II Workshop on Medicines Regulation in the Caribbean

"Strengthening of National Medicines Regulation Authorities"

Barbados, 08-09 September 2009

Final report

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Acknowledgements/Disclaimer

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Abbreviations and Acronyms

ANMAT- National Agency of Medicines, Food and Health Technologies
ANVISA- National Agency of Health Surveillance
API - Active Pharmaceutical Ingredients
CAMT - Central American Common Market
CAN- Comunidad Andina (Andean Community)
CARICOM - Caribbean Community
CECMED- Centre for State Quality Control of Medicines
CRDTL- Caribbean Regional Drug Testing Laboratory
CSME- Caribbean Single Market and Economy
ECC- Eastern Caribbean Countries
FDA- Food and Drug Administration
GCP- Good Clinical Practices
GDP -Good Distribution Practices
GMP- Good Manufacturing Practices
GPP-Good Pharmacy Practices
GSP-Good Storage Practices
GXP – Good Practices
HERA- Health Research for Action
ICH - International Conference Harmonization
MERCOSUR- Southern Common Market
MOH- Ministry of Health
MRA- Medicines Regulatory Authority
NAFTA - North American Free Trade Agreement
OECS- Organisation of Eastern Caribbean States
PAHO- Pan American Health Organisation
PANDRH- Pan American Network for Drug Regulatory Harmonization
PIC/S - The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PPS-Pharmaceutical Procurement Services
SGT – Sub-grupo de Trabajo (sub-group of work)
SOP- Standard Operating Procedure
TAG-Technical Advisory Group
TAMCC- T.A. Marryshow Community College
TOR- Terms of Reference
USP - United States Pharmacopoeia
WHO- World Health Organisation

II Workshop on Medicines Regulation in the Caribbean

"Strengthening National Medicines Regulation Authorities"

September 8-9th, 2009, Grand Barbados Hotel, Barbados

I. Background

It is recognized worldwide that the regulation of medicines is part of the essential function of public health and it is the primary State responsibility of every country. It is a public policy that restricts private-sector activities in order to attain social goals set by the State. It includes the legal, administrative and technical measures, which governments take to ensure the safety, efficacy and quality of medicines, as well as the relevance and accuracy of product information. Medicines Regulatory Authorities (MRAs) are essential to ensure a strict regulation of the manufacture, trade and use of medicines in order to protect public health. A legal framework is required for the MRA, in order to guarantee independent testing and assessment of the quality, efficacy and safety of medicines as well as adequate staff and infrastructure.

Moreover, an effective medicine regulation system can be cumbersome and difficult in terms of availability of human resources and technology as well as extremely expensive. This is more evident in countries whose national pharmaceutical market is small. The Seminar on Pharmaceutical Regulation in the Caribbean was held, from September 17-19th 2007, with the objective of "Presenting and discussing the basic functions of the MRA, as a basis for the Sub-regional assessment of National Regulatory system in the Caribbean countries". During the meeting, the difficulties which each country in the region experienced in fulfilling the regulatory functions, given the lack of human resources and other existing limitations and constraints were discussed. The possibility of a harmonization process that would increase mechanisms of cooperation and communication with some shared activities, in addition to the activities under national responsibility were considered. One concern of the representatives was being able to guarantee each country's autonomy of action as well as possible shared responsibilities.

In 2007, Caribbean Countries provided information that is summarized by the Pan-American Health Organization/World Health Organization in the publication "The Pharmaceutical situation in the Caribbean Countries"[1]. According to this document, in 2003, only four countries of the 13 countries that were surveyed mentioned having legal provisions for a MRA and by 2007 this number of countries increased to eleven (84,6%). In 2003, none of the MRA had a website and by 2007 three MRAs had functioning websites (25%). Regarding the legal provisions for transparency, in 2003

[1] Pan-American Health Organization/World Health Organization**. The Pharmaceutical situation in the Caribbean Countries.** Washington DC: PAHO/WHO, 2009. The complete publication is available at: www.paho.org

three countries (60%) had these provisions and by 2007 the number increased to five (45,5%).

In 2009, Health Research for Action (HERA) conducted the survey *"Regional Assessment of Drug Registration and Regulatory Systems of Caricom Member States and the Dominican Republic"*. The report has been finalized and it will provide valuable inputs for the discussion on the strengthening of Medicines Regulation in the Caribbean.

The establishment of the Pan American Network for Drug Regulatory Harmonization (PANDRH)[2] in 1999, was an important initiative in the region for the strengthening of medicines regulation.The objective of the network is to support processes on medicines regulatory harmonization in the Region of Americas. The network's last conference was held in November 2009 in Buenos Aires (Argentina). The guidelines and technical documents produced by the PANDRH working groups and approved by the Conference are important tools that can be used in Caribbean countries, as well as other technical documents and recommendations from WHO.

Representatives from the Caribbean countries namely, Barbados, Bahamas, Belize, St Lucia, Jamaica, Trinidad and Tobago, Guyana, Suriname, St. Kitts and Nevis, St. Vincent and Grenadines and Haiti, Organisation of Eastern Caribbean States Pharmaceutical Procurement Services (OECS/PPS), the CARICOM Secretariat, University of Technology, T. A. Marryshow Community College (Grenada) and the University of West Indies (UWI) participated in the II Workshop on Medicines Regulation in the Caribbean "Strengthening of National Medicines Regulation Authorities" from 8th to 9th of September, 2009.

It was also supported by experts from Argentina (National Agency of Medicines, Food and Health Technologies - ANMAT), Brazil (National Agency of Health Surveillance - ANVISA), Cuba (Centre for State Quality Control of Medicines, CECMED), United States (Food and Drug Administration, FDA) and Health Research for Action (HERA) as well as advisors from the Pan American Health Organisation/World Health Organisation (PAHO/WHO) (the sub-regional advisor on medicines, health technologies and vaccines, the regional advisor on rational use of medicines and the advisor on health systems and services strengthening for the Eastern Caribbean Countries (ECC) and Barbados).

[2] This is coordinated by PAHO. More information about the network is available at: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=1156&Itemid=513

Opening session and conferences

Opening Session

The opening remarks were done by Beverly Reynolds on behalf of Dr. E. Greene, Caricom Secretariat and Adriana Ivama on behalf of Dr. Bernadette Theodore-Gandi, PAHO/WHO Caribbean Programme Coordinator.

Beverly Reynolds thanked the participants for attending and said that she expected the workshop to be fruitful and that they are able to find concrete objectives and solutions.

Adriana Ivama also welcomed the participants and acknowledged the presence of the Chief Medical Officers from St Kitts and Nevis, Dr. Patrick Martin and Dr. St. Claire Thomas from St. Vincent and the Grenadines as well as representatives from the Ministries of Health of the Caribbean countries, Universities, PAHO/WHO advisors and the specially invited experts from Argentina, Brazil, Cuba, United States and HERA. Among the areas to be strengthened in order to improve regulation in the Caribbean, was the need to improve collaboration among MRAs and strengthen human resources, because nothing was achievable without them.

She mentioned the previous Workshop of Medicines Regulation held in 2007, when the study of regulation of medicines in the Caribbean was initially discussed and several conclusions and recommendations are still valid. She considered that this workshop will be a good opportunity to review the progress achieved and to discuss the way forward.

Objectives and methodology

Dr. Adriana Ivama informed the participants that the reports of the surveys conducted by Hera and PAHO/WHO were available and they also were going to be presented as they can provide important inputs for the discussions to be conducted. She gave an overview of the workshop and informed participants that there would be work group discussions and she suggested that special emphasis be placed on human resources. The general objective of the workshop which was “to strengthen mechanisms of collaboration and harmonization of regulation of medicines in the Caribbean” was presented. The specific objectives were:

- To establish priorities and design strategies for strengthening and harmonizing the regulation of medicines in the Caribbean in the context of the essential public health functions.
- To share the outcomes of surveys related to the pharmaceutical situation and the assessment of national regulatory authorities in the Caribbean
- To design and discuss mechanisms of communication and collaboration among regulatory authorities.
- To identify the possible common legal framework, guidelines and technical documents for strengthening essential regulatory functions.
- To discuss possibilities for strengthening the Human Resource capacity for the regulation of medicines.

Participants were asked to introduce themselves and to share their expectations regarding the workshop. The responses were very similar as all of them wanted to share and gather information, learn how to strengthen their weaknesses and improve regulation, both at the country and sub-region levels.

Regulation as an essential public health function

Gabriel Vivas[3]

Dr. Vivas examined the regulatory dimension as an essential public health function. A general overview of the health system was given as well as the factors that can influence its performance. He also provided information on the regulatory dimension.

In terms of its steering role, the regulatory dimension "is the manifestation of the state's responsibility to order and systematize a reality according to a series of trends prevailing at a given time." This requires consensus building among the different state levels and all sectors of the society; this is the most difficult task in the health sector. Within the steering role, the regulatory dimension is also important because it creates the legal framework needed to protect and promote the health of the population as well as guarantee its enforcement.

In order to have an effective regulatory function, regulatory frameworks, political will, clear policies, strategic alliances, monitoring and evaluation are needed. In addition to regulation, other essential public health functions such as health promotion, public health surveillance, human resources development and training among others have to be present. However, the strengthening of the institutional capacity for regulation and its enforcement was emphasized. This is needed to monitor and protect the populations' health, create new laws and regulations to improve population health, ensure compliance and protect citizens; it is a state responsibility.

[3] Advisor on Health Systems and Services Development of PAHO/WHO, ECC and Barbados.

Strengthening the National Regulatory Authorities and the Essential Regulatory Functions

Adriana Ivama[4]

The dimensions of medicine regulation, the essential regulatory functions, the regulatory assessment tools and the search for regulatory gaps and priority setting were examined by Dr. Ivama.

The basic objective of regulation is to ensure health safety. Therefore, a regional/local authority is needed to regulate medicines; control should be carried out by a body of specialists and all experts should be independent, transparent and free from conflicts of interest.

Medicine regulation has four dimensions and they are as follows: structural and administrative elements (policy, legislation, registration, human resources, finance and infrastructure); technical elements (standards, norms, specifications, guidelines and procedures); functions and processes (manufacturing, imports, wholesale, retail, dispensing, premises, practices and persons and levels (central, state, community). In order to protect and promote public health, countries need to have the core elements and the key functions in place. However, she postulated the view that regulation needed to be part of the agenda of decision makers.

The objective of 2007 Seminar on Pharmaceutical Regulation in the Caribbean whose was to discuss the basic functions of MRA's. The conclusions of that Seminar were examined and were related to the difficulties that the region experienced in fulfilling the regulatory functions, such as the lack of cooperation and communication mechanisms and the general concern for maintaining autonomy. She challenged the participants to determine where to go from 2009 onwards from the lessons learnt and to set priorities.

Participants were also informed of the WHO/PAHO regulatory assessment tools and how to assess a MRA. She advised them to identify gaps and admonished the countries that are more developed in an area to assist others who might be weak in that area. At the same time, she highlighted the importance of enhancing the collaborative work among the national authorities, looking forward to the establishment of a sub-regional regulatory framework, as stated in the recently approved CCH III.

[4] Advisor on Medicines and Biologicals for the Caribbean, PAHO/WHO, CPC Office

Current status of Pan American Network for Drug Regulatory Harmonization (PANDRH)

***Justina Molzon*[5]**

PANDRH was started in 1999 and will celebrate its 10 year anniversary on November 10th 2009. Its Medicines harmonization goals are to search for solutions to common problems; strengthen the establishment of priorities in medicines regulatory harmonization; improve access to quality and safe medicines and promote technical cooperation. PANDRH tries to incorporate different perspectives from the countries of the Americas and to address the issues taking into account the different levels of development and mutual collaboration.

There were a number of working groups that were established to work on harmonization namely, good manufacturing practices, medicine classification, counterfeit medicines and medicine registration working groups, among others. The Network and the PANDRH Steering Committee is composed of representatives from North American Free Trade Agreement (NAFTA), Southern Common Market (MERCOSUR), Andean Community of Nations (CAN), the Central American Common Market (CAMT) and the Caribbean Community (CARICOM). Every two years, the MRA's meet at the PANDRH Conference to work on harmonization goals, check their progress and results.

An overview of the last PANDRH conference held in Buenos Aires, Argentina 2008 and the meeting of the Steering Committee, which took place last July 2009 in Washington DC was presented. They ended the tenure of some working groups and others were renewed. The Steering committee also encouraged countries to utilize the documents of the working groups.

[5] Food and Drug Administration (FDA), member of PANDRH Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH).

The pharmaceutical situation in the Caribbean Countries

Adriana Ivama[6]

Dr. Ivama presented the framework for the development of technical cooperation in the area of medicines as specified by global and regional mandates. The Caribbean's priorities were embodied in the context of the Caribbean Single Market and Economy (CSME), the Port of Spain Declaration which seeks to establish among other things plans for the screening and management of chronic disease and risk factors and the Caribbean Cooperation in Health, phase III (CCH III). At CCH III, the strengthening of the pharmaceutical sector was done by the strengthening of Healthcare System. The objectives were to have the Caribbean Pharmaceutical policy designed and implemented; strengthen medicine regulation and have a harmonized medicine supply system among others. Technical cooperation in the area of medicines is provided as part of the European Union (EU)/World Health Organisation (WHO) - Africa, Caribbean and Pacific (ACP) Project "Partnership on Pharmaceutical Policies" whose overall objective was to "close the huge gap between the potential that essential medicines have to offer and the reality of millions of people".

The Pharmaceutical situation in the Caribbean was presented and this was based on the countries responses to the Level 1 questionnaire on the Pharmaceutical situation in 2007. The results provided an overview that can guide technical cooperation and provide evidence to policy makers in the sub-region.

The questionnaire measured the national medicines policies, medicines regulatory authority, medicines registration, licensing of facilities and professionals, regulatory inspections, quality control and pharmacovigilance among others. However, the per capita expenditure on medicine in the Caribbean (US$ 20.00) was highlighted as it is almost double of that of the region of Americas (US$ 11.00). The presentation was concluding by inviting the participants, based on the results, to think about the possible priorities for the next 2, 4 and 10 years in terms of regulation. The need to integrate the priorities of the Caribbean at the Country levels was also mentioned.

[6] Advisor on Medicines and Biologicals for the Caribbean, PAHO/WHO, CPC Office

Regional Assessment of Drug Registration and Regulatory Systems of CARICOM countries and the Dominican Republic

Marianne Schurmann[7]

The presentation was based on the results of the survey "Regional Assessment of Drug Registration and Regulatory Systems of CARICOM countries and the Dominican Republic". The study was carried out in 15 CARICOM member states and the Dominican Republic, the two assessment instruments used were based on WHO methodology and the assessment phase was from January to April 2009 where seven countries were visited[8] and the consolidation phase was from April to June 2009 where the questionnaire responses were analysed. In short, Ms. Schurmann presented the summary and discussion of the study's findings, the situation of medicines regulation in the CARICOM context and the proposed strategic options and institutional framework.

The results showed that all of countries do not have a fully comprehensive legislation and none of them had provisions for clinical trials; some countries have old and new legislations that have not been harmonized. In several countries, the law cannot be enforced because regulation does not exist. In addition, countries take too long to approve draft legislation. With respect to institutional capacity and setup, all of the MRA's are public sector institutions (the majority are within the Ministry of Health (MOH)). However, it is spread across over several departments which makes it difficult to manage everything. All 16 countries reported that they experienced difficulty in the area of Human Resources (number and qualifications/expertise).

Product assessment and registration is performed only in 6 countries. Over 3000 products are registered but information is not always easily available and accessible or the marketing status is unknown. Therefore, it is not very easy to regulate the pharmaceutical sector. Quality control is another challenge because among other constraints not all tests can be performed in the region, only four countries have designated quality control laboratories but biological substances cannot be tested. In terms of public health, there are some challenges with respect to the safety, quality and efficacy assurance of products because the capacity for Good Manufacturing Practices (GMP) inspections is not always adequate.

Harmonization of medicines regulation is a long process and it requires patience, commitment and time. In the CARICOM context, harmonization has the potential to improve safety, efficacy and the quality of medicines. A proposal was presented for the mission of harmonization in the region "safe, effective and quality pharmaceutical products adequate to address prevalent health problems are marketed timely in all

[7] Health Research for Action (HERA)
[8] The remaining countries were emailed and follow up was done.

CARICOM member states.” However, in order for harmonization to take place there are a number of policy principles that needed to be adhered to such as governments support for medicines regulation, the assessment process be based on appropriate harmonized requirements/guidelines, resources be shared and that there be clear and transparent procedures for priority products.

There are a number of harmonization strategies/options that can be used to assist with the harmonization process such as MRA capacity building, formal cooperation and information sharing and the strengthening of quality control capacity. Regarding the institutional framework, a formal permanent structure is required for effective coordination and a permanent secretariat should be established. This secretariat could be housed using existing structures, such as the Caribbean Regional Drug Testing Laboratory or the Caribbean Public Health Agency to be established soon.

It was emphasized that CARICOM member states can take the following critical steps towards harmonization: formulate and formally adopt a quality assurance policy under the framework of a sub-regional pharmaceutical policy, establish a permanent secretariat, produce strategic work plans for policy implementation, secure funding for work plan implementation. In short, it was found that medicines regulation is required to protect and promote public health and a regional Quality Assurance policy is a prerequisite for harmonisation.

Harmonization and mechanisms of sub-regional integration: The Argentinean Experience

Rodolfo Mocchetto[9]

The National Administration of Medicines, Food and Technologies (ANMAT) is a department of the Ministry of Health of Argentina, whose mission is "to supervise and control all products used for human health." An organisational chart was shown highlighting the break down of the Argentinean National MRA into different departments such as the National Institute of Food and The Medical Technology Direction. He highlighted the need of having a separation of functions which contributes to the good overall functioning of the system.

Argentina participates in different international harmonization initiatives such as the PANDRH Network and MERCOSUR, This enables the country to gain valuable pointers for improving the administration of the pharmaceutical industry. In MERCOSUR, the regulation of medicines is discussed in the Sub-Group of Work (SGT) of Health Products of MERCOSUR that has several ad hoc groups, with representatives from the technical areas from the Ministries of Health (MOH) of the Member States.

Mr. Mocchetto represents Argentina in the Ad hoc group of Good Manufacturing Practices (GMP) of the SGT 11 of MERCOSUR and also in the PANDRH WG of GMP. He shared with participants Argentina's experience participating in these harmonization processes. At SGT 11, the first step was to identify difficulties, the similarities and differences among countries. They found that the difficulties that were faced by harmonization were the different national laws, the different criteria, the disparity in resources and the different procedures and mechanisms. Therefore, they looked at the steps that should be taken in order to rectify the situation such as identifying the needs of each country, harmonizing common standards and procedures, the joint training of inspectors and joint inspections. In order to assist with the harmonization process, they conducted workshops between the member countries and with international experts. Common standards were harmonized such as Resolution of MERCOSUR GMC (Common Market Group) nº 59/92 that establishes the "Guidelines for inspections of pharmaceutical industry establishments", and Resolution MERCOSUR GMC 23/96 that established the "Inspection regimen and procedures for inspections of pharmo-chemical industry" and they are currently using WHO Guidelines for Good Manufacturing Practices (2003).

With respect to inspections, there are three phases of training courses for inspectors with MERCOSUR. Phase 1 is internal and conducted in the countries and phases 2

[9] ANMAT, Argentina

and 3 are conducted internationally. Only inspectors with approved Phase II qualification can perform joint inspections in MERCOSUR. Within the member states, joint inspections are done where both inspectors have decision making power but in an assisted inspection, only the receptor country has that power.

Participants were warned that the harmonization is process is continuous and that harmonized standards need to be continuously updated. Currently, the GMP workgroup was working on a unified report model. It was highlighted that information exchange was also important as there was no mutual recognition of inspections. Countries can exchange inspection reports and perform their own report analysis and decide if they want to have joint inspections. In Argentina, they have assisted inspections because there are many benefits to be derived such as joint training for inspectors and information and experience exchange with regulators from European, Asian and African countries. In addition, ANMAT participates in the expert circle of risk analysis and the rapid alert notification system, where they receive information on defective products from many countries in the world.

Quality Assurance as part of the Essential Regulatory Functions: the experience of the Caribbean Regional Drug Test Laboratory (CRDTL)

***Lucette Cargill*[10]**

The CRDTL was established to provide the region with quality medicine testing thus contributing to the availability of medicines of good quality. However, on opening its doors no products were submitted for testing because the regulation did not exist and they realised that they needed a system of regulation to generate samples. They established a monitoring schedule and the tests are performed as requirement for registration and procurement and for surveillance. Today, one of the main users of the CRDTL is the Pool Procurement Service from the Organisation of Eastern Caribbean States PPS/OECS, the MOH's of CARICOM countries and some pharmaceutical manufacturers and distributors. Occasionally, hospitals submit samples but only when there is a negative occurrence.

There is a routine surveillance programme built largely around a priority list of medicines. However, one of the challenges of the lab was scheduling because they did not know how many products would be sent for testing and when; this makes planning difficult. Products are submitted for various reasons such as routine, pre-registration, pre-tender, product in development and investigation, among others.

The importance of testing during the pre-registration/pre-tender phase was highlighted because according to their statistics, more than half of the new products that were tested over the last few years were defective. Products have failed tests such as disintegration, sterility and identification. An example was given of eye drops that were being used in Jamaica that presented adverse effects. After testing was completed it was determined that the drops were not sterile. She advised the participants that even products from pre-qualified manufacturers have to be tested and recommended that all products from known and unknown manufacturers should be tested. She urged her companions to utilize the services of the lab.

The Challenges for developing the activities of the CRDTL were:

1. The unavailability of product monographs, the usual sources are the United States Pharmacopoeia (USP), British and International Pharmacopoeia and some products do not have monographs. MRA should provide manufacturers monographs.

[10] CRDTL Director

2. Unavailability of reference standards but WHO is updating therefore a number of reference standards are more readily available. However, since the CRDTL is not a regulator, manufacturers do not have to provide them the standards.
3. Scheduling Issues- there is no control over the timing of submission if there no prior knowledge of planned activities.
4. Equipment Issues
5. Resources

As part of the solutions, collaboration with the national labs was mentioned as well as that Countries can perform preliminary testing and strengthen cooperation with regulatory agencies. Currently, CRDLT is preparing the submission for the pre-qualification process of WHO.

Strengthening of Medicines Registration based on PANDRH and WHO recommendations

***Celeste Sánchez González*[11]**

This presentation examined medicine registration as a regulatory function, what is medicine registration, the regulatory requirements for medicine registration, ways to implement registration, the registration process steps and the medicine registration requirements according to the PANDRH[12].

The heart of the medicines regulatory system is medicine registration which is defined as a system which subjects all pharmaceutical products under the scope of the MRA to pre-marketing evaluation; marketing authorization (registration) and post marketing review. This would ensure that they conform to the required standards of quality, safety and efficacy. Registration is interrelated with all other regulatory functions. WHO's book on "How to implement computer assisted drug registration: a practical guide for Drug Regulatory authorities was recommended because it contains detailed information and procedures for implementing drug registration. Another relevant reference mentioned was the *Manual for Marketing Authorization* of WHO (the Blue Book) which has been updated recently. However, the updated version is so far only available in French.

The expected result of Medicine Registration is "the issuance or denial of a pharmaceutical product Marketing Authorization (product license/registry)". The registry holder is obliged to commercialise the product with all the indicated therapeutic conditions, with the specifications, pharmaceutical form as well as presentations among others. When product information is reviewed it should be consistent with administrative, quality, safety and efficacy evidences of the registration dossier. When the product reaches the market, it should be the same product that was approved. If after being reviewed, it does not match, the product is deemed as illegal.

Participants were called to pay close attention to product variations because modifications can lead to a different product. The product files should contain the entire product description. Manufacturers must be licensed and comply with GMP because in terms of quality, they must not add any risks to the product during the manufacturing process and they must maintain consistency from batch to batch. During research and development, the product is studied for quality, safety and efficacy and as a result, it is assumed that if quality is the same, any batch will have the same safety and efficacy. This is why the manufacturers' behaviour is so important. Advertising and promotion which disseminate information about the

[11] CECMED-Cuba

[12] PANDRH is used as the basis for the assessment of options for harmonization strategies in the region.

product, should be aligned with the marketing authorization. Post marketing surveillance will ensure the correct performance of the product during use and will send alerts regarding any of its properties.

In order to develop Medicine Registration the following are needed:

- Legal basis
- Guidelines
- Assessment procedures
- Human Resources and others
- Records (show documented evidence)
- Availability of information

Medicine registration can be based on the MRAs own assessment, it can rely on the exporting country's MRA or it can use the assessment reports from other MRA's. However, to conduct its own assessment trained human resources are needed. If you are going to rely on the MRA of the exporting country or the assessment report from another MRA, a simple decision tree should be followed. If the product is not registered in the exporting country, your own assessment should be done. In the event that the product is registered, you have to ensure that the approved product is the same one that you are receiving. If there are any differences, you should determine if they are acceptable. Even when the product is the same, you should assess if the analytical methods and quality control can be applied.

In addition, one should also check to see if stability studies were conducted including the requirements of the National Climatic Zone. For example, if a product was approved for 25ºC with 60% humidity, it might not react in the same way in the Caribbean where the temperature and the humidity are higher. Therefore, stability studies are important because the climate can affect the performance of the product. With respect to labelling, one has to ensure that the product includes the information that you want for your population. For example, there are places where people cannot read and symbols should be used.

Special emphasis was placed on harmonization strategies options and participants were encouraged to think about all of these options as outlined by HERA:

- Development of harmonized guidelines
- MRA capacity building
- Formal cooperation and information sharing
- Strengthening quality control capacity
- Resource sharing for assessment of technical dossiers
- Product licensing in countries without registration (special project?)
- Capacity building local pharmaceutical industry

Medicine Registration Assessment Phases:

- Reception-checking the validity of the application
- Assessment- (quality, product information, interchangeability)
- Follow up (even after product approval, follow up has to be done)

The PANDRH Medicine Registration requirements were presented. PANDRH's registration working group prepared a proposal for guidelines related to the basic requirements for registration which is yet a draft. It includes legal and administrative requirements as well as basic information for inner containers secondary packaging, inserts and patient information (for whom/what the product is for). Quality evidences and the interchangeability demonstration (when applicable) for multisource products produced by different manufacturers (generics) is also important. PANDRH also has guidelines for the bioequivalence and bioavailability.

Strengthening of Good Manufacturing Practices and Inspection based on PANDRH and WHO recommendation

Rodolfo Mocchetto[13]

There are four groups of inspections: Good Manufacturing Practices (GMP) verification, Verification of Good Practices in any step of the medicines distribution chain (GXP), Inspection for marketing authorization and marketing control and surveillance. Control should be done with transparency, symmetry and equity for all manufacturers and establishments dedicated to manufacturing, importing, marketing or distributing pharmaceutical products, including vaccines and herbal products.

PANDRH is composed of several working groups such as the GMP working group which is made up of MRAs, the pharmaceutical industry and the academic community. The mission of the GMP Working Group is *"to promote knowledge and the implementation of GMP as a strategy to improve the quality of medicines in the Americas".* The objectives of the group were to develop harmonized guidelines or questionnaires for inspection, in order to verify compliance with GMP for the countries of the Americas based on Report 32[14] of WHO; support the MRAs in GMP monitoring inspections and raise the level of awareness and support the regulatory authorities in assuming the leadership in the implementation and monitoring of GMP in each country.

The working group developed guidelines for GMP Inspections, the first draft was prepared by ANMAT as a working document. After revision by the members, it was presented at the IV Pan American Conference for Drug Regulatory Harmonization where it was approved. The working group developed courses on the use and the application of the guidelines. The courses were directed to MRAs, professional associations, pharmacy schools and industry in some Central and South American countries.

The working group then developed three more documents[15], the decision tree for the use of the guidelines, the code of ethics and declaration of conflict of interest and Guidelines for GMP for Active Pharmaceutical Ingredients (API), based on the guidelines of the International Conference Harmonization (ICH) Q7A. All of them were approved at the fifth PANDRH Conference.

The current inspection system in the Argentine Republic is based on GMP for Manufacturers and Importers/exporters of medicines are based on the WHO GMP Guidelines (2003), The Pharmaceutical Inspection Convention and Pharmaceutical

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[13] ANMAT Argentina

[14] This is the minimum standard and under no circumstances should a country use a lower standard.

[15] http://new.paho.org/hq/index.php?option=com_content&task=view&id=1589&Itemid=513&limit=1&limitstart=1

Inspection Co-operation Scheme (PIC/S) report PE 009-1 and ICH 7A and other documents[16]. The classification of GMP non-conformities is based on risk analysis, critical deficiencies, mayor and other deficiencies.

There are also guidelines for inspections. For GMP two inspectors per inspection are required and it takes an average of five days per inspection. A report of the non-conformities is given to the company at the end of inspection. Corrective measures should then be taken, based on the report. A re-inspection can be required to assess the accomplishment of the corrective measures.

There are also several tools for quality assurance for inspection systems such as a quality manual, code of ethics and standard operating procedures (SOP) for all activities of the inspectorate. However, he noted that countries can develop their own system according to their needs and resources, based on WHO guidelines and recommendations and considering the regional harmonization processes.

[16] http://www.anmat.gov.ar/normativas_medicamentos_cuerpo.asp

Post Marketing Surveillance and Pharmacovigilance based on PANDRH and WHO recommendations

Jose Luis Castro[17]

Murilo Freitas Dias[18]

Safety and efficacy surveillance is part of the function of Medicine regulation. **PANDRH Working Group on Pharmacovigilance** is made up of members from Brazil, Colombia, Cuba, Uruguay, Barbados, Canada and other entities. The mission of the working group is *"to develop and strengthen pharmacovigilance through activities and proposals of harmonized regulatory actions that promote the safe and rational use of medicines as a necessary component of Public Health policies in the Americas".* The group has several objectives such as:

1. To promote the development and dissemination of knowledge, criteria and methodologies in Pharmacovigilance to be used in training activities
2. To review and develop tools to support harmonization in Pharmacovigilance
3. To design a system that supports the work in the network to improve and strengthen exchange communication, knowledge and decision making in the area of pharmacovigilance.
4. To foster integration of pharmacovigilance as part of medicines policy and public health programs
5. To promote and disseminate research on Pharmacovigilance and evaluation of their impact in public health and patient safety

In terms of Regional Studies and Special Tasks, at the V PANDRH Conference, the Guidelines for Good Pharmacovigilance practice for the Americas were approved.

Medicine safety knowledge is gained by experience, this knowledge increases according to the experience gained using the medicines. During phases I, II and III of clinical trials (toxicology evaluation, identification of unexpected effects in some patients), there is a Pre-Marketing Evaluation. To register a product, the manufacturer has to present safety and efficacy evidences. After registration, there is a post-marketing surveillance or pharmacovigilance. During this period Drug-Related Problems can be identified. A system should be put in place to collect information for medicine related problems, linked with other regulatory activities. These problems can be a product problem (the patient's health is not necessarily affected) or adverse events (patient health is affected) and can be monitored. Based on the data collected, a risk analysis can be conducted (identification, quantification and evaluation) and a decision can be made. After that risk management (regulatory

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measures and follow up, communication of the risk and specific prevention programmes) is required.

The Brazilian experience of implementing pharmacovigilance as part of the Health Surveillance System was presented. The National Agency of Health Surveillance (Anvisa) is an autonomous agency linked to the Ministry of Health and it is also the coordinator of the Health Surveillance System, which is a decentralized system, composed of states and municipalities. Medicines regulation is part of its scope in collaboration with the other parties of the national system.

The legal framework, the information system and the workflow related to reporting, investigation and decision making and communication was presented. The Brazilian Pharmacovigilance system includes among others, product problems, counterfeiting, illegal product marketing and quality problems.

The Pharmacovigilance function in Brazil was explained by citing an example of a quality deviation problem that had major adverse reactions in Brazil. The product in question was barium sulphate (Celobar) and it was used for x-rays of the oesophagus and the stomach. It was to be taken orally but it caused several deaths. Due to the structure of the network in Brazil, it was relatively easy to recall the product; inspectors were put in place and the information was placed on the TV, radio and in the newspaper.

The knowledge-driven model of decision making was explained. Based on the data collected, the necessary information is selected and then analysed to generate knowledge and to provide a better understanding. Afterwards, based on that, the options can be weighed and a decision can be made[19].

The PANDRH Working group for the **Prevention and Combat of Counterfeit Medicines** members includes Brazil, Argentina, Colombia, St. Lucia, the Dominican Republic, Canada and representatives from the pharmaceutical industry (Fifarma and Alifar). The mission of the group is *"to promote, facilitate and motivate the implementation of proactive strategies for preventing and fighting medicine counterfeiting and thus contribute to the improvement of health care in the countries of the Americas".* An information database has been proposed to help fight counterfeiting[20]. The following content has been suggested for the data base:

- Authorized establishments in the drug trade (such as drug distributors, drugstores, and pharmacies).
- Inspected establishments.
- Establishments where irregularities were detected, with the pertinent results or conclusions.
- Authorized manufacturers.

19 Design and Implementation of Health Information Systems. WHO, 2000. p. 35

20 Working Group to Combat Drug Counterfeiting (WG/CDC). PROPOSAL FOR THE EXECUTING UNIT – PANDRH. 2005 (modified)

- Pharmaceutical products prohibited by the health authority.
- Pharmaceutical products drawn as samples in the inspections.
- Denunciations/reports received.
- Counterfeit drugs detected in the country.
- Counterfeit drugs reported to PAHO/WHO.

The working group is currently supporting countries to implement the recommendations and the guidelines produced such as the executive unit and the workshops for building national task forces.

Working Group Reports

Strengthening of National Regulatory Authorities and discuss a sub-regional regulatory framework

At the first session of the working groups, on September 8th, the participants were divided in three groups for identifying priorities and strategies with the following objectives:

- to identify priorities for improving the situation
- to identify areas of synergy
- identify strategies and broad based actions for improving the situation including communication mechanisms

Priorities for improving Medicine regulation in CARICOM

The identified priorities at sub-regional level are:

1. Formulate aspects of Regional Pharmaceutical Policy that will contribute to the development of National Medicine Policies with focus to improve the health of the population.
2. to develop a regional registration platform
3. Inspection of clinical trials for Good Clinical Practices (GCP) compliance
4. Inspections of manufacturers on GMP compliance
5. to strengthen the regional quality control (CRDTL)

Priority medicines regulatory functions for the region:

1. Licensing of manufacturers and distributors
2. Licensing of importers
3. Inspection of clinical trials for Good Clinical Practices (GCP) compliance
4. Inspections of manufacturers on GMP compliance
5. Medicine Information promotion
6. Safety and efficacy surveillance
7. Quality controls labs
8. Pharmacovigilance

It was also considered that Pharmacovigilance has to be developed and integrated with other regulatory activities as well as with strategies for promotion of Rational Use of Medicines.

Strengthening these functions, would make it possible to have safe and quality products on the market in a timely and consistent fashion. The importance of having enforcement mechanisms to apply the correspondent penalties for those not

adhering to legislation such as threatening to withdraw medicines of the market was highlighted.

Emphasis was also placed on the need to develop/update the legal framework. Therefore, it was recommended to work with PAHO/CARICOM for having a sub-regional framework and to draft model legislation. This should be done at the regional level. It was also highlighted that Parliaments should pass legislation.

For developing the regulatory functions, the existence of human resources is a key issue. Human Resources should be improved by having collaborative efforts with governmental and non-governmental agencies. Training should be provided, in collaboration with external regulatory agencies and experience exchanges (in different countries).

Patient education was also considered to be important. It can be developed using cultural activities, NGO's and the internet (social networking).

Areas of Synergy

Capacity building of human resources and also at institutional level was considered to be pertinent.

1. Training (external/internal)
    a. Training people in academia
    b. Training in the service, with exchange visits
    c. Exchange/sharing of experience (eg. Joint inspections)
    d. Best/good practices
2. Information Sharing
    a. Legal framework across the region
    b. All countries should have a Medicine Policy, those that have one should enforce it and those that do not, should seek to have one.
    c. Emerging trends and changes
3. Communication Strategies
    a. Websites, email, text messaging

There should be harmonization wherever possible and more developed countries should assist the others, especially those countries or organizations (regional and sub-regional) that have a comparative advantage in any regulatory area or technical support. Countries should look to each other for support and work on weaknesses eg common regulatory tools (guidelines, procedures, manuals) and legislative requirements.

Strategies

At the **sub-regional level** the following strategies were identified:

1. Expand the terms of reference (TOR) of the Technical Advisory Group for trade related intellectual property rights (TAG) of CARICOM to encompass regional policy elements;
2. to promote advocacy with policy makers and other stakeholders
3. Secure PAHO pharmaceutical expertise at the sub-regional level
4. Strengthen institutional capacity of CRDTL and the capacity of quality control
    a. Regional laboratory networking
    b. Update CRDTL information
    c. Establish a website
    d. Improve sample/results logistical aspects
5. Introduction of a common technical document related to medicines regulation:
    a. Sharing of expertise
    b. Create exchange platform for existing MRAs to study and emulate regional success stories
6. Legal framework: to revise the legislation oriented to MRA (possible common model legislation)
7. Harmonization network and linkages should be MRA driven

The following strategies were identified for the **strengthening and development of the National Medicines Regulatory Authorities** and to build a sub-regional framework for medicines regulation:

1. Strengthen the Human Resources and financial resources for the MRA
2. to ensure the sustainability of programmes to ensure safety, quality and affordability

The private and public sector should collaborate at the regional or sub-regional level. The key collaborators should be the State, international parties, industry, civil society, NGO's and the private sector. For population sensitization activities, the use of Cultural Activities and Social Networking was suggested.

Strengthening priority essential regulatory functions

At the second session of the working groups on September 9th, the participants were divided in three groups and, based on the presentations and the results from the surveys, they were requested to discuss about strategies for improving the registration, inspection/licensing and marketing surveillance, considering the integration of the regulatory functions.

Group 1. Registration

Scope

- Format
- Procedures
- Integration of Registration and the other regulatory functions
- Strategies for improving the situation, including mechanisms of communication/collaboration

This group identified four areas for improving medicine registration as a team considering that: “united we stand, divided we fall”. Some counties have medicine regulation and others do not. The idea is to have everyone on the same page.

Areas for Improving Medicine Registration

It was presented as a proposal the creation of a network of regulatory authorities. This network can be composed by a steering committee, similar to PANDRH network and integrated to it. At the same time, it was proposed to start to design a sub-regional structure of regulation, as proposed in the HERA Report.

1. Network/links- of Medicines Regulatory Authorities. It would be like a mini PANDRH) should be established and integrated into the PANDRH network. decide and define the extent of the information to be shared. MRA staff and structure emails should be made available to participants. A Caribbean network is needed so that people will know who to call if they need assistance with anything or to share information about drug registration among other things. This should be put in place in less than 6 months.

2. Board of Coordination for the Caribbean for Medicine Regulation. (including a Regional Medicine Registry). This should over see the administration of the website and should be in place by 2010; CARICOM should be asked to assist. The Permanent Pre-registration Caribbean Committee should be established for the region and should have a website; it would be a permanent Medicine regulation committee. The languages used should be English and French. It will administer the website, identify priority areas and promote harmonization of the legal framework.

3. Capacity Building-This is to be a continuous programme that helps with training, courses and knowledge transfer so that the regions resources and efforts can be used advantageously. There should be a capacity building programme for regulatory matters such as registration related matters. This programme should be ready by March 2010.

4. Common requirements for product registration- They should work together to establish common, basic and harmonized requirements for the registration of products in the region. This should be established by 2010. The CRDTL, PAHO and

CARICOM should manage this. The names of the persons to work on this are already in the PANDRH working group (Princess Osbourne from Jamaica and Maryam Hinds from Barbados.

Group 2. Inspection

Scope:

- Good Manufacturing Practices (GMP)
- Good Distribution Practices (GDP) (including importation/exportation)
- Good Pharmacy Practices (GPP)

a. Guidelines and Procedures
b. Integration of inspections and the other regulatory functions
c. Strategies for improving this area, including mechanisms of communication/collaboration

This group examined what they already had and what they needed.

Have

- Inspectorate
- registration bureau
- Regulation of food and medicines

Need

- Legislative framework
- Human Resources
- Financial Resources
- Guidelines
- Regional Body to share expertise
- Collaboration

To do list

1. Review/formulate/strengthen legislation/regulation to accommodate and facilitate the functioning of an effective MRA from 2009 onwards by National authorities at the National level. The different levels in countries should be taken into account; the way forward is to formulate and strengthen legislation

2. Create a cadre of personnel with the requisite expertise starting in 2010

- external training-CARICOM, PAHO/WHO
- internal training-local authorities/academia

Develop a career path for inspectors. In order to become an inspector one has to spend a number of years in the service, therefore there should be a programme where persons can study to be inspectors. It should start in the 2009/2010 academic year. It should be done by PAHO/WHO, CARICOM, local authorities and academia and it should be at the national, regional and international levels.

3. Advocacy for funding (national, regional and international) starting in 2009 at the regional and national levels. At the same time self sustenance should be promoted starting in 2010 at the National level; all of this will be done by the MRA.

4. Review/formulate/strengthen guidelines and procedures for Inspection: GDP, GSP, GMP and Pharmacy inspections, starting from 2010 in terms of :

- manufacturers (plant, machinery, layout)
- distribution (storage, quality assurance)
- pharmacy (pharmacy inspectors)

All of this should be done by the MRA and a regional platform should be created and PANDRH guidelines should be applied.

5. There should be a regional recall procedure and alerts starting in 2010 and done by the MRA.

6. There should be a regional body of expertise starting in 2010 and done by the MRA.

There could be harmonization with what is already in place at PANDRH because several different things are taking place at all levels of the region. There should be a rapid response to product recall and an e-library of all active regulation and all the regulations of all the countries. This should be made available on a website. In order to implement all of the aforementioned, the cooperation of regional bodies is needed.

Group 3. Marketing surveillance/Pharmacovigilance

Scope:

- Substandard,
- Counterfeit

- Pharmacovigilance

a. Procedures
b. Integration of post-marketing surveillance and the other regulatory functions
c. Strategies for improving the situation, including mechanisms of communication/collaboration

This group considered the development of marketing surveillance, including substandard and counterfeit products.

Regarding substandard and counterfeit medicines:

Timeframe – 2 years and the following are the targets/action that need to be developed.

1. Guidelines and an appropriate monitoring system (description of troublesome products)

2. Inspection Schedule- This is needed because it is not feasible to inspect all the facilities, medicine distributors and pharmacies at one time. Trained personnel are needed to carry out this task. The required tools are similar to the forms used for data collection (formats are already in existence).

3. Written Procedure- This includes inspection and testing; inspection can be visual because all the products cannot be tested. Procedures and systems should be integrated.

4. Workshop for counterfeit medicines- A plan of action is needed for counterfeit medicines.

5. Regional Campaign- this would sensitize customers/users/pharmacies in order to make it easier for them to support the campaign because they would understand what the MRA is trying to achieve. There should also be a Pharmaceutical Forum of the Americas Declaration

For Pharmacovigilance:

1. Sensitization (Professionals and communities) - Persons should be asked to look for differences in their medicines, mainly in territories where there is not an operative medicine registration. For example, if a person buys medication this week and it is yellow and the following week it is blue then they should ask questions.

2. Refresh Vigicarib- Review and resume the plan.

3. Complete/ Adopt guidelines and communication procedures (links, inspectorate).

Plenary considerations and conclusions

PAHO/WHO emphasized the importance of establishing mechanisms of integration and collaborative work among the MRA of the Caribbean, the expectation regarding the outcomes of these working groups and pointed out that it is going to provide continuous support for this process. If the countries are motivated, the working groups can continue functioning using available virtual tools and future presencial meetings to implement the proposals.

Regarding the proposal of the network presented by the working groups, it was suggested that a proposal should be prepared to be submitted to the Ministers of Health. The FDA representative encouraged the participants to prepare a proposal based on the initial PANDRH proposal and offered support. Suriname offered support for hosting a possible secretariat of the Caribbean Coordination Board if it was necessary. The following countries volunteered to prepare a proposal: Suriname, Belize, Trinidad and Tobago, Barbados and Jamaica, with support of PAHO/WHO, CARICOM and the invited MRA. The CARICOM representative indicated that they have all of CARICOM's support except for financial support.

Regarding Vigicarib, it was said that it would receive new life and should consider focusing on patient safety as well as integrate pharmacovigilance with the other regulatory functions. At the same time, Vigicarib could integrate its network regulation initiative. All problems should be approached as a team because no man is an island.

With respect to the need for the updating and development of the legal framework for both the sub-regional and national levels, the possibility of working on a model legal framework with the support of the CARICOM's legal desk and PAHO/WHO was considered.

It was agreed among the participants that:

- It was an opportunity to evaluate the progress in the area, to identify priorities and strategies both for the sub-region and at the national level.
- A proposal for a Network among National Regulatory Authorities in the Caribbean, integrated into the Pan American Network on Drug Regulatory Harmonization (PANDRH). Belize, Suriname, Trinidad and Tobago, Barbados and Jamaica, with support of PAHO/WHO, CARICOM and the invited MRA (Argentina, Brazil, Cuba and United States) are responsible for its preparation. The first draft will be circulated by the end of September;
- The working groups will continue to develop the proposed activities within the Network for strengthening and harmonizing regulatory processes related to three priority areas: registration, inspection/licensing and marketing surveillance/pharmacovigilance, taking into account the implementation of

PANDRH recommendations and guidelines. This will be supported by PAHO/WHO and CARICOM.

- PAHO/WHO will circulate the draft of the Report of the workshop by the end of the month and will be responsible for the communication of the meeting's conclusions and inviting the Ministers of Health to participate in this network and nominate representatives.

Annex 1. **Agenda**

08/09/09

8h30 – Registration of Participants

9h00 - Opening remarks – Bernadette Theodore-Gandi PAHO/WHO, Caribbean Programme Coordinator, Beverly Reynolds, Caricom Secretariat

9h30 - Presentation of the objectives, participants and expectative related to the Meeting - Adriana Ivama (Advisor on Medicines and Biologicals for the Caribbean, CPC – PAHO/WHO)

9h45 – The regulation as an essential public health function– Gabriel Vivas (Advisor of Health Systems and Services Development - PAHO/WHO, ECC)

10h10 - Strengthening the National Regulatory Authorities and the Essential Regulatory Functions - Adriana Ivama, CPC – PAHO/WHO)

10h30 - Break

10h45 – The Pan American Network for Drug Regulatory Harmonization (PANDRH) Recommendations regarding strengthening of National Regulatory Authorities – Justina Molzon (FDA, member of PANDRH Steering Committee)

11h10 - The pharmaceutical situation in the Caribbean Countries - Adriana Ivama, CPC – PAHO/WHO)

11h30 - “Regional Assessment of Drug Registration and Regulatory Systems of Caricom Member States and the Dominican Republic”. – Marianne Schurmann (Hera)

12h00 – Discussion

12h45 - Lunch

14h00 – Experiences on harmonization and mechanisms of sub-regional integration: the Argentinean Experience – Cristina Torres (National Agency of Medicines, Food and Technology, ANMAT – Argentina)

14h20 – Quality Assurance as part of the Essential Regulatory Functions: the experience of Caribbean Regional Drug Test Laboratory - Lucette Cargill (CRDTL Director)

14h40 – Discussion

15h00 – Break

15h15 - Strengthening of National Regulatory Authorities and discussion on a sub-regional regulatory framework (Facilitators – Adriana Ivama, Jose Luis Castro, Rodolfo Mochetto, Celeste Sanchez and Beverly Reynolds)

a. Discussion of findings
b. Strategies for improving the situation, including communication and collaboration

16h30 – Summary of preliminary recommendations and next steps

09/09/09

8h30 - Strengthening of Registration based on PANDRH and WHO Recommendations – Celeste Sanchez (CECMED – Cuba)

9h00 - Strengthening of Good Manufacturing Practices and Inspection based on PANDRH and WHO Recommendations – Rodolfo Mocchetto (ANMAT – Argentina)

09h30 - Strengthening of post-marketing surveillance and pharmacovigilance based on PANDRH and WHO Recommendations – Murilo Freitas Dias (National Agency of Health Survellance, ANVISA – Brazil), Jose Luis Castro (Regional Advisor on Rational Use of Medicines, PAHO/WHO)

10h00 – Break

10h30– Working Groups

2. Registration (Facilitators - Celeste Sanchez and Cristina Torres)

   Scope:

   a. Format
   b. Procedures
   c. Integration of Registration and the other regulatory functions
   d. Strategies for improving the situation, including mechanisms of communication/collaboration
3. Inspection (whole chain) (Facilitator – Rodolfo Mocchetto and Adriana Ivama)

   Scope:

   - Good Manufacturing Practices
   - Good Distribution Practices (including importation/exportation)
   - Good Pharmacy Practices

a. Guidelines and Procedures
b. Integration of inspections and the other regulatory functions
c. Strategies for improving this area, including mechanisms of communication/collaboration

4. Pharmacovigilance; counterfeit medicines (Facilitators - Jose Luis Castro and Murilo Freitas)

   Scope:

   - Substandard,
   - Counterfeit
   - Pharmacovigilance

   a. Procedures
   b. Integration of post-marketing surveillance and the other regulatory functions
   c. Strategies for improving the situation, including mechanisms of communication/collaboration

12h30 – Lunch

13h30 – Meeting of Triangular Technical Cooperation Agreement - representatives of National Regulatory Authorities and ANMAT (Coordination: Cristina Torres and Beverly Reynolds)

14h00 – Continuation of Working Groups

15h15 – Break

15h30 – Presentation of results from working groups and discussion

17h00 – Recommendations and closing section

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