



Organización
Panamericana
de la Salud



Organización
Mundial de la Salud
OFICINA REGIONAL PARA LAS Américas

REGIONAL NETWORK OF FOCAL POINTS TO COMBAT FALSIFICATION OF MEDICINES

SESSION SUMMARY

<u>Date:</u>	October 8 th , 2015	<u>Time:</u>	14:00
<u>Attendees:</u>	<u>Countries:</u>	Maximiliano Derecho (ARG), Romina Vinas (ARG), Marisa Gorordo (ARG), Elina Ise (ARG), Jesica Carino (ARG), María José Sánchez (ARG), Maryam Hinds (BAR), Danini Contreras (BLZ), Tiago Rauber (BRA), Érika Mattos da Veiga (BRA), Maysie Vallejos (CHI), Diana Liévano (COL), Diana Viquez Herrera (COR), Reynaldo Hevia Pumariega (CUB), Juan Carlos Galarza (ECU), Sandra Bentolila (ESP), Reina Morales de Acosta (ELS), Darío Castillo de León (GUT), Marlan Cole (GUY), Gladys Paz (HON), Alejandra Oliva (HON), Valerie Germain (JAM), Sara Lilia Gaytán (MEX), Verónica Margarita López (NIC), Ricardo Daniel Pérez (PAR), Víctor Dongo Zegarra (PER), Dalia Castillo Sánchez (DOR), Miriam Naarendorp (SUR), Eleni Anagnostiadis (USA), Emily Barraza (VEN).	
	<u>PAHO/WHO:</u>	Michael Deats (GVA), Pernette Bourdillon (GVA), José Luis Castro (WDC), Robin Rojas Cortés (WDC).	
<u>Moderator:</u>	José Luis Castro (WDC)	<u>Modality:</u>	Face to face – Sheraton Libertador Hotel Buenos Aires, Argentina
<u>Rapporteurship:</u>	Danini Contreras (BLZ) and Robin Rojas (WDC)		
<u>PROPOSED AGENDA:</u>		<u>Approved:</u>	Yes
<div>1. Introductory remarks</div> <div>2. Overview of the Workshops for the Generation of Tools to Combat Falsification of Medicines</div> <div>3. Latest version of the Workshops in Santiago, Chile</div> <div>4. Overview of the FALFRA System</div> <div>5. Regional document on Traceability</div> <div>6. Regional document on Internet Sales</div> <div>7. Working model for the Network of Focal Points</div> <div>8. Considerations on the reporting mechanism</div>			
<u>TOPIC DEVELOPMENT</u>			
<div>1. Introductory remarks</div>			
<p>The PAHO delegates (WDC) opened the session highlighting the importance of internal communication -facilitated through the network- as well as the potentiality for updating and exchanging positions and discussions from the national level through designated focal points.</p> <p>Later, they showed some graphics with contents distributed in the past year through the Focal Points Regional Networks; particularly through the Network to Combat Falsification of Medicines, but also through the listservs of focal points for Pharmacovigilance and Drug & Therapeutics Committees, related to alteration of products (SSFFC), pointing out important cases. They also added that in recent months efforts have been made to distribute - from PAHO (Secretariat) - the majority of contents translated into English (or which main attachment is in English).</p>			

<p>They also recalled the relevance of the main products of the Working Group to date, with special emphasis on the National Workshops Model, the document on Network of Focal Points and also the one on Guidelines to be considered in cases of suspected falsification of medicines.</p>
<p>2. Overview of the Workshops for the Generation of Tools to Combat Falsification of Medicines</p>
<p>The representative from ANMAT presented an overview of experiences of the Working Group in relation to implementation of National Workshops for the Discussion of Tools and Generation of Proposals for the Prevention and Combat of Falsification of Medicines. This representative noted that the main objective of these activities has been to consolidate a national workforce that includes all stakeholders, as well as definition of roles, deadlines and commitments; for each country to set its own priorities, tools and adjusted mechanisms.</p> <p>So far the Workshops have been conducted in Bolivia, Panama, Jamaica/Caribbean and Chile.</p>
<p>3. Latest version of the Workshops in Santiago, Chile</p>
<p>The delegate from Chile updated the group on the last Workshop held with support from the Group at the Instituto de Salud Pública (ISP) in May in Chile. The event had the participation of the Ministry of Health, General Attorney Office, Customs, Police, Interpol and Cenabast (medicines procurement organism). Terms were agreed and arrangements were made including the official nomination of a representative from each institution.</p> <p>The existence of too many overlapping actions was evident before the workshop; and so - based on the discussed – each of those will be defined and coordinated specifying the scope and limits of all instances.</p> <p>It was concluded that some countries have already progressed in creating working groups, but it is vital to continually reinforce the importance of the coordination among the various instances, and that the approach given to the issue in the country is not limited to the concept of falsification as a crime of intellectual property but mainly against public health.</p> <p>Peru suggests taking advantage from the spaces and moments of favorability at political level to look for the approval of national laws and not only regulations.</p>
<p>4. Overview of the FALFRA System</p>
<p>In an effort to update countries who are not members of the FALFRA Network, the representative from the AEMPS recalled that such system was created with the aim of being an online regional alert instance. Spain acts as Secretariat, but it has a horizontal structure in which each Authority decides what to communicate and to which instances the information will be distributed. In general, the contact points receive information on notifications issued by each country.</p> <p>The system, which has been operating for two years, consists of a form to be filled out online with information about the suspect product.</p> <p>Finally, the representative said that, since the last meeting organized by EAMI in Cartagena, Colombia, the exchange of information has increased.</p>
<p>5. Regional document on Traceability</p>
<p>Argentina mentioned that, despite having developed a draft regional document on Systems for Medicines</p>

<p>Traceability, during the next month a global document on the subject will be discussed at the level of the Member States Mechanism in Geneva. For that reason it was agreed to wait for its eventual adoption to make it official at regional level. In case it is not backed by Member States, the possibility of approving (at the level of the Americas) the text prepared by ANMAT (and reviewed by COFEPRIS) this year, will be considered.</p> <p>The global draft document under discussion is attached to this summary as well as the preliminary version drawn up for the Americas (in Spanish), which shows similarity in contents with the global one. Countries are invited to provide feedback directly through the WHO Mednet platform until the week of 9-13 November. https://mednet-communities.net/ssffc</p>
<p>6. Regional document on Internet Sales</p>
<p>Argentina will prepare a draft of this document agreed at the meeting in Quito, and will socialize it with the focal points of the Network during the first half of 2016.</p>
<p>7. Working model for the Network of Focal Points</p>
<p>The PAHO representative said that, for several years, work had been conducted under the structure of the Working Groups of the Pan American Network for Drug Regulatory Harmonization (PANDRH). However, after the last meeting of the Steering Committee of the Network (Washington, May 2015), this structure was modified, launching a scheme of projects by priority areas under the responsibility of a Regulatory Authority of Reference in each case. The pharmaceutical industry, the academy and the civil society will meet as advisory parallel groups, but not under the status of Committee Members.</p> <p>Cuba suggested that the Group develops a strategy for the involvement of civil society. The motion was supported by the participants, and it was agreed that Cuba (coordinator), El Salvador, Venezuela, Costa Rica, Guatemala and the Dominican Republic will prepare a document to be submitted to the Group in March 2016.</p> <p>Argentina suggested to address <i>Good Distribution Practice</i>, for which purpose the PAHO representative suggested to initiate the approach with a diagnosis of the supply chain with information taken from NRA assessments, available at PAHO level.</p> <p>The PAHO representative added that, for this purpose, a prioritization process of relevant areas has been designed, based on different sources of information (PAWG Group, data from NRA assessments, suggestions from Members of the Committee and the Secretariat, etc.) that will allow the identification of areas where there are regional gaps that can be approached through projects supported by the Network (including financing) and in charge of a volunteer country (NRA of Reference). Nevertheless, none of these changes in the governance / prioritization model contradicts or hinders the activities of working regional networks already formed (as CFM, or Pharmacovigilance, for instance), with agendas already set. Should PANDRH determine a specific project related to the CFM area, this will be developed in parallel to the activities (and possibly with the support) of this group.</p> <p>Suriname considered important to count on an eventual support through reference laboratories in cases where the country does not have the ability to do quality control analyses within the framework of SSFFC activities.</p>
<p>8. Considerations on the reporting mechanism</p>
<p><i>In an effort to facilitate open discussion and exchange of opinions from countries on the reporting mechanism, the representatives of the Spanish Agency for Medicines and Health Products and WHO were kindly requested to leave the room for some minutes, due to their proximity to the FALFRA and RapidAlert systems.</i></p>

Cuba expressed concern about the parallel existence of two models for reporting. As discussed in previous instances, the delegate reiterated that reporting by duplicate would be undesirable. He considered that the FALFRA system is already established and functional, and that daily communication is accessible to everyone. It is positive that alerts issued by the country itself are distributed; and -although the system still has some limitations-, it has been improving lately. Regarding the WHO Reporting Mechanism, it needs to be refined because, apparently, it is more a reporting system than an alert tool of which countries only hear until there is resolution of the cases. In Cuba's opinion, the database should be public, and the coordinating unit should be defined at country level. Cuba acknowledges, however, that this latter system provides more opportunities for cooperation, wider access to laboratories, etc.

Mexico agreed with Cuba, but indicated its availability to work with both systems. Although they are used to FALFRA, they will be testing the WHO system, with which they share the primary focus on protection of public health.

Suriname states that the Caribbean is not related to the FALFRA system which is designed for Spanish-speaking countries only. They believe that the WHO system is a very good opportunity, so they will be testing it from now on.

Barbados backs up the position of Suriname, although they find reasonable the arguments of Cuba. They suggest evaluating what is possible to be taken from the regional experience to complement the global reporting system. Ideally, both systems should be articulated together.

Guatemala states they will make an effort to report to both instances in the coming months.

Brazil highlights the importance and their commitment to communicate through the listserv of the Regional Network coordinated by PAHO. They find valuable and important to have access to information from other regions as it is possible with the WHO system; of which they also highlight the possibility to include data in Portuguese. They think each country should decide on which mechanism to adopt.

The PAHO representative allows himself to clarify that the Regional Network coordinated by PAHO socializes relevant information, cases and alerts, etc. However, the reporting of suspected SSFFC products should always be oriented to a global instance like WHO.

The Dominican Republic reiterates the premise to notify only once. A further proposal would be to verify the feasibility to integrate the reporting forms by adding the necessary fields to meet the requirements of both the FALFRA and the WHO mechanisms. The delegate added that "the means can not become the end".

The United States considers the process is not speedy and expresses that it would be ideal to have (even in ten years from now) a single global system. Steps should be taken in that direction.

Argentina agrees with Cuba. As a regional network, the e-mail also becomes a communication tool for alerts. They would like the two systems to be connected, though they reiterate their position on the importance of access to the database. They highlight however, the importance of having many countries of the world (or most of them) involved.

All countries agreed to adopt the Rapid-Alert WHO system (though in some cases they will continue reporting in parallel through the FALFRA Network). After this experience, a new discussion will take place in a period of eight months to a year. Similarly, the communication (from the Secretariat and from countries) will continue and be strengthened through the Regional Network of Focal Points coordinated by PAHO with informations of interest, cases, alerts, and discussions of relevance.

Next Session:

To be confirmed.