. GLP Self-evaluation Guide and the importance of its implementation.

At the conclusion of the meeting, the experts agreed to hold the next meeting at ANVISA to finish the structural guidelines for REBLAS network.

- **18th International Conference on Medical Physics**

The 18th International Conference on Medical Physics was held in Porto Alegre, Brazil, April 17th - 20th, 2011. Organized by the International Organization for Medical Physics (IOMP), the Latin American Association of Medical Physics (ALFIM), and the Brazilian Association of Medical Physics (ABFM), its purpose was to discuss current scientific issues in diagnostic imaging and radiation therapy, as well as aspects of professional certification in medical physics, problems not yet solved in the Region.

Dr. Pablo Jiménez, Regional Adviser of the HSS/MT Radiology and Radiation Protection Program, participated in the session, “Review of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS),” giving a presentation on the process and current status of the review, an introduction on the Standards, and the specific responsibilities assigned to governments, regulatory authorities, and the principal parties involved in medical exposure.

At the special IOMP/WHO/ALFIM/PAHO joint session on Health Technology: Strategies to Improve Access to Safe, Effective, and Appropriate Medical Devices, Dr. Jiménez, representing in PAHO, gave a presentation on the WHO Global Initiative for Health Technologies and the Outcomes from the 1st Global Forum on Medical Devices.

It is recommended that support be provided for regional and global scientific events in the Region on this topic to update information, share knowledge about medical physics in Latin America and the Caribbean, and identify areas and mechanisms for providing PAHO technical cooperation.

For more information on the Conference click [here](#).

- **Stage 2 of the Argentina-Dominican Republic South-South Cooperation Project financed by the Argentine Horizontal Cooperation Fund**

With the object of evaluating the performance of the Argentina-Dominican Republic South-South Cooperation Project financed by the Argentine Horizontal Cooperation Fund (FOAR), a meeting was held on April 11<sup>th</sup>, 2011 at the PAHO Representative Office in Argentina with representatives from ANMAT and PAHO experts from the local level and Washington, D.C.

Given the success of the first two stages of the project, the participants agreed to promote cooperation in this area with Ecuador, Jamaica, and Paraguay during the second half of 2011 through 2012, under the project being developed for CARICOM, in coordination and consultation with the PAHO Representative Offices in the countries.

From 12 to 15 April, Stage 2 of the Technical Cooperation Project for Strengthening Quality Control of Medicines by the Dominican Republic's LNSP was held. The participants included specialists from the Dr. Defilló Laboratory and professional staff from INAME, who provided important training in microbiological assessment of antibiotics and bacterial endotoxins. It is important to point out that the reagents and materials used in the training sessions were provided by PAHO.

Stage 3 of the current Project will be carried out in the Dominican Republic from 6 to 10 June 2011.

- **World Blood Donor Day 2011**

We are pleased to announce that a section on this year's World Blood Donor Day, which will be held in Argentina, is available on the PAHO website. The global theme for the Region of the Americas in 2011 is "MORE BLOOD DONORS, MORE HEALTHY LIVES".

- [Webpage in Spanish](#)
- [Webpage in English](#)

- **Ministers of Health approved Caribbean Pharmaceutical Policy**

The Caribbean Pharmaceutical Policy (CPP) was approved by the CARICOM Ministers of Health at the 21<sup>st</sup> Council for Human and Social Development, held April 15-16, 2011 in Georgetown, Guyana.



The objective of the Caribbean Pharmaceutical Policy is: "to offer guidance to the Caribbean countries to ensure equitable access, quality, and the rational use of

medicines. The Council also approved the mechanism for overseeing the application and assessment of policies, including the establishment of the Expanded Technical Advisory Group on Pharmaceutical Policy (TECHPHARM).

The policy has been developed within the framework of the Caribbean Cooperation in Health Initiative, CCH III, approved by the Ministers of Health in 2009. The Caribbean Pharmaceutical Policy is based on the conclusions and recommendations of the CARICOM Regional Assessments of Drug Regulatory and Registration Systems and of Patent and Related Issues and Access to Medicines, as well as the PAHO/WHO assessment of the pharmaceutical situation in the Caribbean, all of which cover the CARICOM countries and the Dominican Republic.

Technical support for this process was provided by PAHO/WHO and the CARICOM Secretariat, with financial support from the European/ACP/WHO Partnership on Pharmaceutical Policies for the African, Caribbean, and Pacific Island countries. Implementation will be a shared responsibility of the national health authorities, with the participation of the pertinent Caribbean institutions and technical support from the CARICOM Secretariat and PAHO/WHO.

Click [here](#) to find more information about the meeting.

- **Launch of the “Master Catalog of Clinical Practice Guidelines” in Mexico**

Mexico, April 2011. – With a view to improving decision-making in clinical management and supporting a more integrated and unified health sector, the Secretariat of Health of Mexico, through the National Center for Health Technology Excellence (CENETEC), has made available to national specialists 319 sectoral clinical practice guidelines prepared by more than 1,600 experts from the Mexican national health system.

“Over the past two decades a wide range of evidence has been assembled on the practice of medicine. This means that developing evidence-based health care requires a strategic plan—based on well thought-out clinical practice, critical reading of the health literature, and development of skills—in order to compile, analyze, and apply the best available information in a timely, valid, and scientific manner to help improve the quality and safety of health services using the most effective public health strategies as resources permit. The Clinical Practice Guidelines...are a tool for implementing public health policies whose basic objective is to achieve universal access to safe and effective people, family, and community-based health services.”

– Dr. Maki Esther Ortiz Domínguez, Undersecretary for Integration and Development of the Health Sector

<http://www.cenetec.salud.gob.mx/interior/gpc.html>

The guidelines were developed to pull together evidence and recommendations on the most common pathologies in Mexico. They discuss tools for standardizing criteria and procedures for prevention and the diagnosis, treatment, and rehabilitation of patients in a context of multiple service providers, where the main objective is to safeguard the quality of care and the effectiveness of clinical procedures.

The Master Catalog of Clinical Practice Guidelines contains 160 guidelines for internal medicine, 69 for surgery, 41 for pediatrics, and 41 for obstetrics/gynecology. The goal is for the catalog to serve as a national reference guide that supports clinical and managerial decision-making based on recommendations that draw on the best available evidence, in order to optimize the homogeneity, effectiveness, safety, and efficiency of medical care.

It is important to emphasize that in 2009, CENETEC was designated a PAHO Collaborating Center and looks to be a strong contributor in the field of health technology management and assessment at both the national and international levels.

Through Mexico's National Development Plan and Sectoral Health Program, the Bureau for Health Sector Integration and Development, working through CENETEC, implements strategies to make quality part the permanent agenda of the national health system.

Click [here](#) for more information on the Master Catalog.

- **Launch of the Regional Proposal on the Rational Use of Medicines during the celebration of World Health Day**

Washington, D.C. April 7<sup>th</sup>, 2011. This year, the annual celebration of World Health Day focused on combating antimicrobial resistance. As part of the activities, the approved regional proposal for implementing national strategies on the rational use of medicines was presented during the roundtable discussions, with a view to disseminating a comprehensive innovative proposal in the Region.



The panel was introduced and moderated by Dr. José Luis Di Fabio, Area Manager, Health Systems based on Primary Health Care (HSS), and Dr. Perla Mordujovich de Buschiazso, Director of the University Pharmacology Center (CUFAR), a PAHO/WHO Collaborating Center for Problem-based Pharmacotherapeutics Education at the School of Medical Sciences in La Plata, Argentina.

During her presentation, Dr. Mordujovich stated that the pilot phase of this proposal was launched in Nicaragua and Bolivia in 2010 and that support for its implementation was recently requested by the ministries of health of Chile and Guatemala as well. She also noted that while the rational use of medicines has been debated for over 30 years, the action taken in this respect has had very little impact.

Dr. Mordujovich also indicated that the proposal has a key element: a coordinating body headed by the ministry of health that promotes more integrated programs for the rational use of medicines in the countries. She urged the countries of the Region to adopt the proposal and put it into effect through their drug policies.

Dr. James Fitzgerald, Coordinator of the Medicines and Technologies Project (HSS/MT), gave a presentation on the regional proposal for the implementation of a

national strategy for the rational use of medicines, defined as a situation in which “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” WHO 1985.

Dr. Fitzgerald also provided information on the improper use of antibiotics in the Americas and stated the objective and principal lines of the strategy, mentioning the implementation of the rational use strategy in Nicaragua.

Dr. Guillermo González, Social Planning Adviser to the Office of the President of Nicaragua and former Minister of Health, reiterated his government’s commitment to combating antimicrobial resistance and promoting the rational use of medicines, underscoring the view of medicines as a social good. He stated, moreover, that action should be taken in science and clinical practice to develop a good strategy for the rational use of medicines, commenting on the design of the strategic plan based on the PAHO/WHO proposal that was adopted in Nicaragua, and calling for policies to establish where funding should be directed. He also noted the importance of out-of-pocket expenditure and the launch of the plan for the rational use of medicines, beginning with pharmacovigilance activities that will enable governments to support rational use.

Dr. Ludwig Ovalle, Minister of Health and Social Welfare of Guatemala, mentioned Guatemala’s strategic plan to promote equity and citizen participation in access to quality medicines, stating that in 2010 Guatemala had requested support from PAHO/WHO to implement the strategy.

Another expert in this field, Dr. María Teresa Valenzuela, described the legislation and policies supporting the rational use of medicines and a number of documents, noting the irrational use of antidepressants and antibiotics in the population before the regulatory tool was adopted. She touched on the role that reference laboratories play in combating antimicrobial resistance and reiterated that Chile’s health system reform marked the beginning of a strong commitment to rational use.

Finally, Dr. Mordujovich concluded the activity, predicting that the strategy will require a major effort in the countries of the Region to ensure that the population receives treatment consistent with the definition of rational use; that is, treatment that is safe, effective, and at the lowest possible cost.

- **World Health Day Roundtable on “Antimicrobial Resistance: A Hidden Burden”**

Washington, DC, April 7<sup>th</sup>, 2011 – Dr. Orlando Urroz, Assistant Director of the Costa Rican Social Security Fund Children’s Hospital and Chief of Costa Rica’s National Program for Quality, participated in the roundtable on “Antimicrobial Resistance: A Hidden Burden” as part of World Health Day.

During his presentation, “Prevention of Antimicrobial Resistance in Health Care Centers,” Dr. Urroz explained the importance of promoting awareness and education among patients and health personnel about cost-effective measures to reduce the transmission of infections in communities and hospitals. Dr. Urroz also pointed out that the Ibero-American Study of Adverse Events in Hospitalized Patients (IBEAS) provided evidence that hospital infections, regardless of their severity, are the region’s most common adverse event and are preventable in more than 50% of cases.

Among the strategies that can be adopted to reduce hospital infections is the Global Patient Safety Challenge, launched by the World Health Organization. The initiative’s theme is “Clean Care Is Safer Care.” This effort has drawn attention to involving countries in national campaigns and to the large amount of materials available to maintain and/or revitalize these campaigns by adopting and adapting them to specific circumstances on the ground.

- **Andean Ministers of Health adopt a Resolution on Access to Medicines and Pharmacovigilance**

During the XXXII Regular Meeting of Ministers of Health of the Andean Area, held in Santiago, Chile on April 1<sup>st</sup> 2011, the resolution “Access to Strategic Medicines and Pharmacovigilance” was adopted, urging the countries to move forward as a bloc in pharmaceutical matters. It called on them to consolidate subregional needs and arrange for the joint procurement of medicines through the Strategic Fund of the Pan American Health Organization, given the operational and competitive advantages that the Fund has offered in recent years, assisting governments with the management of strategic public health supplies, especially for costly, neglected, or catastrophic diseases.

In the same context, the Subregional Technical Committee for the Policy on Access to Medicines also presented the Andean Price Observatory to the ministers, who recognized its value and issued instructions for its immediate implementation as a mechanism for transparent public management of information on drug prices in the member countries of this subregional initiative, with the Andean Health Organization (ORAS-CONHU) charged with ensuring its sustainability.

At the same time, the decision was made to launch an Andean Pharmacovigilance Program aimed at improving information on drug safety, with a focus on strengthening technical capacity in the countries, promoting reporting and the development of subregional communication networks, and optimizing use of the available information. This strategy is based on the guidelines of the Pan American Network for Drug Regulatory Harmonization and includes technical assistance from the Pan American Health Organization and ORAS-CONHU.

- **Update on the situation in Japan**

PED and HSS/MT held an Elluminate session on March 30<sup>th</sup>, 2011 to update PWRs, Technical Area Managers, and EXM on the emergency in Japan and its repercussions in the Region.

In his introductory remarks, Dr. Jean-Luc Poncelet, PED Manager, stated that while the situation poses no danger to the Americas at this time, it is a good opportunity to address concerns about the risks posed by the current nuclear emergency and preparedness in the countries.

Dr. Leonardo Hernández, EOC Chief, followed with an update on the situation in Japan in the aftermath of the earthquake and subsequent tsunami.

Dr. Pablo Jiménez, HSS/MT Regional Advisor to the Program on Radiological Health, described the nuclear situation in Japan, indicating that while dangerous radiation levels are not anticipated in the Region of the Americas at this time, continued monitoring of the situation is necessary.

Finally, participants from several countries joined in a Q& A session.

The recording is available [here](#)

- **New category, Platform for Regulations and Processes, in the Medicines and Technologies SharePoint**

With the goal of disseminating, sharing, and systematizing information for the Regional Platform for Access and Innovation for Health, especially with respect to the Regulatory Indicators of the Pilot Countries, the Medicines and Technologies Area (HSS/MT) of PAHO created a space on SharePoint known as the Platform for Regulations and Processes—MT. We invite all professionals to learn about this new area.

[Link SharePoint MT](#)

- **Suriname Pharmaceutical Country Profile 2010 available on the WHO website**

Suriname's Pharmaceutical Country Profile, prepared by the Ministry of Health of Suriname with support and technical assistance from the Pan American Health Organization/World Health Organization, is available on the WHO website.

This document contains information on the structures, processes, and results of Suriname's pharmaceutical sector. Some of the data are taken from global sources such as the World Health Statistics Division and from surveys conducted in previous years, in addition to information compiled at the country level for the year 2010.

Click [here](#) to see the document

- **Meeting to Assess the Virtual Course on Pharmaceutical Services based on PHC**

A meeting to assess the course on pharmaceutical services based on primary health care (PHC) was held from March 23rd and 25th, 2011 in Rio de Janeiro, Brazil. The course had been offered in 2010 at the headquarters of the Helio Fraga Institute's Reference Center at the FIOCRUZ National School of Public Health.

The meeting's participants included the course's academic coordinators at the FIOCRUZ National School of Public Health, professors, advisers, and Dr. Dulce María Blanco, representative of the students at the National University of Honduras, and for PAHO, Drs. Rosa María Borrel, Regional Adviser on Human Resources Development, and Nelly Marín, Regional Adviser on Pharmaceutical Policies and general coordinator of the course.

The assessment took into account the reports from the advisers and academic coordinator, the tests taken by the students before, during, and at the conclusion of the course, and the comments of the student representative. This information revealed what, if any, impact the course had had in improving pharmaceutical services in the countries and was used to modify the modules and the proposed intervention for future versions of the course.

Later in the meeting, the next course was planned, and a roadmap for its implementation prepared. It was also agreed that the class size would be increased and platforms in English and Portuguese created for participants from Caribbean and Portuguese-speaking African countries.

At the conclusion of the meeting, there was a consensus among participants that the course was an essential tool for raising awareness in the Region and promoting the development and improvement of quality people-, family-, and community-centered pharmaceutical services as an essential component of health systems and services.

- **Countries of the Americas meet to Evaluate Amazon Malaria Initiative**

Fourteen countries of the Americas met in Panama from March 22<sup>nd</sup> to 24<sup>th</sup> for the X Evaluation Meeting of the Amazon Malaria Initiative.

The participants provided important input for the Regional Strategic Plan for Malaria in the Americas 2011-2015 and visited Panama's Official Medicine Control Laboratory to assess its capacity to perform quality control of antimalarial drugs and help train professionals from the official laboratories of neighboring countries.

Panama's Laboratory reaffirmed its commitment to start the World Health Organization (WHO) prequalification process for becoming a United Nations reference laboratory.

- **X Meeting of the Ibero-American Network/Council on Donation and Transplantation (RCIDT)**

The X Meeting of the RCIDT took place in Cartagena de Indias, Colombia, from March 22<sup>nd</sup> to 24<sup>th</sup> and was attended by specialists from the countries of Ibero-America.

The participating countries discussed the need to develop country self-sufficiency in the area of organs, tissues, and cells for transplantation in order to prevent organ trafficking. The participants also stressed the importance of tracking donors and patients through a biosurveillance system

The meeting addressed such relevant topics as the efforts of South American countries to prevent transplant tourism, the drafting of laws and legislative amendments to regulate the donation of organs, tissues and cells for transplantation, and the funding for this.

Dr. Francisco Delmónico, President-elect of The Transplantation Society, gave a presentation on international concerns about transplant tourism.

The experts discussed the need for a commitment on the part of countries to continue centralizing purchases of immunosuppressants. In addition, the Pan American Health Organization (PAHO) indicated its willingness to send a memorandum to countries interested in procuring these medications through the Strategic Fund.

- **Meeting to discuss the proposal for the Virtual Platform for the Regional Health Technology Profile**



Washington, D.C., March 21<sup>st</sup> and 22<sup>nd</sup>, 2011. PAHO's Essential Medicines and Health Technologies project (HSS/MT) coordinated a meeting to discuss a pilot project with Argentina, Colombia, Panama, and the Dominican Republic designed to systematize the regulatory information to be included in the Virtual Platform.

Based on the discussions about strengthening the regulatory capabilities of the countries during the 50th Directing Council of PAHO and the 14th International

Conference of Drug Regulatory Authorities (ICDRA), the HSS/MT project proposes to create a space on the Virtual Platform to support and promote the strengthening of regulatory capacity and governance at the regional level among national regulatory authorities (NRAs).

The initiative will also serve as a tool for disseminating information, data, and knowledge about experiences related to regulatory processes, all of which will be organized in a module to enhance information sharing and transparency among the countries of the Region.



The countries of the Americas differ in their characteristics, size, and structures. It is therefore important to design a pilot project that includes countries with developed regulatory systems, particularly those involved in evaluating their regulatory authorities.

The meeting enabled participants to obtain a clearer vision of the capabilities, projects, and resources of the national regulatory authorities in each country by sharing data and information about their regulatory systems and the development of the joint project.

Meeting coordinators and participants drew up a timetable of activities and agreed to adopt a series of regulatory indicators as a framework for the project database. The HSS/MT project promotes regulatory transparency for medicines and health technologies by providing national action with a regional perspective to efficiently promote health activities.

- **IAEA Deputy Director visits PAHO**

On Wednesday March 22<sup>nd</sup>, 2011, the Deputy Director of The International Atomic Energy Agency (IAEA), Dr. Kwaku Aning, visited Dr. Juan Manuel Sotelo, Manager of External Relations, Resource Mobilization, and Partnerships at PAHO. In that meeting, they exchange views on Japan's nuclear emergency.

Dr. Pablo Jimenez, Regional Advisor in Radiological Health gave a presentation regarding the collaboration between IAEA and PAHO in several technical areas involving the use of atomic radiation. Including, but not limited to access quality diagnostic imaging, radiotherapy services, radiological safety, cancer control and nuclear and radiological emergencies. He also presented Radiological Health Programs and areas of collaborations between IAEA/PAHO, including two regional projects: the Cancer Control Plan for Central America and the Dominican Republic,

and the Technical Project called “Radiation Protection of Patients & Medical Exposures”.

Moreover, Dr. Jimenez proposed the following guidelines for further collaboration: to continue exchange of information and collaboration within the Region of the Americas; to expand cooperation in other areas such as nutrition, communicable diseases, & environmental health; to establish cooperative relations with State Members that are not part of IAEA; to facilitate a closer relationship between IAEA country offices, PAHO and the Ministry of Health, and develop joint strategies to increase technical cooperation within the region.

The IAEA delegation considered the outcome of the proposal and meeting with PAHO very productive.

- **Workshop on Operating Procedures of the Strategic Fund**

At the request of Chile’s Ministry of Health and as a result of Chile joining the PAHO Strategic Fund, a workshop was held in Santiago, Chile on March 16th and 17th, 2011. Its purpose was to present in detail the updated operating procedures of the Strategic Fund and the procedures and responsibilities of those involved in the management of drug procurement.

The presentation was coordinated by the Bureau for Networks through the Ministry of Health’s National Program for the Coordination of Drugs and Supplies, with support from the Department for Pharmaceutical Policies. The participants included staff from various entities responsible for the supply of drugs for the Ministry of Health as well as other institutions involved, such as the Supply Center (Centro de Abastecimiento – CENABAST), the National Health Fund (Fondo Nacional de Salud – FONASA), the Disease Prevention and Control Division (through the HIV/AIDS and Tuberculosis Programs), Legal Advisory Services, and Chile’s Institute of Public Health, with representation from the areas of the Health Registry and the Quality Laboratory. The head of the Procurement Unit participated on behalf of PAHO/Chile.

The facilitators for the workshop were Dr. Victoria de Urioste, PAHO Subregional Advisor on Drugs for the Andean Subregion; Patricia Ramos, from PAHO’s

Procurement and Supply Management Area; and Nora Girón, Advisor to the Strategic Fund, in coordination with the PAHO/Chile Representative Office.

Among the conclusions of the workshop was that the Strategic Fund represents a way to acquire drugs that are hard to obtain in the national pharmaceutical market, including drugs for tuberculosis and a variety of other drugs that the country needs to treat certain neglected diseases. The Strategic Fund also represents a way to purchase other drugs such as antiretrovirals, oncological drugs, and other high-cost drugs.

In order to initiate procurement through this mechanism, the participants recommended that a multidisciplinary interinstitutional team be created to plan and manage drug procurement. Participants also considered it important to define the procedures and responsibilities for supply management, in coordination with the respective technical and administrative entities. CENABAST was considered to have the necessary structure, experience, and competencies to assume the management of procurement, intermediated by PAHO through the Strategic Fund and coordinated by the Ministry of Health.

- **PAHO supports Nuclear Emergency in Japan**

As of Friday March 11<sup>th</sup>, 2011, the Emergency Operations Center of the PAHO / WHO remains on alert following the earthquake and tsunami, and the declaration of nuclear emergency in Japan.

The Project of Medicines and Health Technologies of PAHO has provided technical support since the beginning of the tragedy. As a result the team is constantly monitoring and managing information, in particular the ones published on the website “Early Notification” and Assistance Conventions (ENAC), the International Atomic Energy Agency (IAEA) and diverse media. In addition, the Project of Medicines and Health Technologies of PAHO has established contact with national and sub-regional offices and generated internal and public reports in coordination with the areas of Knowledge, Management and Communication (KMC), International Health Regulations (IHR) and the Emergency Preparedness and Disaster Relief.

HSS/MT has been participating in different teleconferences with WHO headquarters and the IAEA through the Inter-Agency Committee on Radiological and Nuclear Emergencies (IACRNA), of which PAHO is part of.

Furthermore, HSS/MT has been working in the elaboration of a frequently asked questions document in coordination with WHO (available in English and Spanish) and selection and distribution of technical information relevant to this incident. On March 18th, 2011 Dr. Pablo Jimenez, Regional Advisor in Radiological Health presented the nuclear emergency situation in Japan to the Member States present at the Subcommittee on Program, Budget, and Administration (SPBA).

The websites of PAHO/WHO and the Regional Disaster Information Center (CRID) for Latin America and the Caribbean have been publishing references, technical guides and recommendations on the emergency.

Links of interest:

- [www.iaea.org](http://www.iaea.org)
- <http://www.who.int/hac/crises/jpn/faqs/en/index.html>
- <http://www-ns.iaea.org/tech-areas/emergency/iacrna/login.asp>
- <http://www.paho.org/disasters>
- <http://www.paho.org/radiologicalhealth>

- **Promotion support of generic medicines in the region**

On March 4<sup>th</sup>, 2011, "El Global" issued a press release which stated that the director general of the World Health Organization (WHO), Margaret Chan, who recently participated in a symposium on access to medicines and patent information, highlighted the 2010 World Health Report which focuses on the economic benefits of purchasing generic medicines instead of branded medicines, both equally effective and affordable.

Within the Region of The Americas , the Project of Medicines and Health Technologies (HSS/MT) of the Pan American Health Organization (PAHO) has

coordinated the development of a technical guide for the implementation of pro-generic medicines in countries in Latin America and the Caribbean.

The guide presents PAHO's recommendations regarding strategies promoting generic medicines as a means to improve access and use of quality essential. In addition, the document provides the countries with concepts and tools to implement the strategy.

The "Guide for the implementation of generics medicine strategies in the countries of Latin American and the Caribbean as mechanisms for access to medicines" presented for public consultation on the PAHO website on November 2010. Respondents included institutions and specialists from different sectors which made important contributions that will be included in a future publication to be launched during the VI Pan American Conference on Drug Regulatory Harmonization (CPANDRH) which is to be held in Brasilia, Brazil on July 6th -8th, 2011.

- **Public Consultation: Clinical Studies in Pediatric Populations**

The Technical Working Group on Good Clinical Practices of the Pan American Network for Drug Regulatory Harmonization (PANDRH), invites you to participate in the public consultation [Guide for Conducting Clinical Studies in Pediatric Populations](#) [To download the document click  [here](#) ]

Consultation deadline: May 16th, 2011.

The comments and observations should be included in the following form (to download the form click  [here](#)) and sent to [penaj@chi.ops-oms.org](mailto:penaj@chi.ops-oms.org)

- **XIV Workshop of the Association of Pediatric Hemato-Oncologists of Central America (AHOPCA)**

Panama. - February 24<sup>th</sup> to 26<sup>th</sup>, 2011. The focus of this meeting was to revise the progress of AHOPCA /PAHO in Pediatric Hemato-Oncology Patient Safety AHOPCA national health authorities. The work plan was initiated in 2009 by Dr. José Ramiro Cruz, Senior Advisor for Health Technologies for Quality of Care, and focuses on early diagnosis, access to treatment at the household, community and hospital level combined with timely access to anti-cancer medicines, radiation therapy, blood products and food safety.

In addition, the participants held technical meetings with authorities from the Republic of Panama Ministry of Health (MOH), Social Security System (CSS), Scientific Societies and Foundations to strengthen cooperation with the Program of Quality of Care and Patient Safety within Panama's Health Services.

- **2011 Antimalarial Product Prices for the Regional Revolving Fund for Strategic Public Health Supplies of PAHO**

February 23rd, 2011. The list of Antimalarial Pharmaceutical Products Prices, for the period 1 January - 31 December 2011 for the Strategic Fund can be obtained from the Procurement Services web site:

<https://intranet.paho.org/AM/PRO/English/AGSPWeb/PRObuy/Antimalarial.pdf>.

Member States will be billed according to these prices, unless otherwise stipulated in country agreements. PAHO invoices will include the cost of the products, a 3.5% service charge (applicable only to the cost of the product), and actual charges for packaging, freight and insurance.

PAHO/WHO Representatives are authorized to issue proforma invoices based on the "FCA" prices, in the far right column of the price list. For estimating the cost of packaging, insurance and freight, for budgetary purposes, use 15 % of the value of the requested products by air. Take in consideration that shipments per air, the minimum cost to be paid will be US\$ 500.00. The actual cost of these services may vary, and will be reflected in the PAHO invoice, which is issued approximately 45 days after the order has been delivered. Delivery lead time is approximately 90 days after the purchase order is placed.

Please continue to work closely with HSS/MT in updating quarterly product requirements from Member States. This information is critical to the work of PRO with suppliers to insure the availability of products on a timely basis.

[Click here to view product prices.](#)

- **New Project MPHSW/Rotary International/PAHO to Improve Access to Radiological Services in Guatemala**

On February 11th, 2011, an interinstitutional meeting was held in Antigua, Guatemala with the participation of the Minister of Public Health and Social Welfare of Guatemala, Representatives of the Rotary Districts of Illinois and Guatemala, the Ministry of Public Health and Social Welfare (MPHSW), PAHO Guatemala and the Regional Program of Radiology and Radiation Protection. The purpose of the meeting was to come to an agreement with the installation of 20 digital radiology equipment (WHIS-RAD with CR) throughout the country to build core capacity and improve public access to these technologies in the public health system.

The MPHSW presented the current status of radiology services in the country and health services that form the Integrated Health Care System, with a proposal for the creation of a network of 6 regional centers (Zacapa, Quetzaltenango, Santa Rosa, Guatemala, Coban and Escuintla) for the reception and report of diagnostic imaging.

The proposal was welcomed by Rotarians and as a result increased from 20 to 29 digital radiology units to be installed around the country, at an estimate cost of US\$3,000,000. These services will be located in health care facilities with 24 hours

service and maternity centers that currently do not have radiology equipment in addition to 6 centers in regional hospitals.

The MPHWSW will assume the construction and suitability of the premises according to national regulations and radiation safety. In addition, they will assume responsibility in hiring technical and specialized personnel in radiology and operating expenses.

Rotarians will donate to the MPHWSW 29 digital equipment, in addition to 6 servers and computer program for connectivity and images file. PAHO will support with training of radiographers, the translation and editing of guides and technical manuals, the development of maintenance programs and the regional reference centers, and counseling process.

Finally, it is anticipated that the project will be implemented in a period of 3 years.

- **Workshop: “Pharmacovigilance in the 21st century: its relevance and uses”.**

February 7th -9th, 2011. The pharmacovigilance workshop organized in Nassau, Bahamas, PAHO/WHO and the Bahamas Pharmacy Council discussed the need to strengthen the national regulatory framework and national capacity in pharmacovigilance within this framework.

A national conference was held on February 7th followed by a workshop on February 8th and 9th, supported by the PAHO PWR Dr. Merle Lewis and professionals from the Project of Medicines and Health Technologies (HSS/MT) Dr. Adriana Ivama and Dr. José Luis Castro. The Pharmacy Council in Bahamas will be promoting the establishment of a pharmacovigilance center and strengthening of pharmacovigilance activities at the national level. Bahamas could be a key player to support the VIGICARIB network and foster the implementation of recommendations provided by PAHO/WHO.

- **Workshop to develop study Protocol to characterize the situation of antimalarial supply in Honduras**

In order to improve the management of supply of antimalarial medicines, a workshop was organized from February 1st to February 4th, 2011 in Tegucigalpa, Honduras. During the meeting, the participants discussed the issues related to the availability and access to antimalarial medicines.

As a result of the workshop, the design of a research protocol to characterize the management of the supply of antimalarials in Honduras was created with the participation of officials from the National Malaria Program, Technical Supplies Unit, Medicine Regularoty Authority, Department of Population Risks, Directorate of Health Promotion with technical support from PAHO / WHO, Management Sciences for Health (MSH/USAID) and the Cooperative of Hospitals of Antioquia (COHAN)

The objectives of the workshop were to determine the status of malaria control, the state of medicine supply and the associated problems; define the scope of the study and solutions to problems related to medicines supply; develop a research protocol in order to characterize management of supply of antimalarials and define technical and financial needs that will facilitate implementation by each actor and cooperation agencies, to implement the study.

Within this framework, the Pan American Health Organization has been developing interprogrammatic with the Ministry of Health and has established alliances with partners such as MSH / USAID and COHAN (Colombia) to support countries in improving the availability of antimalarial medicines, promote the rational use and provide better care to those affected by malaria.

The Ministry of Health and cooperating agencies described the meeting as a major step forward since the objectives agreed upon were met, the financing sources were identified, and a work plan was developed by consensus to implement the study, and with the commitment of other institutions such as the Official Medicine Control Laboratory (OMCL).

This activity is being developed within the framework of technical cooperation that PAHO offers through the Strategic Fund and jointly with the Area of Communicable Diseases.

- **Available on the web: “Understanding and Responding to Pharmaceutical Promotion”**

In 2009, Health Action International (HAI) published jointly with WHO the document: "Understanding and Responding to Pharmaceutical Promotion". This document outlined the implementation of a course on pharmaceutical promotion and independent information in medicine and pharmacy schools. The document helps to assess promotional activities and advertising used by the pharmaceutical industry and to support evaluations and decisions with regard to medicines based on evidence and unbiased information

The document is available in English on the PAHO website, specifically in the following section:

-PANDRH Working Group on Drug Promotion. Publications

Click [here](#) for link in English

- **Available on the web: "Buenas Prácticas de Farmacovigilancia para las Américas"**

Available on the Pan American Health Organization (PAHO) website, is the document: PAHO Technical Document, No.5 "Buenas Prácticas de Farmacovigilancia para las Américas". This document was prepared by the PANDRH working group and addresses central issues for the development of activities in countries. The guide aims to provide guidance reference for countries beginning activities in pharmacovigilance as well as to support countries with developing a more advanced system.

The document is available in Spanish, specifically in the following sections:

-Publications and Technical Documents Project of Medicines and Health Technologies

Click [here](#) for link in Spanish

-PANDRH Working Group Pharmacovigilance. Documents

Click [here](#) for link in Spanish

- **Available on the web: WHO good practices for pharmaceutical quality control Laboratories**

Available on the website of the Pan American Health Organization (PAHO) the document: WHO Technical Report Series, No. 957, 2010. 44th Report, Annex 1 (WHO good practices for pharmaceutical quality control Laboratories) and the GLP self-evaluation guidelines carried out by the WG-GLP of PANDRH.

Both documents are published in three languages: English, Spanish and Portuguese, specifically in the following sections:

-Publications and Technical Documents Project of Medicines and Health Technologies

Click [here](#) for link in Spanish

Click [here](#) for link in English

-PANDRH Working Group on Good Laboratory Practices. Important documents

Click [here](#) for link in Spanish

Click [here](#) for link in English

- **Public Consultation: Proposal of Harmonized Requirements for Drug Registration in the Americas**

The Technical Working Group on Drug Registration of The Pan American Network for Drug Regulatory Harmonization (PANDRH), invites you to participate in the public consultation on [the Proposal of Harmonized Requirements for Drug Registration in the Americas](#) [To download the document click  [here](#)]

Consultation deadline: March 1st , 2011.

The comments and observations should be included in the following form (to download the form click  [here](#)) and sent to [ivamaadr@cpc.paho.org](mailto:ivamaadr@cpc.paho.org)